UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

ALLIANCE FOR BIO-INTEGRITY,

et al.

Plaintiffs,

v. Docket No. 98-1300(CKK)

DONNA SHALALA,

et al.

Defendants.

PLAINTIFFS' CROSS MOTION FOR SUMMARY JUDGMENT ON ALL COUNTS

Pursuant to Fed. R. Civ. P. 56, Plaintiffs hereby seeks summary judgment in its favor all counts currently before the Court. The grounds for such motion are set forth in the supporting memorandum, submitted herewith.

Respectfully submitted,

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PLAINTIFFS' MEMORANDUM IN SUPPORT OF ITS

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Introduction

Currently, there is significant national and international interest in the labeling and safety of genetically engineered foods. United States consumers have shown an overwhelming desire for such labeling. A January 1999 poll in Time magazine found that 81% of American consumers believe genetically engineered food should be labeled. In this poll 58% said that they would not buy such foods if they were labeled. James Walsh, Brave New Farm, Time, Jan. 11, 1999, 86, 87. A 1998 National Federation of Women's Institutes poll found that 93% of women surveyed said they want all genetically engineered food clearly labeled. Even a 1997 survey by the biotechnology company Novartis found 93% of Americans want genetically engineered foods labeled.

The American public's interest in the labeling of genetically engineered foods is familiar to the federal agencies. A 1995 United States Department of Agriculture ("USDA") poll found 84% percent of those surveyed wanted mandatory labeling of genetically engineered fruits and vegetables.[1] Further, in the Spring of 1998 over 280,000 members of the public commented to the USDA in the second largest public response ever to a rulemaking by stating their opposition to, *inter alia*, the inclusion of genetic engineering as an acceptable production method for organic food. See generally, 62 Fed. Reg. 65850 (Dec. 16, 1997) (Proposed National Organic Program - Docket No. TMD-94-00-2).

In addition, the issue of labeling genetically engineered foods has made international headlines. Recently, Britain's premier medical association representing more than 80 percent of Britain's doctors stated that genetically engineered foods should be labeled.[2] See, Decl. Richard Lacey, ¶ 13.

This case concerns the actions of the Food and Drug Administration in allowing at least 36 genetically engineered foods to be approved for marketing without mandatory safety testing or labeling. As a result of this rulemaking millions of American are unwittingly consuming foods which contain an unstable mix of novel genetic material and proteins, and other additives including antibiotic marker systems, and viral vectors and promoters which have never been in food before. As a result of FDA's failure to require labeling of genetically engineered foods, consumers are not given the choice to avoid these foods which, as illustrated above, the majority of them do not wish to consume. Because of the FDA's failures to abide by its own food additive regulations these consumers, including

plaintiffs, are treated essentially as guinea pigs for foods which have not been subjected to any mandatory safety testing.

Plaintiffs challenge to FDA's actions on genetically engineered foods has two prongs. The first involves the arbitrary and capricious nature of defendant's 1992 Statement of Policy: Foods Derived From New Plant Varieties (hereinafter "1992 Policy"), in which FDA makes its rulings on the safety testing and labeling of genetically engineered foods. 57 Fed. Reg. 22984 (May 29, 1992). Plaintiffs' challenges to the 1992 Policy involve several procedural objections including defendants failure to comply with the Administrative Procedure Act's notice and comment requirements in promulgating this substantive rule; their violation of the National Environmental Policy Act by failing to prepare an environmental assessment or environmental impact statement taking a "hard look" at the environmental and human health impacts of the 1992 Policy; and their failure to abide by procedures mandated by the FFDCA and their own regulations when unilaterally finding that genetically engineered foods are "generally recognized as safe" (GRAS).

Further, plaintiffs assert that the 1992 Policy is arbitrary and capricious in its finding that genetically engineered foods need not be labeled because the novel functions and characteristics of genetically engineered are not "material" pursuant to section FFDCA § 201(n) labeling requirements. Plaintiffs final objection to the 1992 Policy is that it is violative of the Religious Freedom Restoration Act (RFRA) and the First Amendment Free Exercise clause.

The second prong of plaintiffs' case involves three claims which are related to, but independent of, the challenges to the 1992 Policy. The first is a claim that the labeling of genetically engineered food is required by RFRA and the First Amendment Free Exercise clause. Plaintiffs also seek this Court's enforcement of the FFDCA and the FDA's own regulations in ordering that the defendants treat the new material in the 36 genetically engineered foods described in the Plaintiffs' 2nd Amended Complaint as food additives and not as GRAS. Plaintiffs also seek the Court's enforcement of FFDCA's § 201(n) in declaring that the 36 genetically engineered foods described in the Plaintiffs' 2nd Amended Complaint are "misbranded" under FFDCA § 343 unless appropriately labeled.

Defendants have throughout the regulation of genetically engineered foods ignored thousands of public comments, the views of their own scientific experts, the overwhelming desire of the American people, the religious beliefs of millions, numerous federal statutes, their own regulations and their own overriding mission to protect public health. Their actions have been arbitrary capricious and an extraordinary abuse of agency discretion.

Procedural History

On May 27, 1998, Plaintiffs filed their original case. Pls.' Compl. The complaint was amended on July 24, 1998. Pls.' 1st Amend. Compl. On September 14, 1998, the plaintiffs filed their 2nd Amended Complaint. Pls.' 2nd Amend. Compl.

On September 28, 1998, defendants filed their Answer to Plaintiffs 2nd Amended Complaint. Defs.' 2nd Amend. Answer. Thereafter, on December 1, 1998, defendants provided plaintiffs with an Administrative Record consisting of over 44,000 pages.

The parties now come forward to the Court with cross-motions for summary judgment.

Statement of Facts

On May 29, 1992, the Food and Drug Administration published a "policy statement" creating a regulatory framework for foods created through genetic engineering technology. Statement of Policy: Foods Derived From New Plant Varieties 57 Fed. Reg. 22984 (hereinafter 1992 Policy). The 1992 Policy concluded that the majority of genetically engineered foods, present and future, would be granted generally recognized as safe (GRAS) status which immunized them from pre-market safety testing. The 1992 Policy also held that the genetic and other novel materials inserted into these foods, both presently and in the future, were not "material" facts which would typically trigger the agencies labeling requirement. Pls.' 2nd Amend. Comp. ¶ 117; A.R. at 37659.

The 1992 Policy contained no scientific studies or data. Its regulatory findings were primarily based on hypotheses and conclusory statements. A key conclusion in the 1992 Policy, a finding which was used to support both the GRAS and labeling rulings, was that genetically engineered foods did not differ from foods developed through traditional plant breeding. 57 Fed. Reg. at 22991. This assertion was rejected by the FDA's own "technical experts" who cited the "profound difference" between genetically engineered foods and those produced by traditional breeding, including the fact that they lead to "different risks." A.R at 19179, 18952, 18953. FDA's scientists also warned that the artificial insertion of DNA into plants, a technique unique to genetic engineering, could cause a variety of significant problems with plant foods including an increase in levels of known toxicants, the appearance of new toxicants, loss of nutrients, poor growth and higher concentrations of herbicides and pesticides. A.R. at 18619, 18620.

The finding by FDA scientists that genetic engineering can create new toxicants in foods is of particular concern in that the genetic engineering of a food supplement, the amino acid L-tryptophan, may have led to it becoming toxic. The non-genetically engineered version of this supplement was not associated with any human health impacts. The genetically engineered version manufactured in 1988 caused the deaths of 37 people and

the permanent disability of at least 1500 others. The FDA did not rule out the possibility that the genetic engineering of the supplement was responsible for it becoming toxic. A.R. at 22923.

Since issuance of the 1992 Policy, defendants have continued to operate under it including the release of guidance in 1996 and 1997 for voluntary consultations with producers of genetically engineered foods. Pls.' 2nd Amend. Comp. ¶¶ (second) 121, 122; Defs.' 2nd Amend. Answer ¶ 121, 122; A.R. Defendants now view the 1992 Policy as final. Defs.' 2nd Amend. Answer ¶ 121. As a result, at least thirty-six genetically foods have been commercially developed and potentially millions of unsuspecting consumers are already consuming these genetically engineered foods. Pls.' 2nd Amend. Comp. ¶ 126, 127; Defs.' 2nd Amend. Answer ¶ 126, 127. In the future, under the 1992 Policy, untold numbers of genetically engineered foods will enter the marketplace without any mandatory pre-market testing and without labels.

Consumers motivated primarily by health and environmental concerns, as well as religious obligations, have expressed to the agency through thousands of comments their overwhelming desire for the labeling and safety testing of foods produced through genetic engineering. Pls.' 2nd Amend. Comp. ¶ 123, 124. However, the FDA has consistently ignored the thousands of comments it has received and finalized its rules on genetically engineered foods without complying with the notice and comment requirements contained at § 553 of the Administrative Procedure Act. Pls.' 2nd Amend. Comp. ¶ 121. FDA also finalized the 1992 Policy without completing or releasing any documentation which assessed the human health, environmental and socio-economic impacts of the commercialization of unlabeled and potentially untested genetically engineered foods. Such a "hard look" analysis is required under NEPA, 42 U.S.C. § 4332(2)(C), and was initiated by FDA staff. Pls.' 2nd Amend. Comp. ¶ 128; Defs.' 2nd Amend. Answer ¶ 128, 157.

Further, the FDA finalized its 1992 Policy which determined that most genetically engineered foods are GRAS without observance of the proper rulemaking and other procedures and requirements mandated by the FFDCA and their own regulations. Pls.' 2nd Amend. Comp. ¶127. Moreover, FDA's conclusion that the genetic material, antibiotic marker systems, viral vectors and promoters and novel proteins inserted into and contained in genetically engineered foods was not material for purposes of § 201(n) labeling requirements was made despite the agency's own scientific findings. FDA's admissions establish that genetically engineered foods contain significant changes in physical properties, function, performance characteristics and/or organoleptic changes.

Defendants have also failed to comport their 1992 Policy to the requirements of the Religious Freedom Restoration Act. This violation occurred despite the fact that numerous commenters to the agency requested labeling so that they could ensure their ability to choose food in accord with their beliefs -- and to avoid being subjected to foods they deem religiously objectionable. Pls.' 2nd Amend. Comp. ¶¶ 17-20, 25-29, 34-47, 50-53, 56-63, 68-83, 90-106, 125; Defs. 2nd Amend. Answer ¶ 125; A.R. at 19591, 19593.

Standard of Review

Pursuant to Fed. R. Civ. P. 56(c) summary judgment "shall be rendered forth with if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show there is no genuine issue as to material fact and that the moving party is entitled to judgment as a matter of law." *See,* Celotex Corp. v. Catrett, 477 U.S. 317, 91 L. Ed. 2d 265, 106 S.Ct. 2548 (1986). *See also*, Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-248, 91 L. Ed. 2d 202, 106 S.Ct. 2505 (1986); Konst v. Florida East Coast Ry. Co., 71 F.3d 850, 852 (11th Cir. 1996). Summary judgment is an appropriate procedure in cases arising under the FFDCA. AMP Inc. v. Gardner, 389 F.2d 825, 831 (2nd Cir.), *cert. denied sub nom.*, AMP, Inc. v. Cohen, 393 U.S. 825, 89 S.Ct. 21 L.Ed. 2d 95 (1968). For the reasons stated below, plaintiffs are entitled summary judgment on all counts.

Defendants' Actions and Decisions In This Case Are Subject to a "Hard Look" Test

It is well established that a reviewing court must set aside an agency decision if that decision is arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with the law. Motor Vehicle Mfgs. Ass'n v. State Farm Mut. Auto Ins., 463 U.S. 29, 41 (1982); Bowman Transportation, Inc. v. Arkansas Best Frieght System, Inc., 419 U.S. 281 (1974). An agency may be afforded some deference because of its specialized experience, Western Fuels-Illinois v. ICC, 878 F.2d 1025, 1030 (7th Cir. 1989). However, claims of special expertise or scientific competence are no defense against rigorous judicial examination of agency actions, and this includes procedural violations of the Admisitrative Procedure Act. See Syncor International Corporation v. Shalala, 127 F.3d 90 (1997). Courts also must intervene when they become aware that "the agency has not really taken a 'hard look' at the salient problems, and has not genuinely engaged in reasoned decisionmaking." Greater Boston Television Corp. v. FCC, 444 F.2d 841, 851 (D.C. Cir. 1971). Courts should not give unwarranted deference to complex agency decisions or "bow to the mysteries of administrative expertise." Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 597 (D.C. Cir. 1971). Additionally, when issues of human health are involved judicial scrutiny should be at its most intense. Id. at 598.

The Supreme Court has concluded that an agency decision must be overturned, despite claims of scientific expertise and statutory limits on review, if an agency has failed to articulate a satisfactory explanation for its actions and decision including a "rational connection between facts found and the choice made." Motor Vehicle Mfr. Ass'n, 463 U.S. at 43, *citing* Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962). The Supreme Court has also held that regardless of any deference, an agency decision must be overturned when the agency failed to consider an important aspect of

the problem, offered an explanation for its decision which runs counter to the evidence before the agency, or relied on factors Congress has not intended it to consider. SEC v. Chenery Corp., 332 U.S. 194, 196 (1947).

In sum, "agency decisions must make sense to reviewing courts." Puerto Rico Sun Oil Co. v. U.S.EPA, 8 F.3d 73 (1st Cir. 1993). The requirement that an agency decision must be rational, and not 'arbitrary or capricious,' is especially important in cases that involve technical areas of regulation. Public Citizen's Health Research Group v. Tyson, 796 F.2d 1479 (D.C. Cir. 1986).

Argument

I. Count I (D): FDA Failed to Comply with the Notice and Comment Procedures of the Administrative Procedure Act When Promulgating the "Statement of Policy: Foods Derived from New Plant Varieties."

A. FDA's 1992 Policy is Neither a Policy Statement Nor Interpretive Rule.

FDA has legislative power under the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.,* to promulgate rules governing the pre-market safety and labeling requirements for genetically engineered foods. Congress granted FDA specific authority to regulate whether a producer of a food product must satisfy specific labeling requirements. 21 U.S.C. §§ 343(a), 321(n). These and other of the agency's legislative functions can only be accomplished through the issuing of a substantive rule. Syncor Int'l v. Shalala, 127 F.3d 90, 94 (D.C. Cir. 1997).

Congress also granted FDA regulatory authority to exempt substances in food from pre-market safety requirements if the use of the food additive is found to be "generally recognized as safe" ("GRAS"). 21 U.S.C. § 321(s). However, an agency GRAS affirmation can only be accomplished through the issuance of a substantive rule. Further, FDA's own regulations require the agency to engage in rulemaking when affirming the GRAS status of a substance. 21 C.F.R. § 170.35. FDA has always employed the rulemaking process when determining the GRAS status of foods. See 61 Fed. Reg. 43447 (1996) (final rule affirming the GRAS status of high fructose corn syrup); 47 Fed. Reg.

47373 (1982) (final rule affirming the GRAS status of certain red and brown algae and alginic acid); 63 Fed. Reg. 28893 (1998)(final rule affirming the GRAS status of sheanut oil). The Administrative Procedure Act (APA), 5 U.S.C. § 551, *et seq*., requires agencies to undergo a thorough notice and comment process prior to finalizing substantive rules, such as those required for the implementation of FDA's labeling and food additive decisions. The APA requirements for such rules require the issuing of a public notice of proposed rulemaking describing the substance of the proposed rule, offering the public an opportunity to submit written comments, and publishing a final rule which meaningfully responds to such comments and states the basis and purpose of the rule. 5 U.S.C. § 553(b) & (c). These requirements "help to ensure that the rule is subjected to thoroughgoing analysis and critique by interested parties and the agency." American Medical Ass'n v. Reno, 57 F.3d 1129, 1134 (D.C. Cir. 1995). Failure to comply with these notice and comment requirements renders a substantive rule invalid.

There are exceptions to these APA requirements. The notice and comment provisions of the APA do not apply to "interpretative rules" or "general statements of policy." 5 U.S.C. § 553(b)(A). However, any exceptions to the rulemaking provisions of the APA are to be narrowly applied. See American Hosp. v. Bowen, 834 F.2d 1037, 1044 (D.C. Cir. 1987) ("Congress intended the exceptions to § 553 notice and comment requirements to be narrow ones.").

In this case, it is undisputed that defendants issued the 1992 Policy without complying with the appropriate notice and comment procedures. Defs.' 2nd Amend. Answer ¶ 121. This is not to say that the agency did not solicit or receive comments on its rule. The 1992 "Statement of Policy" did invite comments and thousands were received, over 80% being opposed to the agency position. See 57 Fed. Reg. at 22984. On April 28, 1993, within a few months of the close of the comment period on the 1992 Policy, FDA responded to the flood of negative comments by publishing in the Federal Register a "request for data and information" which asked the public to respond to a lengthy list of questions about the labeling and safety of genetically engineered foods. 58 Fed. Reg. 25837 (1993). Once again they received numerous comments, the vast majority urging the labeling and safety testing of such foods. FDA violated the APA by failing to respond to *any* of the public's comments. Under 5 U.S.C. § 553(c), an agency is required to consider the comments submitted by the public. The opportunity to respond to proposed rules is "meaningless unless the agency responds to significant points raised by the public." Home Box Office, Inc. v. FCC, 567 F.2d 9 (D.C. Cir. 1977). In June 1996, the agency issued a "document" outlining the voluntary consultation process recommended in the 1992 Policy for those producing genetically engineered foods. Defs.' 2nd Amend. Answer ¶ 121 (second). Comments were not solicited. This document was superseded by what the agency termed a "Guidance on Consultation Procedures" in October 1997. Id. No comments were solicited on this "Guidance."

Defendants recognize that in promulgating their 1992 Policy Statement, they did not comply with required notice and comment procedures of the APA. Defs.' Opp. Pls.' Mot. Admin. Rec. at 7. They further acknowledge that the Policy is "final." Defs.' 2nd Amend. Answer ¶ 121. Defendants claim that the "Policy Statement" is exempt from APA notice

and comment requirements because it embodies both possible exemptions allowed under the APA in that it "is an interpretive rule and statement of policy." Defs.' Opp. Pls.' Mot. Admin. Rec. at 7.

Courts have consistently held that an agency's own characterization of its policy is not dispositive, and is to be given some "albeit not overwhelming" deference. Community Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C.1987). This limited deference is fatally undermined here as the FDA has made the legally incoherent claim that its policy embodies two mutually exclusive regulatory actions, namely an interpretive rule and a policy statement. This circuit has made it clear that "interpretive rules and policy statements are quite different agency instruments." Syncor, 127 F.3d at 93. An agency policy does not seek to impose, elaborate, or interpret the words of a statute or regulation. Further, a policy is not binding on the public or the agency. Id. By contrast, an interpretive rule does involve the agency's interpretation of a statute and it is binding on the agency. Id. at 94. Defendants cannot ask this Court for deference for the contradictory claims that the 1992 Policy is an interpretive rule which binds the agency, and at the same time a policy statement which does not bind the agency. Nor can defendants credibly argue that it is an interpretive rule that interprets a statute and/or regulations and at the same time a policy statement which does not.

However confused defendants are about the regulatory instrument they have fashioned, both the content and effect of the 1992 Policy establish that it is a substantive rule, not an interpretive rule or statement of policy as claimed by defendants. The 1992 Policy, *inter alia*, creates a binding labeling scheme for an entire class of novel foods and makes dispositive scientific findings on the safety of these novel foods. Such rulings are applications of the agency's legislative powers and can only be made via substantive rulemaking. Syncor 127 F.3d. at 94. In that it is undisputed that defendants failed to fulfill the APA requirements for the issuance of the 1992 Policy, the Policy should be declared invalid. See Hoctor v USDA, 82 F.3d 165 (7th Cir. 1996).

(1). Defendants Did Not Issue a "Policy Statement."

Although the distinction between legislative rules, interpretive rules, and policy statements can be tenuous, Community Nutrition, 818 F.2d at 946, the case law identifies specific criteria to use when deciphering between these three agency actions. Initially, defendants labeled their action in the Federal Register as a "statement of policy," 57 Fed. Reg. at 22984, and, as noted supra, now maintain that it is both a statement of policy and an interpretive rule. Defs.' Opp. Pls.' Mot. Admin. Rec. at 7. As underscored by defendants own admission that the 1992 Policy is an interpretive rule, the claim that it is merely a statement of policy cannot withstand even a cursory review of the content and effect of the "policy."

The courts have established a two-part test for determining whether an agency's action is a statement of policy or a substantive rule. Troy Corp. v. Browner, 120 F.3d 277, 286 (D.C. Cir. 1997), *citing* American Bus Ass'n v. United States, 627 F.2d 525 (D.C. Cir. 1980). First, a statement of policy "does not impose any rights and obligations" because it

does not have a binding effect. Id. Second, a statement of policy "generally leaves the agency and its decision makers free to exercise discretion. Id. In contrast, a legislative rule, (1) "supplements" a statute (2) "effects a change in existing law or policy," or (3) "grants rights, imposes obligations, or produces other significant effects on private interests." Id. at 287, citing National Family Planning & Reprod. Health Ass'n v. Sullivan, 979 F.2d 227, 237-38 (D.C. Cir. 1992).

The 1992 Policy's content fits that of a substantive rule not that of a "statement of policy." For example, in the 1992 Policy defendants rule that "transferred genetic material" [foreign genetic material engineered into foods] will not "be subject to food additive regulation" and that "in regulatory terms such material is presumed to be GRAS." 57 Fed. Reg. at 22990. The 1992 Policy further holds that "the agency does not believe that the method of development of a new plant variety . . . is normally material information within the meaning of 21 U.S.C. 321(n) and would not usually be required to be disclosed in labeling for the food." Id. at 22990-22991. As a result of this language, the 1992 Policy changes existing law by granting producers the right to market most genetically engineered foods without having to comply with any statutory and regulatory pre-market safety and labeling requirements. Due to the rights and obligations conferred by defendants, this is clearly a substantive rule not a"statement of policy." The agency action has a present binding effect, and thus should have been subject to notice and comment procedures.

The binding effect of defendants' purported "statement of policy" is further evidenced by the fact that FDA considers it necessary to list exemptions to the GRAS and labeling status of transferred genetic substances. See Community Nutrition, 818 F.2d at 947 (explaining that an exemption is proof of a binding norm). Here, FDA states that a "substance that differs significantly in structure, function, or composition from substances found currently in food . . . may not be GRAS and may require regulation as a food additive." 57 Fed. Reg. at 22990. Based upon this language, producers of genetically engineered food are obligated to submit a food additive petition if the transferred genetic substance is novel. In the absence of a food additive petition for novel transferred genetic substances, the food additive is presumed to be unsafe and prohibited from entering interstate commerce. 21 U.S.C. §§ 348, 331.

FDA then states that "consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted." 57 Fed. Reg. at 22991. In light of this statement, genetically engineered food producers must comply with labeling requirements when the substance is novel or a safety or usage concern exists. Therefore, if the GRAS or labeling status of transferred genetic material in the so-called "statement of policy" is not binding, then it would not have been necessary for FDA to identify these exceptions.

Defendants' 1992 Policy also limits the agency's discretion, further revealing it to be a substantive rule. By exempting most genetically engineered foods from pre-market safety

approval and labeling requirements, the FDA is assuring food producers that the agency will not prevent the marketing of genetically engineered foods. This case is similar to the FDA's action in Community Nutrition. 818 F.2d at 949. In that case, the D.C. Circuit Court explained that FDA's policy in setting action levels was actually a substantive rule because the agency assured food producers that it would not enforce the FFDCA against them. Id. As a result of the agency's assurance that it will not prevent the marketing of genetically engineered foods (in that the agency finds that the majority of such foods satisfy the GRAS requirement and are exempt from labeling requirements), FDA's discretion to enforce the FFDCA is limited.

Even if the Court were to find that the agency's language in the 1992 Policy is inconclusive in demonstrating whether this agency action is a policy or a rule, the agency's subsequent conduct demonstrates the binding effect of this rule. See Public Citizen Inc. v. U.S. Nuclear Regulatory Comm'n, 940 F.2d , 679, 682 (explaining that [w]here the language and context of a statement are inconclusive, we have turned to the agency's actual applications"); McLouth Steel Products Corp. v. Thomas, 838 F.2d 1317, 1321(D.C. Cir. 1988) (holding that EPA's statement was a substantive rule because the agency's application of the statement demonstrated its binding effect). In this case, the binding effect of defendants' "statement of policy" is evidenced by the at least 36 genetically engineered foods already commercially viable and approved for marketing without labeling or mandatory safety testing. Defs.' 2d Amend. Answer ¶ 126.

Additionally, if FDA's challenged action is a "statement of policy," then any change to this "policy" will not affect the legal norm. Syncor, 127 F.3d at 94 (explaining that when an agency issues a policy statement, it has the authority to change its position without affecting the legal norm). Here, FDA has not challenged the GRAS or labeling status of any of these foods. If the agency changes its legal position that such foods are GRAS and exempt from labeling, however, obviously the private interest of the producers of the 36 genetically engineered foods approved for marketing would be significantly impacted. In that these 36 genetically engineered foods have not had to comply with *any* safety or labeling requirements, it is equally obvious that any change in these procedures will affect the legal norm.

By repeatedly allowing genetically engineered foods to enter the market, the agency has demonstrated the binding effect of its rule. Consequently, FDA improperly excluded this substantive rule, published under the guise of a "statement of policy," from APA's notice and comment procedures.

(2). Defendants Did Not Issue an Interpretive Rule.

Defendants' contradictory claim that the 1992 Policy is an interpretive rule fares no better than their attempt to characterize it as a policy statement. An interpretive rule merely clarifies and explains existing laws or regulations. See Caraballo v. Reich, 11 F.3d 186,

194 (D.C. Cir. 1993) (explaining that "[a] statement seeking to interpret a statutory or regulatory term is, therefore, the quintessential example of an interpretive rule."). When an agency not only explains statutory or regulatory terms, but also creates rights or modifies a legal norm, then the agency is engaging in legislative rulemaking. Syncor, 127 F.3d at 95 (explaining that a "substantive rule has characteristics of both the policy statement and the interpretative rule . . . [b]ut the crucial distinction between it and the other two techniques is that a substantive rule modifies or adds to a legal norm based on the agency's own authority.")

Examination of the 1992 Policy and its impacts reveals that it is not an interpretive rule, especially under the narrow application of this exception demanded by the courts. The primary purpose of the 1992 Policy is not to interpret or construe statutory language. Rather, the 1992 Policy consistently makes scientific findings which allow it to reach regulatory decisions about novel foods created through genetic engineering. Typical is the Policy's discussion of the impact of genetic engineering on nutrients in foods:

Another unintended consequence of genetic modification of the plant may be a significant alteration in the levels of important nutrients. In addition, changes to bioavailability of a nutrient due to changes in form of the nutrient or the presence of increased levels of other constituents that affect absorption or metabolism of nutrients must be considered for potential nutritional impact. 57 Fed. Reg. at 22987.

Here, as in numerous other key provisions in the 1992 Policy, defendants make legislative findings (genetic engineering can negatively impact the nutrients in food) and proscribes how producers of genetically engineered foods should respond (the "must" consider nutritional impact). This section as in others goes far beyond "interpretation." Rather, the agency is using its legislative powers to make findings and establish a regulatory protocol (however arbitrary, negligent and inadequate) for genetically engineered foods.

Perhaps most tellingly, FDA, consistent with its congressional authority to determine the safety and labeling requirements for food, uses the 1992 Policy to extend its regulatory reach over the products of a new technology by specifically exempting most genetically engineered foods from safety and labeling requirements. Indeed, FDA is granting producers of genetically engineered foods the right to market these products free, in all but a few exceptions, of mandatory statutory and regulatory burdens. This is not an interpretation of a statute and regulation, but rather the application of statutorily granted powers to construct a regulatory regime, a regime which the agency has applied consistently to dozens of genetically engineered foods. As this Circuit expressly noted in Syncor, it is precisely when FDA applies its regulatory powers to a class of products created by "advancement ... in technology" that a substantive rule results "which notice and comment rulemaking is meant to inform." Syncor, 127 F.3d at 95.

The fact that FDA issued a legislative rule rather than an interpretive rule is further evidenced by FDA's request for public comment. FDA requested comments not once but *twice*. See 57 Fed. Reg. 22984 (1992); 58 Fed. Reg. 25837 (1993). It is established that significant fact finding and scientific investigation to clarify such fact finding are the hallmarks of legislative not interpretative rulemaking. Hoctor, 82 F.3d 165 ("statutory interpretation normally proceeds without the aid of elaborate factual inquiries."). Interpretive rules do not require facts but rather statutory or regulatory analysis. The FDA's primary task in the 1992 Policy was to arrive at a regulatory regime for a whole new class of foods, not to refine its interpretation of the FFDCA, so extensive scientific investigation and fact finding were necessary.[(3)]

In sum, neither of defendants contradictory claims that the 1992 policy is a policy statement or an interpretive rule has merit. The 1992 Policy is a substantive rule issued without complying with the APA's notice and comment procedures. As a result, the 1992 Policy is invalid and must be vacated.

II. Count I (G): FDA's Failure to Prepare an Environmental Impact Statement on the 1992 Policy Was Arbitrary, Capricious and an Abuse of Discretion.

A. The National Environmental Policy Act and its Implementing Regulations.

The National Environmental Policy Act ("NEPA") is the "basic national charter for protection for the environment." 40 C.F.R. § 1500.1. Its purposes are to "promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man," 42 U.S.C. § 4321, and to "insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken." 40 C.F.R. § 1500.1(b).

To accomplish these purposes, NEPA requires all federal agencies to prepare a "detailed statement" regarding all "major federal actions significantly affecting the quality of the human environment . . ." 42 U.S.C. § 4332 (C). This statement - known as an Environmental Impact Statement ("EIS") - requires a federal agency to review, *inter alia*, the adverse environmental effects which cannot be avoided should its proposal be implemented. Id. The possible effects from a proposed action that must be reviewed include not only ecological impacts, but also direct, indirect, or cumulative impacts affecting public health. 40 C.F.R. § 1508.8(b); Baltimore Gas & Electric Co. v. NRDC, 462 U.S. 87, 106 (1983) (explaining that "NEPA requires an EIS to disclose the significant health, socioeconomic, and cumulative consequences of the environmental impact of a proposed action"). The duties under this section of NEPA are not "inherently flexible." Calvert Cliffs Coordinating Comm. Inc. v. U.S. Atomic Energy Comm'n, 449 F.2d 1109 (D.C. Cir. 1971). In fact, "[c]onsideration of administrative difficulty, delay or economic cost will not suffice to strip the section of its fundamental importance." Id.

To determine whether an EIS is required, federal agencies must prepare an Environmental Assessment ("EA") that provides sufficient evidence and analysis to support the agency's determination on whether a proposed action will significantly affect the environment. As a limited exception to NEPA's requirements, agencies may categorically exclude a class of actions. However, if any action among that class of actions has "a significant effect on the human environment," then the agency must comply with NEPA's requirements by preparing an EA or EIS. 40 C.F.R. § 1508.4.

B. FDA Improperly Invoked a Categorical Exclusion for Its

Actions Addressing the Regulation of Genetically Engineered Food**.**

An agency may "categorically exclude" a proposed action from NEPA review only if the project falls squarely in a category of agency decisions that do not "individually or cumulatively have a significant effect on the human environment." 40 C.F.R. § 1508.4. If there is any doubt about whether a proposed project may have a significant effect on the environment, the federal agency must at least prepare an EA.

The Council on Environmental Quality ("CEQ"), an agency within the Executive Office of the President, has promulgated regulations implementing NEPA that set forth specific factors that agencies must consider when determining whether to prepare an EIS, including whether an action will "significantly" affect the environment. See 40 C.F.R. §§ 1500-1508.[(4)] These factors for determining the "significance" of an action include: (1) the degree to which the effects on the quality of the human environment are likely to be highly controversial; (2) the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks; or (3) the degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration." 40 C.F.R. § 1508.27(b)(4),(5),(6). The "presence of one or more of these factors should result in an agency decision to prepare an EIS." Public Service Co. of Colo. v. Andrus, 825 F. Supp. 1483, 1495 (D. Idaho 1993).

In this action, FDA arbitrarily and capriciously categorically excluded its genetically engineered food legislative rule from NEPA review by stating that "this action is of a type that does not individually or cumulatively have a significant effect on the human environment." 57 Fed. Reg. at 23005. This statement is contrary to the evidence before the agency which shows that, by allowing unlabeled and untested genetically engineered foods on the market, all three CEQ factors of "significance" are present, thereby triggering full NEPA review.

(1). The Effect of the Genetically Engineered Foods on the

Human Environment Is Highly Controversial.

The defendants' action regarding genetically engineered foods have been "highly controversial." See Foundation for North American Wild Sheep v. U.S. Dep't of Agric., 681 F.2d 1172, 1182 (9th Cir. 1982)(explaining that the term "controversial" refers to the existence of a "substantial dispute . . . as to the size, nature, or effect" of the proposed action). The agency has allowed the marketing of genetically engineered foods based upon its findings that these novel foods are substantially equivalent to traditionally bred foods and generally recognized as safe. This action has sparked a substantial public outcry and is contrary to the evidence before the agency showing that these novel foods present many unknown safety and environmental effects.

The controversial nature of FDA's action is immediately apparent by reviewing the large number of comments sent to the FDA by outraged consumers protesting the marketing of these novel foods. See e.g., A.R. at 25605-31300. Only 2% of commenters supported FDA's action whereas 68% questioned the safety (testing and allergies) and environmental effects posed by these novel foods. A.R. at 19593. Many commenters challenged the safety of the "changes in the soil where bioengineered plants are grown, in animals that eat the bioengineered plants, and in the plants themselves." A.R. at 19592; See A.R. at 29700("[w]e object to FDA's redefinition of GRAS, because FDA "presents no valid scientific evidence"). Other commenters were concerned that novel plants genetically engineered to be herbicide tolerant will result in the indiscriminant and greater use of pesticides. Id.

Beyond the immediate comments, the public has consistently responded that the presence of genetically engineered foods in the human environment is controversial. A January 1999 poll in Time magazine found that 81% of American consumers believe genetically engineered food should be labeled. The New York Times Sunday Magazine recently ran a cover story detailing both consumer and farmer concerns about the use of genetically engineered food.[(5)] Additionally, new studies indicating that some genetically engineered crops could be contributing to declining populations of Monarch butterflies have triggered significant public outcry.[(6)]

Furthermore, FDA's actions been extremely controversial among the agency's own scientific experts. In a memo to the Toxicology Section of the Biotechnology Workgroup, an FDA official expressed two warnings regarding the safety of genetically engineered foods by stating: (1)"it is possible that all of the recommended test methods could miss an unexpected toxicological effect of novel foods that is only detected in a heterogeneous human population" and (2) "some proteins in genetically modified plant foods (*i.e.* novel foods) might induce allergic reactions in people, because certain proteins from normal plant foods have been documented to cause food allergies." A.R. at 18688. See also, Id. at 18953 (explaining that "[t]here is no data that addresses the relative magnitude of the risks" connected with genetically engineered food). Despite these warnings from defendants' own scientific experts about the potential safety hazards with genetically

engineered foods, FDA allowed these novel foods to enter the market without considering any impacts on human health or the environment as required under NEPA.

Accordingly, there can be no legitimate question that the effects of FDA's action are "highly controversial" within the meaning of the CEQ regulations and therefore, the agency cannot use a categorical exclusion to avoid preparing an EA or an EIS.

(2). The Possible Effects of Genetically Engineered Foods

on the Human Environment is Highly Uncertain.

FDA's actions are also "significant" because the effect on human health and the environment involves "highly uncertain" and "unique or unknown risks." Defendants even admit that "unlike classical breeding methods, the theoretical possibility exists that pleiotropic and other related unintentional effects may occur through the use of DNA insertion techniques now available, and that these could cause a detrimental change in the level of natural nutrients or toxins in a transformed plant." A.R. at 18690 (emphasis added). These pleiotropic effects or unintentional effects include "poor growth, reduced levels of nutrients, increased levels of natural toxicants, etc." and are expected to occur as much as 30% of the time in genetically engineered plants. Id. at 18620. Furthermore, FDA's own molecular biologists caution that "the interactions between the host and inserted gene's DNA, RNA, and expressed product are still not predictable." Id. at 18626 (emphasis added).

Evidence of "unique" environmental impacts is also demonstrated by defendants' scientific experts who conclude that "animal feeds derived from genetically modified plants present some unique safety concerns." A.R. at 18984 (emphasis added). It is precisely these kind of "uncertain" and "unique" environmental impacts that must be analyzed under NEPA before an agency implements its action. The very purpose of the EIS requirement, as the Supreme Court has emphasized, is to ensure that an "agency will not act on incomplete information only to regret its decision after it is too late to correct." Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 371 (1990) (emphasis added). In light of the incomplete information showing that genetically engineered foods are safe, FDA's action in allowing genetically engineered foods to enter the market is clearly "significant" agency action.

(3). Defendants' Action Sets A Precedent Concerning the

Regulation of Genetically Engineered Foods.

FDA's action is also "significant" in that it establishes a precedent for the future regulation of all genetically engineered foods. For the first time, manufactures of genetically engineered foods are now able to market these novel foods without seeking FDA approval. Defendants have recognized the unprecedented nature of this action. James Maryanski, FDA's coordinator for the 1992 Policy, describes the agency's rule as an "unprecedented step" because it was first time the agency specifically stated "the safety issues that should be taken into account in developing new varieties of fruits and vegetables." A.R. at 33696.

The precedent setting nature of defendants' action is also demonstrated by the number of genetically engineered foods on the market. At least 36 different genetically engineered foods are commercially viable or currently available to consumers. Despite opening the door to these unique foods with uncertain effects, FDA never considered any environmental or human health impacts resulting from this agency action. Without question, the unprecedented nature of defendants' action is "significant " within the meaning of the CEQ regulations.

Thus, the defendants' 1992 Policy has all the characteristics that the CEQ regulations equate with "significant" effects on the environment. The Policy is a controversial, precedent setting legislative rule that has unique and uncertain health and environmental impacts. As such, defendants cannot apply a categorical exclusion to the 1992 Policy and subsequent actions. The agency's invocation of a categorical exclusion is arbitrary and capricious, and the Court must overturn the agency's determination. See, Motor Vehicle Manufacturers' Ass'n., 463 U.S. at 43 (explaining that an agency's decision is arbitrary and capricious if the agency "offered an explanation for its decision that runs counter to evidence before the agency").

C. FDA Must Prepare an Environmental Assessment

or an Environmental Impact Statement.

NEPA has a dual purpose. First, it "places upon the agency the obligation to consider every significant aspect of environmental impact of a proposed action." Baltimore Gas & Electric Co. v. NRDC, 462 U.S. at 97. Second, it "ensures that the agency will inform the public that it has considered environmental concerns before going forward with a proposed action." Id.; Weinberger v. Catholic Action of Hawaii/Peace Education Project, 454 U.S. 139, 143 (1981)(explaining that the purpose behind NEPA is to "inject environmental considerations into federal agency's decision making process" and "to inform the public that the [federal] agency has considered environmental concerns in its decision making process"). In the case before the Court, the defendants have completely abdicated their responsibilities under NEPA by issuing a legislative rule allowing the marketing of genetically engineered foods without first considering the environmental and human health impacts in an EA or an EIS. Defs.' 2nd Amend. Answer ¶ 157.

As previous courts have found, the "courts must play a cardinal role in the realization of NEPA's mandate." Foundation on Economic Trends v. Heckler, 756 F.2d 143, 151 (D.C.

Cir. 1985). Since NEPA requires the agency to "take a 'hard look' at the environmental consequences before taking a major action," Baltimore Gas & Electric Co., 462 U.S. at 97-98,quoting Kleppe v. Sierra Club, 427 U.S. 390, 410 n.21 (1976), the "judiciary must see that this legal duty is fulfilled." Foundation on Economic Trends, 756 F.2d at 151. Thus, although the "agency commencing federal action has the initial and primary responsibility for ascertaining whether an EIS is required," Committee for Auto Responsibility v. Solomon, 603 F.2d 992, 1002 (D.C. Cir. 1979), cert. denied sub nom, Committee for Auto Responsibility v. Freeman, 445 U.S. 915 (1980), the "courts must determine that this decision accords with traditional norms of reasoned decision making, and that the agency has taken the 'hard look' required by NEPA." Foundation on Economic Trends, 756 F.2d at 151.

In this case, by failing to prepare either an EA or an EIS, defendants not only did not take the requisite "hard look" at the environmental consequences of its actions, but it took no look whatsoever at the potential impacts caused by genetically engineered foods on the human environment. This procedural abdication occurred in direct contravention of recommendations from within the FDA. In a memo to FDA's Task Group on Food Biotechnology, the Environmental Sciences Staff stated "[i]t is our opinion that the full integration of environmental safety, as mandated by NEPA, into the decision-making process for the evaluation of transgenic plants and microorganisms is required for the promulgation of this policy." A.R. at 18429 (emphasis added). Consistent with FDA's obligations under NEPA, the environmental staffs from the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine developed a point by point 11 page framework for the FDA to use in assessing the environmental impacts associated with the commercial applications of plant biotechnology. A.R. at 18773-18783; Pls.' Ex. No. 1. This assessment framework laid out a host of specific environmental impacts associated with genetically engineered foods including, but not limited to, the impacts directly associated with the expression of the modified genome of the subject plant, with the transfer of genetic sequences to other plants and with the production of modified plant varieties. The framework also noted the need to review the numerous indirect impacts associated with changes in agricultural and processing practices that result from the commercial use of these genetically engineered plants. Id. at 18773-4. Despite the framework's acknowledgment of such impacts, agency review of the Policy under the framework was terminated because it was too detailed and could have provided "a possible basis for later legal challenges." A.R. at 19431.

Coinciding with the completion and subsequent dismissal of its review framework, defendants have specifically admitted several new environmental concerns resulting from genetically engineered food including: "FDA is concerned with the potential environmental impacts associated with changes in current agricultural practices that may arise during the commercialization of a modified food crop;" "FDA is concerned that some commercial applications of genetically modified food crops may involve changes in processing methods;" and "FDA is concerned with the potential release, movement, and establishment of transforming vectors in the environment." A.R. at 18773-83; Pls' Ex. No. 1. The agency even concluded that an umbrella regulation concerning genetically engineered foods "would require that FDA develop an environmental assessment under

NEPA and possibly an Environmental Impact Statement." A.R. at 18541-42 (emphasis added).

In sum, the FDA's application of a categorical exclusion to the 1992 Policy is unsupported by the administrative record, its decisionmaking process, and ignores specific internal recommendations. The agency's actions are characteristic of a major federal action significantly affecting the environment and trigger full NEPA review. Here, the defendants specifically avoided NEPA compliance for fear of future legal liability. Accordingly, the invocation of a categorical exclusion is arbitrary, capricious, and an abuse of discretion, and not in accordance with law. Pending completion of its NEPA obligations, the Court should direct defendants to suspend all activity under the 1992 Policy including the allowance of any and all genetically engineered foods. As a result of defendants' failure to comply with NEPA's requirements, the plaintiffs are entitled to summary judgment.

III. COUNTS I (B) - XXXVI(B) & I (C): FDA's Failure to Require the Submission of Food Additive Petitions for All Genetically Engineered Foods Is A Violation of the Federal Food, Drug and Cosmetic Act.

The Administrative Procedures Act (APA) requires a reviewing court to hold unlawful and set aside any agency action that is arbitrary, capricious, an abuse of discretion, not in accordance with law, or in excess of statutory jurisdiction, authority or limitations. 5 U.S.C. § 706(2)(A)&(C). Defendants have exceeded their authority under the FFDCA by determining, without adequate scientific evidence, that most transferred genetic materials and intended expression products used in genetically engineered foods are "generally recognized as safe" for their intended use and thus are exempt from regulation as food additives.

Under the FFDCA, the FDA must regulate all food additives to ensure their safety of use. Rather than complying with this mandate, the FDA's 1992 Policy excludes virtually all transferred genetic material and expression products used in genetically engineered foods on the grounds that these substances are "generally recognized as safe" (GRAS). The FDA's exclusion of these substances from regulation as food additives is arbitrary and capricious and not in accordance with law based on the Supreme Court's holding in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). The holding in Chevron directs a court to apply a two-part test when reviewing an agency's construction of a statute. First, the court is to look to the plain meaning of the statute. Id. at 842-3. If the statute is unambiguous, then the court and the agency must give effect to Congress' intent. Id. Only if a statute is silent or ambiguous may the court then look at whether the agency's interpretation of the statute is reasonable. Id. at 843.

In this case, the FDA 1992 Policy should be overturned because it lacks the generally recognized expert consensus based on scientific evidence required by the FFDCA. In addition, all of the transferred genetic materials and expression products thereof used in the genetically engineered foods subject to this suit should be declared to be food additives and not generally recognized as safe pursuant to the FFDCA.

A. The First Step of the Chevron Analysis Shows That the Plain Meaning and Purpose of the FFDCA Does Not Support FDA's GRAS Determination.

The FFDCA, as amended by the Food Additive Act of 1958, defines a "food additive" as follows:

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* (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), 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, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use . . . .21 U.S.C. § 321(s)(emphasis added).

Thus, the FFDCA excludes from the definition of "food additive" only substances that are GRAS either: (1) because they were used in foods before January 12, 1958; or (2) because they have been proven GRAS through scientific procedures. Here, the agency concedes that, but for the GRAS exclusion, the transferred genetic material and intended expression products used in genetically engineered foods meet the statutory definition of "food additive." 57 Fed. Reg. at 22990 ("Thus, in the case of foods derived from new plant varieties, it is the transferred genetic material and the intended expression product or products that could be subject to food additive regulation, if such material or expression products are not GRAS.") See also, A.R. at 18130.[(7)]

(1). Genetic Engineering Was Not Used in Foods Before 1958.

In its 1992 Policy the FDA misapplied the GRAS exclusions. First, because genetic engineering (including rDNA) technology was not "in use before 1958," substances used and expressed through this technology are not exempt on the grounds of "prior safe use."[(8)]

(2). Genetically Engineered Foods Cannot Be Determined GRAS

Through Scientific Procedures.

In addition, the substances added by genetic engineering do not qualify as GRAS through scientific procedures. The GRAS exclusion can only apply to a substance that has been "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use." 21 U.S.C. § 321(s). For reasons set out below, the agency has not complied with this standard.

The use of untested (and potentially unsafe) substances as food additives is precisely the situation that the Food Additive Amendments of 1958 were enacted to prevent:

Nonetheless, existing law permits any processor who chooses to pay no heed either to the public's health or to his continuance in one particular line of business to unfairly compete with responsible processors, to defy the FDA and to endanger the health of millions by using an untested additive for as long a time as it may take for the Government to suspect the deleteriousness of his additives, schedule research into its properties and effects, and, finally - perhaps years later - to begin the years-long experiments needed to prove the particular additive safe or unsafe. S. Rep. 2422, 85th Cong., 2d Session, 1958 U.S.C.C.A.N. 5300, 5301.

While Congress did not want to unnecessarily stifle technological advances, it nevertheless intended that additives created through new technologies(9) be proven safe before they go to market. S. Rep. 2422, 1958 U.S.C.C.A.N. 5301-2.

However, the FDA clearly violated the express intent of Congress by applying the GRAS exclusion to the genetic materials and intended expression products without the necessary expert consensus based in scientific procedures. Specifically, the agency improperly (1) chose to treat genetically engineered crops as if they were the same as, and entail no different risk than, crops developed through traditional breeding and (2) determined that genetically engineered foods were generally recognized as safe, even though they knew that -- (a) such general recognition did not, in fact, exist and (b) they could not have been based upon scientific procedures as required by law.

(a). Genetic Engineering Is Not Equivalent to Traditional Cross-Breeding.

The FDA 1992 Policy on genetically engineered foods asserted that genetic engineering is just a "more advanced" form of traditional plant breeding and therefore need not be regulated any more stringently. 57 Fed. Reg. at 22985-6. "The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding." Id. at 22991.

However, the agency made the above assertion despite substantial and repeated warnings from its own scientists about the extent to which genetic engineering differs from conventional practices and entails a unique set of risks. For example, Dr. Louis J. Pribyl of the FDA's Microbiology Group critiqued a draft of the Policy Statement by saying:

The unintended effects cannot be written off so easily by just implying that they too occur in traditional breeding. There is a *profound difference* between the types of unexpected effects from traditional breeding and genetic engineering which is just glanced over in this document. This is not to say that they are more dangerous, just quite different, and this difference should be and is not addressed. A.R. at 19179 (emphasis added).

Dr. Pribyl added that several aspects of gene insertion ". . . may be more hazardous . . ." than traditional crossbreeding. A.R. at 19180. Regarding the possible activation of "cryptic" pathways to generate unexpected toxins, Dr. Pribyl stated: "This situation IS different than that experienced by traditional breeding techniques." A.R. at 19181 (emphasis in original). Similarly, Dr. E.J. Matthews of the FDA's Toxicology Group warned that " . . . genetically modified plants could also contain unexpected high concentrations of plant toxicants." A.R. at 18572. He explained that some of these toxicants could be unexpected and could " . . . be *uniquely different chemicals* that are usually expressed in unrelated plants." A.R. at 18572 (emphasis added). In the same vein, Dr. Linda Kahl, an FDA compliance officer, objected that a draft of the Statement of Policy was " . . . trying to fit a square peg into a round hole . . . [by] trying to force an ultimate conclusion that there is no difference between foods modified by genetic engineering and foods modified by traditional breeding practices." A.R. at 18952-3. She declared: "The processes of genetic engineering and traditional breeding are different, and according to the technical experts in the agency, they lead to different risks." A.R. at 18953. Thus, the record shows that FDA's own scientists consistently informed the agency that genetically engineered crops significantly differ from their conventionally produced counterparts and entail a different set of risks.

(b). There Is Not A General Recognition That Genetically Engineered Foods Are Safe.

The FDA also ignored the fact that a substantial number of its own scientists did not regard genetically engineered foods as safe, all the while claiming that a general recognition of safety existed within the scientific community. The agency's Division of Food Chemistry and Technology cautioned, "it would . . . be necessary to demonstrate that edible seed and oils produced from genetically engineered plants do not contain unintended potentially harmful substances at levels that would cause concern." A.R. at 18613. Concerning marker genes, the division warned that because they " . . . produce proteins that are new with respect to plants . . . they should be considered to be new proteins in the human diet and be subjected to safety evaluation." A.R. at 18619. Regarding unintended changes, the division concluded that although most of these effects can be managed by subsequent procedures, "[n]evertheless, 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. Such evaluations should be performed on a case-by-case basis, i.e., every transformant should be evaluated before it enters the marketplace. (A similar approach was recommended by the International Food Biotechnology Council . . .)." A.R. at 18620. The same division added that in order to adequately address the potential of unexpected toxins, " . . . toxicological evaluation of the edible plant tissue may be more appropriate than using chemical identification and quantitation procedures." Id.

Dr. Pribyl pointed out that in addition to the risks posed by unintended products of rDNA technology, even those substances intentionally introduced could pose problems. He stated that a protein " . . . while acting on one specific, intended substrate to produce a desired effect, will also affect other cellular molecules, either as substrates, or by swamping the plant's regulatory/metabolic system and depriving the plant of resources needed for other things." A.R. at 19182.

Not only was the agency aware of uncertainties within its own ranks, it also knew that there was a lack of consensus about the safety of genetically engineered foods in the scientific community at large. For instance, FDA's Biotechnology Coordinator acknowledged in a letter to the Chairman of Canada's Food Directorate, Working Group on Biotechnology, dated Oct. 23, 1991, commenting on a document that working group produced: "As I know you are aware, there are a number of specific issues addressed in the document for which a scientific consensus does not exist currently, especially the need for specific toxicology tests. Also, the quantity and quality of data that would be required is not addressed and is difficult to specify at this time. I think the question of the potential for some substances to cause allergenic reactions is particularly difficult to predict." A.R. at 22925.

Finally, the agency recognized that there was a lack of proper scientific evidence on which to base any general recognition of safety. Dr. Matthews acknowledged that "(t)he paucity of data on recombination results with, but not exclusively on food plants, results in a difficulty in analyzing the data." A.R. at 18695. Dr. Kahl also emphasized the lack of adequate scientific data:

" . . . (A)re we asking the scientific experts to generate the basis for this policy statement in the absence of any data? It's no wonder that there are so many different opinions - it is an exercise in hypotheses forced on individuals whose jobs and training ordinarily deal with facts." A.R. at 18953. She continued, " . . . there is no data that could quantify risk" and acknowledged that " . . . the scientific issues section of the document [i.e., the Policy Statement] deals totally in hypotheses about 'possibilities' . . . ." A.R. at 18953.

Where an agency's interpretation is inconsistent with the statute and its legislative history, the agency's interpretation is not entitled to deference. U.S. v. Two Plastic Drums, 984 F.2d at 817, citing, Demarest v. Manspeaker, 498 U.S. 184 (1991). Moreover, the court should not accord any deference to an agency decision that fails to consider an important aspect of the problem, offers an explanation for its decision which runs counter to the evidence before the agency, or relied on other factors Congress had not intended it to

consider. Chenery Corp., 332 U.S. at 196. Therefore, the Court should invalidate the FDA's 1992 Policy Statement. In addition, the Court should rule that the transferred genetic materials and expression products used in genetically engineered food products are food additives and are not GRAS.

B. The Second Step of the Chevron Analysis Shows That FDA's GRAS Determination Is Not Reasonable.

The agency's decision to apply the GRAS exclusion to virtually all substances added to genetically engineered foods is inconsistent with the agency's own regulations and past interpretations of the law.

Defendants' regulations require two elements for a substance to be considered GRAS: (1) technical evidence of safety, and (2) a showing that this technical evidence is generally known and accepted among qualified experts. Looking to the technical element of the GRAS showing, the FDA's regulations define "safety" as "a reasonable certainty in the minds of competent scientists that the substance is not harmful[(10)] under the intended conditions of use" and set out certain factors to be considered:

(a) The probable consumption of the substance and its expression products under the intended use.

(b) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substances.[(11)]

(c) Any other safety factors that qualified experts generally recognize as appropriate. 21 C.F.R.170.3(i).

To meet the "common knowledge" element, GRAS regulations ordinarily require published studies that may be corroborated by unpublished studies and other data and information. 21 C.F.R. § 170.30(b). The requisite studies must be based on human, animal, analytical and other scientific studies on the particular use[(12)] in question. 21 C.F.R § 170.3(h).

As stated above, the FDA has failed to demonstrate any general recognition of safety among qualified experts based in scientific procedures. Instead, the FDA based its 1992 Policy Statement only upon hypotheses and inferences, arguing that because nucleic acids are present in the cells of every living organism, the transferred genetic material used in bioengineered foods would be GRAS and that because many of the products "expressed" (expression products) by the transferred genetic materials would be somewhat similar to substances already present in currently consumed foods, these substances too would generally be presumed to be GRAS. 57 Fed. Reg. at 22990.

However, GRAS status cannot be based primarily on hypothesis and inferences. United States v. Seven Cartons . . . Ferro-Lac, 293 F.Supp. 660 (N.D. Il. 1968), *modified on other grounds*, 424 F.2d 136 (7th Cir. 1970).(13) In the Ferro-Lac case, the proponents of the food additive presented an affidavit from a scientific expert claiming that because the three constituents of the compound were GRAS when used alone, "'it is a reasonable scientific certainty'" that their use in combination would also be safe. Id. The affidavit further claimed such a conclusion is based upon "principles of chemistry" and that "any chemist would 'necessarily recognize' the result stated." Id.

In opposition, the FDA, which had seized the substance as containing unsafe food additives, submitted two expert affidavits which emphasized that the use of the three ingredients in combination was a new use and that their safe use in isolation did not support an inference that they could be safely used together. Id. These affidavits stated the only way to determine whether the compound is safe is through "actual testing . . . to demonstrate that long term ingestion of potential residues of the chemical in edible tissues will not be harmful to humans." Id. at 664. Both affiants also stated that they were not aware of any reports of tests of this particular compound in the pharmacological-toxicological literature. Id.

The court held that the FDA's affidavits established that, as a matter of law, there was no general recognition of safety based upon scientific procedures and awarded summary judgment to the agency. It dismissed the affidavit submitted by claimant because it was solely based on "theoretical evaluation" and contained "at best, an inference that safety might be shown by scientific testing and procedures." Id. at 665.

Here, the Court has an even stronger reason to reach a similar conclusion about all genetically engineered foods currently on the market. First, while the constituents of Ferro-Lac were each recognized to be safe in separation, most of the intended expression products of transgenes are not themselves recognized as safe. Rather, they are inferred to be safe by supposed similarity (but not established identity) with GRAS substances. Second, it is admitted by the FDA that the bioengineering process could yield a wide range of unintended and unexpected deleterious substances. Third, even though there was testimony that the safety of the concerted action of the components of Ferro-Lac could be inferred with a reasonable scientific certainty, the court held this was insufficient to establish its safety. In the case of genetically engineered foods, scientists both within and without the FDA acknowledge that the dynamics of DNA and living systems are so complex, and the disruptive potential of rDNA technology so great, that it is not possible

to predict all the outcomes and hence impossible to establish safety based on mere theoretical evaluation and inference.

Additionally, several qualified experts have submitted declarations in the present case attesting to the fact that there is currently no consensus on the safety of genetically engineered foods among those scientific experts qualified to evaluate the issue and that even if there were, it could not be based on scientific procedures as required by law, since the standard scientific literature is devoid of any reference to tests that establish the safety of even one genetically engineered food. *See* Decl. Regal, Lacey, and Fagan.[(14)]

The FDA's interpretation of the GRAS standards also is inconsistent with its past interpretations of the GRAS requirements. The agency consistently has argued in favor of a strict interpretation of the GRAS requirements, as evidenced by its prosecution of Ferro-Lac, *supra*. Further, the agency has asserted, and the courts have upheld, arguments that containers and dinnerware can be unsafe food additives. Natick Paperboard Corp. V. Weinberger, 525 F.2d 1103 (1st Cir. 1975) (where paper food packaging containing polychlorinated biphenyls was found to be a food additive); U.S. v. Articles of Food . . . Pottery, 370 F.Supp. 371 (E.D.Mi. 1974) (pottery dinnerware containing lead may be a food additive, denying intervenor's motion to dismiss, for judgment on the pleadings and for summary judgment). So, too, courts have supported the FDA's arguments that DDT found in processed seafood is a "food additive," U.S. v Ewig Bros.Co., 502 F.2d at 722-25, as is mercury in swordfish, U.S. v. An Article of Food . . . Swordfish, et al., 395 F.Supp. 1184 (S.D.N.Y. 1975).

The agency's position in this long line of food additive cases directly conflicts with its position in the 1992 Policy Statement. In the Policy Statement, the agency failed to address the scientific uncertainties and risks in a pre-market review of these genetically engineered substances, as required by the FFDCA. This, in effect, is an attempt via regulation to overturn the law which presumes that food additives are "unsafe" and cannot be marketed until they are demonstrated to be safe to a reasonable certainty. Instead, defendants have presumed that the transferred genetic materials and expression products are "safe" and can be marketed freely. Defendants will challenge these substances only after they can be determined to have caused harm--which, in effect, renders them "innocent until proven guilty."

Therefore, companies that profit from the sale of genetically engineered foods will decide which products are safe--and not the defendants, who are charged with this duty. The threat of enforcement is no assurance of safety, however, since companies are not required to notify the government or label when genetically engineered foods are marketed, making it difficult to find--let alone prosecute--genetically engineered food additives.

When one compares the stance of the FDA as exhibited in its prosecution of Ferro-Lac, with its current position on genetically engineered foods, a glaring inconsistency is evident. Courts are skeptical of an agency position that is inconsistent with its earlier positions. U.S. v. 29 Cartons Of . . . An Article of Food, 987 F.2d 33, 38 at n. 6 (1st Cir.

1993), citing, Bowen v. Georgetown Univ. Hosp., 488 U.S. 204 (1988) and Skidmore v. Swift & Co., 323 U.S. 134 (1944). For this reason, the agency's novel reading and application of the statute should not be persuasive.

Therefore, the FDA 1992 Policy Statement should be overturned because it lacks the consensus based on scientific evidence required by the FFDCA. In addition, all of the transferred genetic materials and expression products thereof used in the genetically engineered foods subject to this suit should be declared to be food additives and not generally recognized as safe pursuant to the FFDCA.

IV. Counts I (A) - XXXVII(A): FDA's Failure to Require the Labeling of All Genetically Engineered Foods Is Arbitrary, Capricious, and an Abuse of Discretion.

A. Determinations of What is Material for Purposes of Food Labeling is Subject to Review Under an Expanded Reasonableness Standard.

Under the FFDCA food is deemed misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. § 343(a)(1) (1992 & Supp. 1997). Further, in accordance with Section 201(n), 21 U.S.C. § 321(n), the FFDCA provides that:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary. (emphasis added)

These sections of the FFDCA have been interpreted to mandate food labeling in favor of consumer interests.

Section 201(n) appeared for the first time four years into the debate over legislation that would eventually become the Food, Drug and Cosmetic Act of 1938.[(15)] S.5 [Confidential Committee Print No. 2],75th Cong., 1st Sess., § 201(n) (July 23, 1937) *reprinted in* FDA, A Legislative History of the Food, Drug & Cosmetic Act, Vol. 5 at 772 (1979). The language has been amended only once to add the clause "or advertising" in two locations. See, Pub. L. No. 94-278 (1976).

The language triggering whether a commission or omission on a food label make such food misbranded is the failure of its labeling to reveal "material" fact. The materiality requirement was written into the FFDCA of 1938 to have the same meaning as a corresponding paragraph in a bill addressing false advertising. The bill, S.1077, became known as the Wheeler-Lea Act and provided new powers to the Federal Trade Commission. S.5, H.R. Conf. Rep. No. 2139, 75th Cong., 3rd Sess. 3 (April 14, 1938) *reprinted in* FDA, A Legislative History of the Food, Drug & Cosmetic Act, Vol. 6 at 302 (1979); See also, S.1077, H.R. Conf. Rep. No. 1774, 75th Cong. 3d Sess. § 15 (February 8, 1938) *reprinted in* Charles Wesley Dunn, Wheeler-Lea Act: A Statement of Legislative History (1938) at 163. The FFDCA legislative history is quiet as to what type of fact is "material" stating only the "purpose is obvious." H.R. Conf. Rep. No. 2139 at 3. However, the drafters explicitly connected the language of § 201(n) with the Wheeler-Lea Act language. In that context the language has been traced back to the 1938 Restatement of Torts §538 which defined a fact to be material "if its existence or nonexistence is a matter to which a reasonable man would attach importance in determining his choice of action in a transaction in question."(16) See, Milton Handler, "The Control of False Advertising under the Wheeler-Lea Act," 6 Law & Contemp. Probs. 91, 97-98 (1939). Therefore, at a minimum legislative history suggests that a material fact would be an omission on a food label that a reasonable person would view as important and would thus trigger a finding of misbranding under 21 U.S.C. § 343(a).

Subsequent court decisions concerning the FFDCA have interpreted this standard of review even more broadly in favor of the consumer. The courts "have construed Section 343 broadly, since the test is not the effect of the label on a reasonable consumer, but upon the 'the ignorant, the unthinking and credulous consumer.'" United States v. Strauss, 999 F.2d 692, 696 (2nd Cir. 1993) (quoting United States v. An Article . . . Sudden Change, 409 F.2d 734, 740 (2nd Cir. 1969)). As the Supreme Court has stated, "Remedial legislation such as the Food, Drug and Cosmetic Act is to be given liberal construction consistent with the Act's overriding purpose to protect the public health." United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969); United States v. 25 Cases More or Less, 942 F.2d 1179, 1182 (7th Cir. 1991). Therefore, in considering whether the omission of a material fact from a food label renders that food misbranded under § 343 the court must determine what is "material" in the light most favorable to the consumer, even a less than reasonable, credulous consumer.

Whether or not labeling is false or misleading in any particular is a question of fact for determination by the trial judge in the absence of a jury. United States v. An Article of Drug . . . 47 Bottles of . . . Jenasol,320 F.2d 564, 571 (3rd Cir. 1963), citing, Colusa Remedy Co. v. United States, 176 F.2d 554, 561 (8th Cir. 1949). For the reasons below, plaintiffs have shown there is no genuine fact dispute that genetically engineered foods have all the characteristics that are "reasonably" construed as material under § 201(n) and mandate labeling. Further plaintiffs have shown that defendants have arbitrarily and capriciously enacted a regulation allowing misbranded food into interstate commerce.

B. Alteration of Food By Genetic Engineering is Material Fact.

In the 1992 Policy and subsequent regulatory actions defendants claim that genetically engineering does not differ in principle from older plant breeding techniques, and that the products of genetic engineering do not have traits that distinguish them from products of older techniques. A.R. at 18648. The defendants further assert that genetic engineering is an extension of traditional plant breeding at a molecular level and, as such, the novel genes, antibioitic markers, promoters and vectors added to these foods are not "material" and do not require labeling. 57 Fed. Reg. at 22991; See also, A.R. at 18650.

Such a determination is arbitrary and capricious and not based upon a reasonable, consumer-oriented standard of review for "materiality". Genetic engineering is a radical new technology that fundamentally alters the type and range of genetic material (and other additives) which can be incorporated into food producing plants. In comparison, traditional plant breeding is limited to the transfer of traits present in closely related species. The defendants own scientific experts have contradicted this finding of "substantial equivalence." As Linda Kahl of FDA's Office of Compliance relays to the 1992 Policy coordinator James Marayanski concerning the 1992 Policy:

I believe that there are at least two situations relative to this document in which it is trying to fit a square peg into a round hole. The first square peg into a round hole is that the document is trying to force an ultimate conclusion that there is no difference between foods modified by genetic engineering and foods modified by traditional breeding practices. This is because of the mandate to regulate the product, not the process.

a. The processes of genetic engineering **<u>are</u>** different and according to the technical experts in the agency, they lead to different risks. There is no data that addresses the relative magnitude of the risks - for all we know, the risks may be lower for genetically engineered foods than for food produced by traditional breeding. But acknowledgment that the risks are different is lost in the attempt to hold to the doctrine that the product and not the process is regulated. A.R. at 18952-53 (emphasis in original).

As defendants themselves further admit, genetic engineering allows "for the possibility of transfering (sic) to any organism a gene from any other organism or from a synthetic source (i.e., an enzyme composed of several domains of unrelated proteins). This potential is beyond the realm of possibility of standard breeding practice. The food safety of organisms derived from recombinant DNA technologies do not have the history of the safe use that has come to be associated with organisms derived by standard breeding practices." A.R. at 18625. Further, defendants admit that "recently developed

recombinant DNA technologies allow the transfer genetic material between sexually-incompatible organisms, for example, between plants and insects or plants and bacteria." A.R. at 18742. As a FDA scientists cautions a mere two months before release of the 1992 Policy:

The document is inconsistent, in that it says (implies) that there are no differences between traditional breeding and recombinant, yet consultations, and premarket approvals are being bantered around, when they have not been used for foods before. In fact the FDA is making a distinction, so why pretend otherwise. A.R. at 19179.

Another FDA document sums up the novel nature of these foods, "We should also keep in mind that plant genetic engineering is an entirely new adventure with potentially new effects." A.R. at 19165.

Genetic engineering transfers to plants novel material never before inserted into whole plant foods including virtually any gene(s) including those of animals and insects, a selectable marker, and regulatory DNA sequences such as promoters and terminators. A.R. at 18743. Genetic engineering also utilizes viral vectors to transfer genetic material into the plants. A..R. 18742-43.

Genetically engineered plants most often include at least one marker gene to monitor the inserted DNA. A.R. at 18743. The most frequently used selectable marker genes code for proteins that inactivate kanamycin, neomycin and other antibiotics. A.R. at 18743. All of the newly introduced marker genes produce proteins that are new with respect to the host plants. A.R. at 18744. FDA admits that the insertion of markers adds proteins which have never before been in in foods, and which "should be considered new proteins in the human diet." A.R. at 18744. These inserted antibiotic resistance genes may impact human health by possibly interfering with the oral therapeutic usage of antibiotics and by creating resistance in consumers to important antibiotics. A.R. at 11723, 37744-45.

Genetic engineering technology fundamentally alters foods in other ways making them substantially different from those produced through traditional breeding methods. Genetic engineering, in the laboratory, randomly forces foreign genetic material into a recipient plant's genetic structure. This disturbs the function of the region of native DNA into which the foreign material has been spliced. Further, the foreign genes will not usually not express themselves within their new environment without an artificial boost, which is supplied by fusing them to promoters from viruses or pathogenic bacteria. As a result, these genes operate in an unprecdented way in plant foods as they act in virtual independence from the host plants regulatory system, which can lead to deleterious imbalances. See, Decl. Lacey; Regal; Fagan.

In sum, despite numerous and significant differences between genetic engineering and traditional breeding, the defendants have trivialized the unique nature of genetically

engineered plants in an attempt to justify its failure to require labeling. This trivialization may have reached a low point when an FDA senior policy advisor, responding to the filing of the current lawsuit, told the media that labeling genetically engineered food would be "similar to saying whether grapes are picked by scab labor or union labor."[(17)] Defendants misguided use of the "substantially equivalence" argument contravenes the views of their own scientfic experts and any reasonable examination of the novel techniques and effects of genetically engineering.

C. Reasonable Consumers Do Not

Expect Their Food To Be Genetically Engineered

In addressing the issue of irradiation, the agency stated, "in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed." 51 Fed. Reg. 1375, 13390 (April 18, 1986). Genetic engineering presents consumers with a similar implied representation. In the absence of labeling a person who walks into the supermarket to purchase a tomato does not have a reasonable expectation that the tomato they may purchase contains novel proteins never before present in food, genetic material from a flounder and/or a genetic marker system based upon conferring antibiotic resistance.

Similarly, the reasonable consumer, much less the credulous consumer, does not go into the supermarket and purchase a tomato with a reasonable expectation that they may be consuming proteins that could ultimately impact the efficacy of antibiotics they are currently taking. As evidenced by the over 80% requesting labeling to defendants, consumers reasonably expect that changes in their food of the magnitude created by genetic engineering will trigger labeling. A.R. at 19593. Such reasonable expectations are further borne out in 1992 a USDA poll found that 85% of consumers thought that the labeling of products of genetic engineering "very important."[(18)] Defendants' failure to require the labeling of genetically engineered plant foods violates the reasonable expectation of consumers and therefore is violative of § 201(n) of the FFDCA.

D. Court and Agency Interpretations Material Fact Mandate the Labeling

of Genetically Engineered Foods.

Defendants' failure to label offends not only the statutorily mandated "reasonable" standard of materiality, but also more specific standards of materiality articulated by the courts and the FDA. In 1995, a district court determined that milk and dairy products derived from cows treated with a cow hormone known as bovine growth hormone (rBGH

or rbST) did not have to be labeled. Stauber v. Shalala, 895 F.Supp. 1178 (W.D. Wis. 1995). In addressing the standard under 21 U.S.C. § 321(n), the court found that the products did not have to be labeled because there was no evidence that milk derived from rBGH differed in performance characteristics or organoleptic properties from milk derived from untreated cows. Stauber, 895 F.Supp. at 1193 (emphasis added). Thus, the court established that changes in performance characteristics or organoleptic differences in food will mandate labeling. Unlike the case in Stauber, there is ample evidence and admissions that genetically engineered food is both changed in performance characteristics and organoleptic properties.

Past food labeling rulemakings by the defendants have emphasized that when there are performance or organoleptic changes in foods they must be labeled to that effect. In addressing regulatory changes for food nutrient content claims the agency stated:

Under section 201(n) (21 U.S.C. §321(n)) and 403 (a) of the act, the label or labeling of food must disclose to consumers what they are buying when they purchase these modified foods. Information disclosing differences in performance characteristics (e.g. physical properties, flavor characteristics, functional properties and shelf life) is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label, or the labeling would be misleading and the product would be misbranded under section 403(a) of the act. 58 Fed. Reg. 2431, 2437 (June 6, 1993) (emphasis added). See also, Stauber, 895 F.Supp. at 1193.

(1). Genetically Engineered Foods Contain for Performance and Organoleptic Changes.

Defendants admit that the genetically engineered plants and foods are altered for, *inter alia*, performance changes. 2nd Amend. Answer at ¶¶ 162, 177, 192, 207, 222, 237, 252, 268, 282, 297, 312, 327, 342, 357, 372, 387, 402, 417, 432, 447, 462, 477, 492, 507, 522, 537, 552, 567, 582, 597, 611, 625, 639, 654, 669, 684. This is confirmed throughout the Administrative Record. Indeed, the defendants even have provided a compendium on how genetic engineering is leading to performance changes such as herbicide-tolerance, new possibilities for improving food composition (protein modification, oil modification, carbohydrate modification) and modifying processing and other characteristics. A.R. at 18745-18751. More specifically, the Flavr Savr tomato is genetically engineered to control the expression of the enzyme polygalacturonase (PG) thereby slowing ripening and increasing shelf-life. A.R. at 11, 72-73. The resulting tomatoes also have an altered molecular weight as result of increased pectin content. A.R. at 16. Use of Flavr Savr tomatoes in juice and tomato paste showed an increase in serum viscosity. A.R. at 234. Thus, the Flavr Savr exemplifies the performance changes such as new physical properties (increased pectin) functional qualities (increased viscosity) and longer shelf-life initiated by genetic engineering.

Similarly, DNA Plant Technology's Improved Ripening Tomato is genetically engineered to suppress ethylene enzyme production thereby leading to a performance change of delayed ripening. A.R. at 36163. Zeneca Plant Science's Delayed Softening Tomato is genetically engineered to alter ripening enzymes so the tomato's performance is changed by softening less quickly. A.R. at 35397. Agritope Inc.'s Modified Fruit Ripening Tomato is genetically engineered to lower enzyme levels in tomatoes affecting ripening performance. A.R. at 36604. These tomatoes are all genetically engineered to, *inter alia*, have improved production dynamics and reduced losses in distribution because of longer shelf life. A.R. at 36654.

Other plants provide examples of the clear intention of genetic engineering to alter performance characteristics as it relates to a crop's physical properties. Numerous plants are engineered to be resistant to indiscriminant herbicide application. For example, AgrEvo's glufinosinate tolerant corn was genetically engineered to alter the performance characteristics of corn to be resistant to the application of the herbicide Liberty®. A.R. at 38387. Similarly, Monsanto's Gylphosate Tolerant Corn is genetically engineered to be similarly tolerant to the application of the herbicide Roundup®. A.R. at 40672. Also, Ciba Geigy's Insect Protected Corn (and Popcorn) is genetically engineered to be pest-resistant through the expression of the "most radical alteration" of an insecticidal protein gene from the bacterial strain *Bacillus thuringiensis (B.t.)*. A.R. at 37672. The newly introduced B.t. protein is present in all the kernels of the corn. A.R. at 37676.

Other examples abound. Dupont's High Oleic Acid Soybean has performance changes including the characteristics of the derived soybean oil during cooking. See 56 Fed. Reg. 60421 (November 27, 1991) (changes in functional properties for cooking are performance changes). The soybean oil is compositionally different from conventional soybean oil and will be used in, *inter alia*, food frying and baking operations because of its enhanced natural stability and favorable fatty acid profile. A.R. at 39855.

While by no means exhaustive, the examples cited provide undisputed fact that genetic engineering directly alters the performance characteristics of food including, *inter alia*, its physical and functional properties and shelf-life. Such evidence is material fact under § 201(n) and mandates labeling.

Additionally, genetically engineered foods are organoleptically (taste, color, smell, texture, etc . . .) altered. See generally, 62 Fed. Reg. 8248, 8249 (February 24, 1997). Defendants have admitted that one food has such changes. 2nd Answer at ¶ 312. Calgene's Laurate Canola is genetically engineered to produce high levels of lauric acid and modest amounts of myristic acid in canola seed oil. A.R. at 37783. It has been specifically genetically altered to change the fatty acid composition of canola oil. A.R. at 37797.

Similar to the Calgene Canola that defendants admit has organoleptic changes, Dupont's High Oleic Acid Soybean is genetically engineered to produce soybean oil "with a dramatically modified fatty acid spectrum." A.R. at 39850. The modified soybean oil has oleic acid content of at least 55% greater than conventional soybean oil. A.R. at 39850. Also, Dupont's Sulfonylurea Tolerant Cotton is genetically engineered to be tolerant to

sulfonylurea herbicides and Staple® herbicide use. A.R. at 38543. Differences in cottonseed oil from this cotton were significant for the level of three fatty acids myristic, linoleic, and linolenic acids. A.R. at 38589.

Other genetically engineered foods have organoleptic alterations. Flavr Savr tomatoes have increased solids as a result of greater pectin content. A.R. at 16. And the FDA approved voluntary labeling language in which the tomato's maker, Calgene, states "Flavor you can see. And feel. And smell. And taste." A.R. at 2211. These engineered tomatoes are also significantly firmer than non-genetically engineered tomatoes. A.R. at 235, 277.Monsanto's Improved Ripening Tomato has the explicit goal to produce a better tasting tomato through genetic engineering. A.R. at 35375. Zeneca Plant Science's Delayed Softening Tomato is genetically engineered to intentionally alter its structure, composition and level of carbohydrates. A.R. at 35404. These tomatoes have less breakdown in pectin and improved thickness. A.R. at 35387. Defendants' further admit that alterations of fruit ripening enzymes in tomatoes will yield organoleptic changes stating, "For example, genetic modifications of plant enzymes involved in fruit ripening may yield tomatoes with improved ripening characteristics, texture and flavor." 57 Fed. Reg. at 22986. Additionally, Monsanto's Insect Protected Potatoes are genetically engineered to express novel proteins from the B.t. bacteria. In one version of these potatoes there were found statistically significant lower levels of solids. A.R. at 39477. Also, statistically significant lower levels of dextrose and sucrose were found in the potatoes. A.R. at 39491.

Again, while by no means exhaustive, these examples cited provide clear evidence that genetic engineering directly alters the organoleptic characteristics of food including, *inter alia*, there sensory conditions such as increased or decreased solid content, direct attempts to change taste and potentially nutrient content such as fatty acid content levels.

In addition to these specific foods, there are potential organoleptic changes which could occur in any genetically engineered plant food because insertion of DNA by genetic engineering into a host plant can produce phenotypic [observable constitution of an organism] changes (desirable and undesirable) referred to as pleiotropic effects. A.R. at 18744 (bracketed explanation added). Pleiotropic effects have been shown to occur at frequencies up to 30% in genetically engineered plants. A.R. at 18745. The resulting undesirable phenotypes may include, *inter alia*, increased levels of natural toxicants, the 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 which may escape a breeder's attention unless genetically engineered plants are evaluated specifically for these changes. A.R. at 18620. As defendants further admit, genetically modified plants might contain unexpectedly high concentrations of plant toxicants. This can occur by at least two mechanisms. One could be the amplification of normal levels of existing toxicants into higher levels. Second, normally inactive plant toxins could become activated. A.R. at 18682. As one of defendants' scientist suggests about the 1992 Policy, "the unintended effects cannot be written off so easily by just implying that they occur too in traditional breeding. There is a profound difference between the types of unexpected effects from

traditional breeding and genetic engineering which is just glanced at in this document." A.R. at 19179.

Both the intended and unintended changes in the physical and organopetic properties of genetically engineered plants mandate labeling under § 201(n).*(2). Consumer Demands for the Mandatory Labeling of*

Genetically Engineered Contribute to a Finding of Material Facts.

Significant consumer interest bolsters a finding of material fact which triggers defendants' labeling requirements. Stauber, 895 F.Supp. at 1193. Defendants have even "interpreted this section of the Act to mean that whether information is material depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer." A.R. at 18858, lines 17-23. In the case at hand, defendants have invited comments from the public as to the types of compositional changes that may be considered significant. A.R. at 19581. More specifically, in addressing consumer interest in labeling the agency has stated:

[T]he large number of consumer comments requesting retail labeling attest to the significance placed upon such information by consumers. Moreover, several comments argued irradiation of food altered the organoleptic properties of food thereby reducing its nutritional value. These changes in the food, the comments asserted, make the irradiation of the food a material fact that must be disclosed under section 403(a) and 201(n) of the act 51 Fed. Reg. 13376, 13388 (April 18, 1986).

In addressing the role of public concern as it relates to labeling, the agency has further elaborated that:

In determining whether labeling is misleading, the agency must take into account the extent to which labeling fails to reveal material facts in light of representations made about the food or consequences that many result from the use of such food [section 201(n) of the act]. Therefore, the agency must decide whether the changes in the organoleptic properties of irradiated foods constitute a material fact or whether the information that a food has been irradiated constitutes information that is material to a consumer even if the organoleptic changes were not significant. Id. at 13390 (emphasis added).

The public is clearly interested in demanding the labeling of genetically engineered foods. See generally, A.R. at 25605-31300 (sample of consumer comments). The

defendants' "Preliminary Analysis of Comment FDA Statement of Policy: Food From New Plant Varieties" indicates that approximately 80% of the comments received by the agency request labeling of "genetically engineered" foods. A.R. at 19593. Additional analysis of the comments by the defendants states: "Not surprisingly, most consumers believed that genetically engineered foods should be labeled. Almost every comment reflected this sentiment. Many also said that labels should be clear, prominent, and not restricted to fine print." A.R. at 19591. As one FDA employee notes: "it is immaterial that the FDA doesn't believe methods of genetic modifications are material information important to consumers if regulations do indeed indicate that the former will be a material fact when consumers view such information as important." A.R. at 18961. At a minimum, when combined with the performance and organoleptic changes in genetically engineered food, the consumers high level of interest in labeling renders such characteristics "material" under § 201(n).

(3). Religious Demands for the Mandatory Labeling of Genetically Engineered Contribute to a Finding of Material Fact.

Religious interest also contributes to a finding of material fact which triggers defendants' labeling requirements. See infra, Brief at V & VI. In addressing the labeling issues involving protein hyrdolysates used as food flavors or flavor enhancers the defendants have stated:

The agency tentatively finds that food source of a protein hydrolysate is information of material importance for a person who desires to avoid certain foods for religious or cultural reasons. This information is necessary for such an individual to determine whether the food is acceptable or non-acceptable for inclusion in their diet. If such information is not included in the declaration of a protein hydrolysate, a consumer would have no way of knowing that he/she was consuming a food prohibited or discouraged by his/her personal convictions. The agency thus tentatively concludes that the food source of a protein hydrolysate is a material fact under 21 U.S.C. 321(n), and that the failure to identify the food source in the declaration of a protein hydrolysate would cause the food to be misbranded. 56 Fed. Reg 28592, 28600 (June 21, 1991).

In addition, defendants have asserted that if it were to learn that the derivation of a gene is relevant in a consumer's consideration of whether eating a food violates ethical or religious beliefs, it may require labeling. A.R. at 18649. Yet defendants' "Preliminary Analysis of Comment FDA Statement of Policy: Food From New Plant Varieties" indicates that approximately 15% of the comments received by the agency mention concern related to vegetarian, religious or ethical beliefs." A.R. at 19593. The agency also states, "many consumers who avoid certain types of food for health, religious, or moral reasons expressed concern that they would not know what they were eating when eating genetically engineered foods." A.R. at 19591. Nonetheless, the defendants have

failed to make a passing analysis of the impact of it failure to require labeling has had on religious consumers. As a number of the plaintiffs assert, absent mandatory labeling they have no way of knowing if they are consuming foods "discouraged by his/her personal convictions." See e.g., Decl. Jaworowsky, Kedala, Kucynda and Speck. Thus, when combined with the performance and organoleptic changes in genetically engineered food and the consumers high level of interest in general labeling, the concerns of religious consumers renders a failure to label "material" under § 201(n).

(4). Potential Allergencity of Genetically Engineered Foods is a Material Fact.

The consumer interest in food labeling is of particular interest to those with food sensitivity and allergies. The FDA admits that:

Since certain proteins from normal plants have caused documented allergic reactions in people, it is possible that the edible portion of genetically modified plants (i.e. novel plants) may cause food allergies. Antigenic plant proteins (i.e. allergens) could be come concentrated in novel plant foods by two different mechanism. First, novel food contains new DNA that could constitutively produce a new protein allergen which was not present in the wild type plant. Alternatively, the process of insertion of the new DNA in the novel plant may cause positional mutagenesis (i.e. pleiotropy) that could enhance the synthesis of existing plant food allergens." A.R. at 18673.

The FDA has addressed materiality, food allergies and labeling requirements under sections 201(n) and 403 when regulating foods named by a nutrient content claim (such as "fat free") in conjunction with a traditional standardized name (for example "reduced fat sour cream"). In addressing an FDA mandated labeling requirement of certain ingredients the agency stated:

The highlighting of ingredients that are not part of the traditional standard of identify, or that are added in excess of what is permitted by that standard, is appropriate to ensure continued consumer confidence in standardized foods. FDA believes under section 201(n) and 403(d) of the act, consumers are entitled to know how the new standardized food differs from traditional standardized food. In some case, consumers may have allergies to certain ingredients that may not be normally encountered in the standardized food. Therefore, FDA finds that these ingredients must be highlighted. 58 Fed. Reg. 2431, 2443 (January 6, 1993) (emphasis added).

Thus, defendants have now taken the position that "fat free sour cream" mandates labeling because of potential consumer allergy concerns, but genetically engineered foods containing proteins never before consumed by the public do not mandate labeling.

Potential allergenic responses in consumers resulting from novel proteins raise serious health concerns. Such concerns are not trivial. In 1996, the New England Journal of

Medicine reported that a soybean genetically engineered with a gene from a Brazil nut could cause significant adverse, and potentially fatal reaction to the soybeans in consumers allergic to the Brazil nut.[19]

Defendants have clearly held that other potentially allergenic material mandates labeling. In the case of sulfiting agents defendants have stated:

Because, as stated above, sulfiting agents can cause allergic-type responses of unpredictable severity, the presence of a detectable amount of sulfites . . . in a food is a material fact. Therefore the absence on the label of a food of the material fact that the food contains sulfiting agents renders that label misleading and the food misbranded under sections 403(a) and 201(n) of the act. 53 Fed. Reg. 51062, 51063 (December 19, 1988) .

Defendants admit that one possible consequence of genetically engineering plants is that they may contain new proteins which are not found in the parental plant. The defendants continue, "Since a number of proteins have been shown to cause allergic responses in man, the possibility exists that the new proteins in novel plant foods could be allergic in humans." A.R. at 18865.

Defendants also admit that every new genetically engineered plant will have novel proteins present in it. "DNA transferred to plants usually contains a gene or genes of interest, a selectable marker gene, and regulatory DNA sequences such promoters and terminators. It may also contain a scorable marker gene." A.R. at 18743. These marker genes "produce proteins that are new with respect to plants. Because background exposure to these proteins, e.g. microorganism present in the environment, would negligible (see Chemistry memoranda), they should be considered to be new proteins in the human diet and be subject to safety evaluation." A.R. at 18744.

For virtually every food there is someone who is allergic to it.[20] See e.g., A.R. at 11576, 25605 (consumer comment letters noting uncommon food allergies). See also, Plaintiff Sheila Slade, 2nd Amend. Compl. at ¶¶76-79. Proteins are what cause allergic reactions, and virtually every genetically engineered transfer results in some protein production. Genetic engineering will bring proteins into food crops not just from known allergens, like peanuts, shellfish, and dairy, but from plants of all kinds, bacteria and viruses, whose potential allergencity is uncommon or unknown.

Almost 25% of all members of the public who commented to the defendants on the 1992 Food Policy requested the FDA to adequately protect consumer health from the effects of unrecognized or uncommon allergens, all genetically engineered foods need to be labeled so that allergenic food consumers have the material facts necessary to distinguish genetically engineered foods. A.R. at 19593. As the agency summed up, "A great deal of fear was expressed by consumers that they would not know whether they were eating foods to which they might be allergic." A.R. at 19591. The need for labeling is particularly material since one of the potential consequence is sudden death, and the most affected population will be children. Thus, when combined with the performance and

organoleptic changes in genetically engineered food, the high level of consumer interest in general labeling, and the concerns of religious consumers, the potential risks posed to allergenic and food sensitive consumers renders a failure to label "material" under §201(n).

E. Plaintiffs Are Entitled to Summary Judgement on All Labeling Counts.

Defendants' actions in not requiring labeling of genetically engineered foods despite the reasonable expectations of consumers, admitted performance or organoleptic changes in such foods and the widespread public desire for labeling (including for purposes of religious conviction and allergenic sensitivity) are, under FFDCA §§ 321(n) and 343(a)(1), arbitrary and capricious, an abuse of discretion and not in accordance with law. Defendants have made a central regulatory decision which runs counter to the undisputed evidence before it. Motor Vehicles Mfr. Ass'n., 463 U.S.at 43

Moreover, the FDA's actions ignore prior agency decisions concerning the mandatory labeling of foods. Ignoring such agency precedents is in itself an arbitrary and capricious agency action. The defendants' actions on the labeling genetically engineered foods must be implemented and enforced consistently and predictably. See, United States v. One 1985 Mercedes, 917 F.2d 415 (9th Cir. 1990), citing Morton v. Ruiz, 415 U.S. 199, 232 (1974). Therefore, plaintiffs are entitled to summary judgment on all counts of labeling.

V. Count I (E): FDA's Failure to Require the Labeling of Genetically Engineered Food Violates the Religious Freedom Restoration Act.

In relevant part, the Religious Freedom Restoration Act (RFRA) provides:

Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability. . . . Government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person -- (1) is in furtherance of a compelling government interest; and (2) is the least restrictive means of furthering that compelling government interest. 42 U.S.C. § 2000bb 1(a)-(b) (West 1994).

Congress passed RFRA in response to the Supreme Court's decision in Employment Div., Dept. of Human Resources of Ore. v. Smith, 494 U.S. 872 (1990), because, in its view, the decision "virtually eliminated the requirement that government justify burdens on

religious exercise imposed by laws neutral toward religion." 42 U.S.C. § 2000bb(a)(4). RFRA's purpose, therefore, was to reinstate by statute the pre-Smith strict scrutiny review of neutral laws that substantially burden religious exercise.

As enacted, RFRA applies to the actions of any government branch, department, agency, instrumentality or official, covering "all Federal and State[21] law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993." *Id.* at § 2000bb-2(1); § 2000bb-3.

Under RFRA, a claimant must demonstrate that the government has substantially burdened his or her religious belief or practice, whereupon the burden shifts to the government to demonstrate that its actions served a compelling interest and used the least restrictive means of accomplishing that interest. 42 U.S.C. § 2000bb-1. See also, Campbell-El v. D.C., 874 F. Supp. 403, 408-09 (D.D.C. 1994). In the instant case, defendants' actions violate RFRA because they substantially burden religion without a compelling reason and without using the least restrictive means.

A. Defendants' Actions Substantially Burden Religion.

By allowing genetically engineered foods now available and those developed in the future to be sold without labeling, defendants, in effect, have exposed and will continue to cause plaintiffs to be unknowingly exposed to foods that they deem religiously objectionable. Defendants have thereby substantially burdened the religious beliefs and practices of plaintiffs Conroy, Epstein, Gracey, Green, Jaworowsky, Kedala, Kucynda, Mitchell, Reigstad, Serebryanski, Slade, Speck, Steinbrecher, White, Williams, Pariwar-Yugnirman and Beth Shalom.

Defendants' actions fall within the purview of RFRA, because the statute applies to virtually every government action:[22]

(T)he definition of governmental activity covered by the bill is meant to be all inclusive. All governmental actions which have a substantial external impact on the practice of religion would be subject to the restrictions in this bill. . . . (T)he test applies whenever a law or action taken by the government to implement a law burdens a person's exercise of religion. H.R. Rep. No. 103-88, at 6 (1993).

This legislative history makes it clear that RFRA applies to defendants' rule regardless of how it is characterized--as a legislative rule, *supra*, or as a policy and/or interpretive rule, as defendants contend. See Defs. Opp. to Pls. Mot. for Admin. Rec. at 7.

In addition, RFRA applies to a wide range of religious beliefs and practices. Pre-Smith jurisprudence established that any "religiously based" conviction must be protected, even if that expression of faith is not shared by others of the same faith or "acceptable, logical, consistent, or comprehensible to others." Thomas v. Review Bd. of Indiana Empl. Sec. Div., 450 U.S. 707, 714-16, (1981). By way of example, the courts have upheld the rights of a Washington, D.C., church to feed the homeless, Western Presbyterian Church v. The

Board of Zoning Adjustment of the District of Columbia, 849 F.Supp. 77 (D.D.C. 1994), as well as the rights of military chaplains to encourage parishioners to contact Congress, Rigdon, et al. v. Dr. William Perry, et al., 962 F. Supp. 150 (D.D.C. 1997).

Here, plaintiffs are seeking protection of well-established and widely-recognized dietary restrictions and theological tenets that flow from, and are central to, their faiths. For example, plaintiffs Sue Speck and Igor Jaworowsky are prohibited during Lenten observance from eating foods, additives and ingredients that contain substances from insects and certain types of animals, Pls.' 2nd Amend. Compl. at ¶¶ 47, 83. As another example, plaintiffs Rabbis Green, Serebryanski, and White, as well as Sheila Slade and the Beth Shalom Synagogue, are required by Hebrew scriptures and rabbinical teaching to follow the kosher dietary regimen, which prohibits the eating of foods with food additives and ingredients derived from insects and specific kinds of animals. Pls.' 2nd Amend. Compl. at ¶¶ 41, 74, 77, 92, 100.

In the same vein, plaintiffs Speck, Jaworowsky, and Kedala object, on the grounds of Eastern Orthodox doctrine, to the use of viruses and pathogens to manipulate existing plants and accordingly regard these new organisms as spiritually unacceptable. Pls.' 2nd Amend. Compl. at ¶¶ 45, 82. Rabbis Green, Serebryanski and White, as well as the Beth Shalom Synagogue, based on Hebrew scriptures and rabbinical teachings, similarly believe that genetically engineered organisms have a degraded spiritual quality that attaches to the substances derived from them. Pls' 2nd Amended Complaint at ¶¶ 40, 73, 91, 99.

Although courts may examine the "sincerity" of a RFRA claimant's religious belief, Wisconsin v. Yoder, 406 U.S. 205, 215-19 (1972), courts may not question the truth of the belief itself, merely whether it is "truly held." U.S. v. Seeger, 380 U.S. 163, 184 (1966). "(I)t is not within the judicial function and judicial competence to inquire whether the petitioner . . . correctly perceived the commands of (his or her) faith. Courts are not arbiters of scriptural interpretation." Thomas, 450 U.S. at 713-16. In the present case, the sincerity of plaintiffs' beliefs is established by, among other things, their activities: religious training, memberships in various religious organizations and employment. For example, plaintiff Rabbi Jossi Serebryanski is an Orthodox Rabbi and a supervisor at O.K. Laboratory, a kosher certifying laboratory located in Brooklyn, New York. Pls.' 2nd Amend. Compl. at ¶ 72. Plaintiff Rabbi Harold White is Director of Jewish Chaplaincy and a lecturer of Religion at Georgetown University in Washington, DC. Pls.' 2nd Amend. Compl. at ¶ 90. Plaintiff Reverend Dr. Donald B. Conroy, S.T.L., Ph.D. is an ordained Roman Catholic priest and is President of the North American Coalition on Religion and Ecology, as well as the Chair of the International Consortium on Religion and Ecology and Adjunct Faculty of the Washington Theological Union. Pls.' 2nd Amend. Compl. at ¶ 17.

In examining the magnitude of the burden on religion, courts routinely hold that the lack of food content information is a substantial burden on the religious practices of inmates. As one such court explained, to the degree that access to normal food content information is restricted, an inmate's ability to practice his or her religions has been so burdened.

Masjid Muhammad-D.D.C., et al. v. Paul Keve, et al., 479 F. Supp. 1311, 1320 (D.C. Del. 1979). See also, Barnett v. Rodgers, 410 F.2d 995, 1001 (D.C. Cir. 1969) (remanding for consideration of the government's claim of compelling interest). So, too, in this case plaintiffs' religious practices have been substantially burdened by defendants' unilateral rule allowing genetically engineered foods -- those now available and those developed in the future -- to be sold without labeling. As a result of defendants' rule, plaintiffs have been exposed and will continue to be exposed unknowingly to foods that they deem religiously objectionable.

B. Defendants Cannot Demonstrate a Compelling Interest to Support Their Actions.

Once a RFRA claimant has established that the government has substantially burdened his or her religious beliefs, the burden shifts to the government to establish that its actions served a compelling government interest. 42 U.S.C. § 2000bb-1(b)(1).

RFRA's legislative history underscores the importance of this showing: "The compelling interest test reflects the First Amendment's mandate of preserving religious liberty to the fullest extent possible in pluralistic society." S. Rep. No. 103-111, at p. 8, citing, Smith, 494 U.S. 872, 903 (1990) (O'Conner, S., concurring on the ground that the state had demonstrated a "compelling interest.")

Only interests of the "highest order" and those "not otherwise served" can outweigh Free Exercise claims under pre-Smith standards. Yoder, 406 U.S. at 215. A rational relationship to some colorable interest cannot withstand RFRA scrutiny - only the "gravest abuses, endangering paramount interests, give occasion for permissible limitation" on religious belief. Sherbert, 374 U.S. 398, 406, 10 L.Ed. 2d 965, 83 S.Ct. 1790 (1963). Neither "safety," "peace" or "order" are compelling interests, Id. at 403, nor is mere "administrative convenience." See Memorial Hospital v. Maricopa County, 415 U.S. 250 (1974). But in the present case, defendants have made no clear case for any underlying interest. To the extent that they have referred to an interest, the reference is vague and the interest is not more than administrative convenience:

FDA does not claim itself as an arbiter of ethical issues, such as the criteria by which a vegetable may be altered such that is no longer acceptable as food by those holding particular beliefs. Given the nonscientific nature of ethical and religious concerns, and the enormous variety of such concerns possible, FDA considers it more appropriate for people holding such views to shop from marketers who guarantee that their products meet relevant criteria, similar to people shopping in kosher butcher shops or from stores that sell "organic"[(23)] produce. Admin. Rec. at 18653

Thus, defendants have failed to establish any compelling interest to justify their actions.

C. Defendants Failed to Use the Least Restrictive Means to Accomplish Their Objectives.

Even if the government were to present credible evidence of a compelling interest in this case, it has not tailored its actions to use the least restrictive means to accomplish its goals, as required by 42 U.S.C. § 2000bb-1(b)(2). Specifically, the government must establish that there are no alternative actions to reach its goals without infringing on the plaintiffs' religious practices. Barnett, 410 F.2d at 999, citing Shelton v. Tucker, 364 U.S. 479, 488 (1960). The government must make more than a cursory showing. "However attractive the end to be achieved, the means employed must hoard First Amendment values." Barnett, 410 F.2d at 999.

Rather than attempting to lighten the burden on plaintiffs' religious beliefs, defendants here chose to lighten their own burden, stating it "more appropriate" for concerned individuals to find a grocer they trust than for the agency to require labeling of genetically modified foods. AR. at 18653. This is not even practical because of defendants' policy encourages most genetically engineered crops in the United States to be mixed together with non-genetically engineered crops after harvest, and therefore it is virtually impossible for most grocers to guarantee that their foods are free of ingredients derived from genetically engineered organisms. In unilaterally issuing their rule, defendants ignored the significant number of comments raising religious issues and requesting labeling, comments which by their very nature suggested ways for defendants to tailor their rule. A.R. at 19593. Defendants' actions manifest their cavalier attitude toward religion and are precisely the sort of government action that RFRA was enacted to prevent.

By allowing genetically engineered foods, whenever and however developed, to be sold without labeling, defendants have substantially burdened plaintiffs' exercise of religion without compelling interests and without narrowly tailored means. Therefore, defendants' actions are invalid and must be vacated pursuant to RFRA.

VI. Count I (F): FDA's Failure to Require the Labeling of Genetically Engineered Food Violates the Free Exercise Clause of the United States Constitution.

The First Amendment provides: "Congress shall make no law . . . prohibiting the free exercise (of religion)." U.S. CONSTIT. amend. I.

As a result of the Smith holding, most courts[(24)] now apply the rational basis test to neutral, generally applicable laws challenged under the Free Exercise Clause. Smith, 494 U.S. at 879 (upholding Oregon's application of criminal drug laws to the ceremonial use of peyote).

A. Defendants' Actions Substantially Burden Religion.

As established above, by allowing genetically engineered foods whenever and however developed to be sold without labeling, defendants, in effect, have exposed and will continue to cause plaintiffs to be unknowingly exposed to foods that they deem religiously objectionable. Defendants have thereby substantially burdened the religious beliefs and practices of plaintiffs Conroy, Epstein, Gracey, Green, Jaworowsky, Kedala, Kucynda, Mitchell, Reigstad, Serebryanski, Slade, Speck, Steinbrecher, White, Williams, Pariwar-Yugnirman and Beth Shalom.

B. Defendants Cannot Establish a Rational Basis for Their Actions.

Even using the less stringent rational basis test, courts have protected inmates' rights to follow dietary restrictions consistent with their faiths. McElyea v. Babbitt, 833 F.2d 196, 198 (9th Cir. 1987) (overturning summary judgment against prisoner's Free Exercise claim where the prison relied on second-hand knowledge of past behavior in determining whether claimant was sincere in his religious beliefs). See also, Kahane v. Carlson, 527 F.2d 492 (2d Cir. 1975), *citing,* Barnett, 410 F.2d 995 (D.C. Cir. 1969); Chapman v. Kleindienst, 507 F.2d 1246, 1251 (7th Cir. 1974); and Ross v. Blackledge, 477 F.2d 616 (4th Cir. 1973).

Plaintiffs in the instant case deserve, at the very least, the same sort of religious freedom granted to the inmate plaintiffs in McElyea and Kahane. By failing to require food content information for genetically engineered foods sold in the marketplace, defendants have effectively diminished Americans' freedom to follow religiously-mandated dietary regimens, whether they are incarcerated or not. As a result, plaintiffs' exercise of religion has been substantially burdened by a rule that lacks any rational basis and defendants' actions must be vacated pursuant to the First Amendment.**Conclusion**

For the reasons stated herein, and on the basis of Plaintiffs' Complaint, Defendants' admissions in its Answer, and the entire record together with plaintiffs' supporting exhibits, Plaintiffs' Motion for Summary Judgment should be granted on all counts.

Respectfully submitted,

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1. Hallman, W. and Metcalfe, J. "Public Perceptions of Agricultural Biotechnology: A Survey of New Jersey Residents" obtained from USDA website April 1996. Based upon "Public Perceptions of Agri-Biotechnology, Genetic Engineering New 15 (13) July 1995.

2. British Medical Association, "The Impact of Genetic Modification on Agriculture, Food and Health, " May 1999; See also, Rick Weiss, British Report: Label Gene-Modified Food, *Washington Post*, May 18, 1999, at A2.

3. In the end, however, the FDA ignored the thousands of comments it received on its 1992 Policy, opting instead to exempt virtually all genetically engineered foods from labeling and safety requirements.

4. CEQ issued its regulations implementing NEPA in response to President Carter's Executive Order 11991 (1977). See Andrus v. Sierra Club, 442 U.S. 347, 357 (1979). The Executive Order directed federal agencies to "comply with the regulations issued by the Council." Id. quoting Executive Order 11991. The Supreme Court has held that the regulations are entitled to substantial deference by the courts. Id. at 358; Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 372 (1989).

5. Michael Pollan, "Fried, Mashed or Zapped with DNA?" New York Times Sunday Magazine (October 25, 1998).

6. Rick Weiss, "Biotech vs. Bambi of Insects?" Washington Post, (May 20, 1999).

7. FDA scientist Eric Flamm argued that applying the Food Additives Amendment would *be "consistent with the original intent behind the passage of the f.a.a.*: to assure that FDA was reviewing the safety of those new ingredients entering the food supply *whose safety was unknown.*" (emphasis added). Id.

8. See, infra, for a discussion of the agency's argument that transferred genetic material is not novel and that the products expressed by those genetic materials are somewhat similar to those currently used in food.

9. While agency documents state that the Food Additive Amendments were limited only to new chemicals, this is incorrect because 1) the substances used in genetically engineered foods are chemicals and 2) had the Congress intended to regulate only chemicals as food additives, it would have done so-just as it exempted "pesticide chemicals" from the definition of food additive. FAA § 201(s)(1),(2), codified at 21 U.S.C. § 321(s)(1),(2).

10. The definition concedes the impossibility of proving, with complete certainty, absolute harmlessness. 21 C.F.R. § 170.3(i).

11. . Recognizing that chronic ingestion of a substance poses more significant health impacts than short-term ingestion, the 1958 Act required the FDA to consider the cumulative effects of food additives in evaluating their safety. S. Rep. No. 2422, 85th Cong. 2d Sess. 5, reprinted in 1958 U.S.C.C.A.N. 5300; H. Rep. No. 2284, 85th Cong. 2d Sess. 6 (1958).

12. The scientific data must establish the safety for use as human food. U.S. v 45 Drums of Pure Vegetable Oil, et al., 961 F.2d 808, 812 (9th Cir. 1992).

13. The 7th Circuit upheld, in a per curiam opinion, the District Court's findings on the GRAS issue. Id.

14.See also , MacKenzie, D., *Unpalatable Truths*, New Scientist, 17 Apr. 1999 at 18-19. (This article reports that "(s)cientists from the 29 industrialised countries of the OECD concluded at a meeting in Paris in December that a whole new approach is needed . . ." regarding assessing the safety of genetically engineered foods. Id at 18.

15.See also , David F. Cavers, "The Food, Drug and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provision", 6 Law And Contemp. Prob. 2-42 (1939).

16.See also , 1977 Restatement of Torts 2d. §538(2)(a) retaining identical language.

17. "FDA Sued Over Genetically Altered Food", Omaha World-Herald, May 28, 1998, at 9, quoting Eric Flamm, senior policy adviser at FDA.

18. Hoban, T.J., and P.A. Kendall. 1992. Consumer Attitudes About the Uses of Biotechnology in Agriculture and Food Production. Report to Extension Service, USDA.

19. Nordlee, J.A., Taylor, S.L., Townsend, J.A., Thomas, L.A., Bush, R.K., Identification of a Brazil-nut Allergen in Transgenic Soybeans, *New England Journal of Medicine*, 334, 688-692, 1996.

20.See A.R. at 18674 citing common allergies in people include not only cow's milk, eggs, peanuts and seafood but also food grains and enriched sources of protein (i.e. rice, soybean, wheat and yeast), vegetables (i.e. lima beans, peas, potatoes, soybeans, squash, and tomatoes) and fruits (i.e. bananas, oranges, peaches and strawberries)

21. . Although the Supreme Court has invalidated RFRA as it applies to state and local governments, Boerne v. Flores, 521 U.S. 507 (1997), RFRA continues to apply to actions by the federal government. EEOC v. Catholic University, 83 F.3d 455, 469-70 (D.C. Cir. 1996). See also, In re Young, 141 F.3d 854, 863 (8th Cir. 1998), cert. denied, 1998 U.S. LEXIS 4780 (Oct. 5, 1998) ("RFRA's protection against federal interference with religious liberties is independent and distinct from its protection against state interference, and there is nothing in RFRA's text or legislative history to suggest that Congress would have declined to protect religious liberties from federal interference merely because it was unable to protect those liberties from state interference.").

22. . The only exceptions noted in the legislative history are for the government's internal administration and the use of its property and resources. S. Rep. No. 103-111, at 9 (1993).

23. Note that "organic" produce is not necessarily a dependable alternative for religious plaintiffs because the federal standard for organic foods has not been completed and at this point it is unclear whether genetically engineered foods will be categorically prohibited from consideration as "organic" foods. 62 Fed. Reg. 65,680 (Dec. 16, 1997)(proposed National Organic Program subsequently withdrawn and awaiting reproposal).

24. Although some courts today analyze both RFRA and Free Exercise claims under the pre-Smith First Amendment standards, Best v. Kelly, 879 F.Supp. 305 (W.D.N.Y. 1995), other courts consider those claims under different standards--RFRA claims under a compelling interest standard and First Amendment claims under Smith's rational basis test. Campbell-El, 874 F.Supp. at 408-09.