UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALLIANCE FOR BIO-INTEGRITY,
406 W. Depot Street,
Fairfield, IA 52556,

INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT,
310 D Street, N.E.
Washington, DC 20002,

DR. LIEBE CAVALIERI,
c/o Division of Natural Sciences,
State University of New York,
Purchase, NY 10577-1400,

REV. DONALD B. CONROY,
3019 Fourth Street, N.W.
Washington, DC

DR. RAMA DWIVEDI,
635 LeClaire Avenue,
Wilmette, IL 60091,

Civil Action No.98-1300 (CKK)

DR. DAVID W. EHRENFELD,
c/o Ecology, Evolution and
Natural Resources, Rutgers University,
14 College Farm Road,
New Brunswick, NJ 08903,

RON EPSTEIN,
2800 Mill Creek Road,
Ukiah, CA 95482

DR. JOHN B. FAGAN,
c/o Maharishi Univ. of Mgmt,
Fairfield, IA 52557,

DR. DAVID FANKHAUSER, 3569 Nine Mile Road,
Cincinnati, OH 45255,

REV. COLIN B. GRACEY, 18 Monmouth Court,
Brookline, MA

RABBI ALAN GREEN,
58 Vanier Drive,
Winnipeg, Manitoba R2V 2N6,
Canada,

IGOR JAWOROWSKY,
10 Augusta Drive #1
McAfee, NJ 07428

DR. GARY P. KAPLAN,
c/o North Shore Univ. Hospital,
300 Community Drive,
Manhasset, NY 11030,

REV. SAMUEL KEDALA,
98 Route 284
Wantage, NJ,

HANIF KHALAK,
18405 Lost Knife Circle #202,
Gaithersburg, MD 20886,

PAUL C. KUCYNDA,
285 French Hill Road
Wayne, NJ 07470,

DR. MARGARET MITCHELL
10513 Miles Avenue
Cleveland, OH,

RICK MOONEN
c/o Oceana Restaurant
55 East 54th Street
New York, NY 10022,

DR. JOHN REIGSTAD
12254 8th Street
Jesup, IA 50648,

DR. PHILIP J. REGAL,
c/o Univ. of Minnesota,
100 Ecology Building,
1987 Upper Buford Circle, St. Paul, MN 55108,

RABBI JOSSI SEREBRYANSKI,
443 Crown Street,
Brooklyn, NY 11225,

BETH SHALOM SYNAGOGUE,
308 South B Street,
Fairfield, IA 52556,

SHEILA SLADE,
322 Sunshine Court,
Englishtown, NJ 07726,

SUE SPECK
100 Route 23
Franklin, NJ,

SAUL A. STADTMAUER,
5 West 86th Street,
New York, NY 10024,

ED STEINBRECHER,
c/o P.O. Box 46146,
Los Angeles, CA 90046,

DR. RICHARD STROHMAN,
c/o University of California at Berkeley,
Dep't. of Molecular and Cell Biology,
c/o Stanley/Donner Adm Serv Unit,
229 Stanley Hall #3206,
Berkeley, CA 94720-3206,

RABBI HAROLD WHITE,
c/o Office of Campus Ministry,
1 Healy Bldg.,
Georgetown University,
Washington, DC 20007,

REV. DEWITT S. WILLIAMS,
6368 Guilford Road
Clarksville, MD 21209,

GAYATRI PARIWAR-YUGNIRMAN
8413 W. North Terrace
Niles, IL 60714,

Plaintiffs,

v.

DONNA SHALALA,
in her official capacity as,
Secretary of the Department of
Health and Human Services,
200 Independence Avenue, S.W.
Room 615F
Washington, DC 20201,

MICHAEL A. FRIEDMAN,
in his official capacity as,
Lead Deputy Commissioner of the
Food and Drug Administration,
5600 Fishers Lane
Room 1471
Rockville, MD 20857,

Defendants.

SECOND AMENDED COMPLAINT FOR

DECLARATORY AND INJUNCTIVE RELIEF

This is an action to declare unlawful and enjoin certain actions of the defendants, and others acting under their authority, regarding the approval and non-labeling of genetically engineered food. These actions include a failure to regulate new foods produced through methods of genetic engineering, a failure to require the labeling of foods produced through method of genetic engineering and an arbitrary and capricious determination that foods produced through genetic engineering are generally recognized as safe. Defendants' actions regarding the approval of genetically engineered foods violate statutes and regulations of the defendants' including the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301, et seq., the Administrative Procedure Act (APA), 5 U.S.C. §§ 500- 706, the Religious Freedom Restoration Act (RFRA), 42 U.S.C. §§ 2000bb - 2000bb 4, the Free Exercise Clause of the United States Constitution, U.S. Const., amend. I, and the National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321, et seq.

JURISDICTION AND VENUE

1. This court has jurisdiction over this action pursuant to the Federal Food Drug and Cosmetic Act , 21 U.S.C. § 332, as well as 28 U.S.C. § 1331 (federal question), 28 U.S.C. §1346 (United States as defendant), and 28 U.S.C. § 1361 (mandamus).

2. The relief requested is specifically authorized by 28 U.S.C. §2201 (declaratory relief) and 28 U.S.C. § 2202 (injunctive relief) and the plaintiffs have a right to bring this action pursuant to 5 U.S.C. §§ 701 - 706 (Administrative Procedure Act).

3. Venue is proper in this court pursuant to 28 U.S.C. §1391(e) because the defendants in action reside in this district and a substantial part of the events and omissions which gave rise to this action occurred in this district.

PLAINTIFFS

4. Plaintiff Alliance for Bio-Integrity (Alliance)is a private, non-profit organization incorporated in Iowa. Its office is located at 406 W. Depot Street, Fairfield, IA 52556. Steven M. Druker is the Alliance's Executive Director and a member of its Board of Directors. The activities of the Alliance and its Executive Director have been centered on addressing the environmental, economic, ethical, health, and social impacts raised by the development and commercialization of genetic engineering.

5. The Alliance's goals include encouraging public participation in defining the issues presented by genetic engineered food and to provide consumers with a means of identifying genetically engineered foods on the market. It also seeks to obtain rigorous testing of genetically engineered foods.

6. The Alliance's Executive Director and Board of Director member Steven Druker seeks to avoid the purchase and consumption of genetically engineered foods during office functions that include meals. Additionally, Mr. Druker seeks to avoid the purchase and consumption of genetically engineered foods in his daily life.

7. The interests of Alliance and Steven Druker are being, and will be, adversely affected by defendants' actions complained of herein. In particular, defendants' issuance of its Statement of Policy concerning food derived from new plant varieties and its failure to require food additive petitions for all genetically engineered foods (including those complained of herein), and their non-complaince with NEPA, injures Alliance's ongoing

operations by, *inter alia*, adversely affecting the organization's ability to disseminate information to public, federal employees and others in order to ensure that the environmental, economic, ethical, health and social impacts of genetically engineered foods are fully assessed.

8. The interests of the Alliance are additionally being, and will be, adversely affected by the defendants' action complained of herein. In particular, the defendants' failure to require food additive approvals and labeling for genetically engineered food injures the Alliance, and its Board of Director member Steven Druker by preventing the organization from avoiding genetically engineered foods during its functions serving food and during Mr. Druker's personal life.

9. Plaintiff International Center for Technology Assessment (CTA) is a private, non-profit organization incorporated in the District of Columbia. Its office is located at 310 D Street, N.E., Washington, DC 20036. Andrew Kimbrell is CTA's Executive Director and a member of its Board of Directors. The activities of CTA and its Executive Director have been centered on addressing the environmental, economic, ethical, health, and social impacts raised by the development and commercialization of technologies, including genetic engineering.

10. Over the last three years, CTA has, and continues, to disseminate to government agencies, members of Congress and the general public a wide array of educational and informational materials addressing the introduction of genetically engineered foods into the marketplace. These materials include, but are not limited to, reprints of news articles, policy reports, legal briefs, press releases, action alerts and fact sheets. Collectively, the dissemination of this material has made CTA an information clearinghouse for public involvement and governmental oversight of the use of genetic engineering in our nation's food supply. CTA's goal is to encourage full public participation in defining the issues presented by genetic engineered food and to provide consumers with a means of identifying genetically engineered foods on the market.

11. To achieve its goals, including those described above, CTA participates extensively in the agency decision-making process through petitions to various agencies, comments on agency rulemakings, calls for formal investigations, Freedom of Information Act requests, other administrative actions and appeals, and meetings with agency officials. It also pursues its goals through lectures, publications, Congressional testimony, and public consumer counseling by its staff. CTA also litigates when agencies fail to meet statutory environmental, human health and procedural requirements.

12. CTA's Executive Director and Board of Director member Andrew Kimbrell seeks to avoid the purchase and consumption of genetically engineered foods during office functions that include meals, such as board meetings, office planning conference, and a variety of office events at which food is served. Additionally, Mr. Kimbrell seeks to avoid the purchase and consumption of genetically engineered foods in his daily life.

13. The interests of CTA and Andrew Kimbrell are being, and will be, adversely affected by Defendants' actions complained of herein. In particular, Defendants' issuance of its Statement of Policy concerning food derived from new plant varieties, its failure to require food additive petitions for all genetically engineered foods (including those complained of herein), and their non-compliance with NEPA, injures CTA's ongoing operations by, *inter alia*, adversely affecting the organization's ability to disseminate information to public, federal employees and others in order to ensure that the environmental, economic, ethical, health and social impacts of genetically engineered foods are fully assessed.

14. The interests of CTA are additionally being, and will be, adversely affected by the Defendants' action complained of herein. In particular, the Defendants' failure to require food additive approvals and labeling for genetically engineered food injures CTA, and its Board of Director member Andrew Kimbrell by preventing the organization from avoiding genetically engineered foods during its functions serving food and during Mr. Kimbrell's personal life.

15. Plaintiff Dr. Liebe Cavalieri's principal place of business is Division of Natural Sciences, State University of New York, Purchase, NY 10577-1400. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein.

16. Plaintiff is a molecular biologist and professor in the Division of Natural Sciences at the State University of New York at Purchase, NY. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

17. Plaintiff Reverend Dr. Donald B. Conroy, S.T.L., Ph.D., resides at 3019 Fourth Street, N.W., Washington, DC. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is an ordained Roman Catholic priest and is President of the North American Coalition on Religion and Ecology. He is also the Chair of the International Consortium on Religion and Ecology and Adjunct Faculty of the Washington Theological Union.

18. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio, products that contain ingredients and food additives derived from these foods, and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and © degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

19. Plaintiff believes that the redesign of the food supply through the forcible transfer of genetic material across nature's cross-breeding barriers (in the way currently done) is in violation of basic principles of environmental ethics and is disruptive of the divine plan. He further believes that, for purposes of food design, any artificial insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. He therefore views the venture of genetically reconfiguring plants and animals for the purpose of redesigning food as a transgression against God. Thus, as a matter of religious principle, plaintiff feels obliged to separate himself from this enterprise by avoiding the purchase and consumption of its products.

20. To follow his ethical and religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which plaintiff is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

21. Plaintiff Dr. Rama Dwivedi resides at 635 LeClaire Avenue, Wilmette, IL 60091. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff serves as Associate Director, Targeted Mutagenics, Department of Pediatrics, Northwestern University Medical School.

22. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and

substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and (c)degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

23. Plaintiff Dr. David W. Ehrenfeld's principal place of business is Ecology, Evolution and Natural Resources, Rutgers University, 14 College Farm Road, New Brunswick, NJ 08903. The interests of this Plaintiff are being and will be adversely affected by Defendants' actions complained of herein.

24. Plaintiff is a Professor of Biology at Rutgers University in New Brunswick, NJ. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

25. Plaintiff Ron Epstein, Ph.D. resides at 2800 Mill Creek Road, Ukiah, CA 95482. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is the Chancellor of the Americas Dharma Realm Buddhist University and a research professor at the Institute for World Religions in Berkeley, CA.

26. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could

cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

27. Plaintiff believes that the forcible transfer of genetic material across nature's cross-breeding barriers is contrary to Buddhist principles, as is any artificial insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. Thus, as a matter of religious principle, plaintiff feels obliged to separate himself as much as possible from genetic engineering by avoiding the purchase and consumption of its products.

28. Additionally, plaintiff follows a vegetarian dietary regimen as an important ethic of his religious beliefs. Accordingly, he must religiously avoid foods with food additives and ingredients derived from insects and animals. He believes that when genes from insects and animals are inserted into an otherwise nonanimal organism, the substances produced by these genes are themselves nonvegetarian and render that organism (and all food products derived from it) unacceptable.

29. Plaintiff consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio, products that contain ingredients and food additives derived from these foods, and other food products that may currently be genetically engineered. To follow his religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which it is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

30. Plaintiff Dr. John B. Fagan's principal place of business is Maharishi University of Management, Fairfield, IA 52557. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein.

31. Plaintiff is a Professor of Molecular Biology at Maharishi University of Management in Fairfield, IA. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Plaintiff is a consumer of tomatoes, potatoes, soy products,

cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

32. Plaintiff Dr. David Fankhauser resides at 3569 Nine Mile Road, Cincinnati, OH 45255. The interests of this Plaintiff are being and will be adversely affected by Defendants' actions complained of herein.

33. Plaintiff is a Professor of Biology and Chemistry at the University of Cincinnati in Cincinnati, OH. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and (c)degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

34. Plaintiff Reverend Colin B. Gracey resides at 18 Monmouth Court, Brookline, MA. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is the Episcopal Chaplain at Northeastern University in Boston, MA.

35. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could

cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

36. Plaintiff believes that the forcible transfer of genetic material across nature's cross-breeding barriers for the purpose of redesigning food is a disruption of the divine plan. He further believes that, for the purposes of food design, any artificial insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. Therefore, plaintiff views the genetic reconfiguration of plants and animals for purposes of redesigning food as a transgression against God. Thus, as a matter of religious principle, plaintiff feels obliged to separate himself as much as possible from genetic engineering by avoiding the purchase and consumption of its products.

37. To follow his religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which it is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

38. Plaintiff Rabbi Alan Green resides at 58 Vanier Drive, Winnipeg, Manitoba R2V 2N6, Canada. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is a rabbi at Beth Israel Synagogue in Winnipeg, Manitoba, Canada. He is a U.S. citizen and spends significant time each year in the United States.

39. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and (c) degradation of

nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

40. Plaintiff believes that the forcible transfer of genetic material across nature's cross-breeding barriers for the purpose of redesigning food is a disruption of the divine plan. He bases this belief in the Hebrew scriptures and rabbinic teaching. He further believes that, for the purposes of food design, any artificial insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. Therefore, plaintiff views the genetic reconfiguration of plants and animals for purposes of redesigning food as spiritually degrading and a transgression against God. Thus, as a matter of religious principle, plaintiff feels obliged to avoid the purchase and consumption of these foods and any products derived from them.

41. Additionally, plaintiff free exercise of Judaism includes observance of the laws of Kashrut, a dietary regimen which is an important ethic of Judaic thought and practice. Accordingly, he must religiously avoid foods with food additives and ingredients derived from insects and specific kinds of animals. He believes that when genes from such prohibited species are inserted in and otherwise permitted organism, the substances produced by these genes are themselves prohibited and render that organism (and all food products derived from it) unacceptable.

42. Plaintiff consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio, products that contain ingredients and food additives derived from these foods, and other food products that may currently be genetically engineered. To follow his religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which it is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

43. Plaintiff Igor Jaworowsky resides at 10 Augusta Drive #1, McAfee, NJ 07428. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is a member and parishioner of the Eastern Orthodox church.

44. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, products that contain ingredients and food additives derived from these foods, and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

45. Plaintiff believes that the forcible transfer of genetic material across nature's cross-breeding barriers is contrary to basic principles of Eastern Orthodox Christian theology, especially since such transfers are heavily dependent on the use of viruses and other pathogenic entities. He further believes that, for purposes of food design, any artificial insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. Thus, as a matter of religious principle, plaintiff feels obliged to separate himself as much as possible from genetic engineering by avoiding the purchase and consumption of its products.

47. To follow his religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which plaintiff is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

48. Plaintiff Dr. Gary P. Kaplan principal place of business is North Shore University Hospital, 300 Community Drive, Manhasset, NY 11030. The interests of this Plaintiff are being and will be adversely affected by Defendants' actions complained of herein.

49. Plaintiff is a Director of Clinical Neurophysiology, North Shore University Hospital, and Associate Professor of Clinical Neurology at New York University School of Medicine. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and

substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

50. Plaintiff Reverend Samuel Kedala resides at 98 Route 284, Wantage, NJ. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is a member of the Eastern Orthodox church and Priest and Pastor of Holy Spirit Orthodox Church of Wanyage,NJ.

51. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, products that contain ingredients and food additives derived from these foods, and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

52. Plaintiff believes that the forcible transfer of genetic material across nature's cross-breeding barriers is contrary to basic principles of Eastern Orthodox Christian theology, especially since such transfers are heavily dependent on the use of viruses and other pathogenic entities. He further believes that, for purposes of food design, any artificial insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. Thus, as a matter of religious principle, plaintiff feels obliged to separate himself as much as possible from genetic engineering by avoiding the purchase and consumption of its products.

53. To follow his religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all

genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which plaintiff is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

54. Plaintiff Hanif Khalak's resides at 18405 Lost Knife Circle #202, Gaithersburg, MD 20886. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein.

55. Plaintiff is a Computational Biologist at TIGR in Rockville, MD. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

56. Plaintiff Reverend Paul G. Kucynda resides at 285 French Hill Road, Wayne, NJ 07470. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is a member of the Eastern Orthodox church and Pastor of Holy Spirit Orthodox Church of Wayne,NJ.

57. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, products that contain ingredients and food additives derived from these foods, and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and (c)degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of

mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

58. Plaintiff believes that the forcible transfer of genetic material across nature's cross-breeding barriers is contrary to basic principles of Eastern Orthodox Christian theology, especially since such transfers are heavily dependent on the use of viruses and other pathogenic entities. He further believes that, for purposes of food design, any artificial insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. Thus, as a matter of religious principle, plaintiff feels obliged to separate himself as much as possible from genetic engineering by avoiding the purchase and consumption of its products.

59. To follow his religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which plaintiff is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

60. Plaintiff Reverend Dr. Margaret J. Mitchell resides at 10513 Miles Avene, Cleveland, Ohio. She is an ordained minister in the Baptist Church. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein.

61. Plaintiff consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio, products that contain ingredients and food additives derived from these foods, and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of the DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing, and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered in a material way and pose potentially harmful impacts to her health.

62. Moreover, Plaintiff believes that the venture to redesign the food supply through the forcible transfer of genetic material across nature's cross-breeding barriers is disrupting the divine plan. She further believes that, for purposes of food design, any artificial insertion of genetic material into an organism's DNA strand that interrupts and permanently alters the inherent sequence of genetic information is similarly problematic, even when the inserted material is derived from the organism's own genome. Her beliefs are in part based on her perception that the above-mentioned venture, as currently conducted, is grounded in assumptions that are anti-theistic and is being carried out with an attitude that is arrogant and irreverentially reckless. Thus, as a matter of religious principle, she feels obliged to separate herself as much as possible from this enterprise by avoiding the purchase and consumption of its products.

63.To follow her religious convictions, plaintiff needs to be informed about foods (1) that have been genetically reconfigured through genetic engineering and (2) that contain ingredients derived from organisms that have been so reconfigured. By failing to require the comprehensive labeling of all genetically engineered foods (including substances that derive from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring her by substantially burdening her free exercise of religion, since they are fostering a situation in which it is virtually certain that she is being (and will continue to be) unwillingly and unknowingly exposed to foods she deems religiously objectionable.

64. Plaintiff Richard Moonen's principal place of business is 55 East 54th Street, New York, NY 10022. The interests of this Plaintiff are being and will be adversely affected by defendants' actions complained of herein.

65. Plaintiff is the head chef and owner of Oceana Restaurant, a restaurant nationally recognized for its use of wholesome and sustainably produced ingredients. Throughout the course of regular business operation at Oceana, plaintiff cooks, serves and consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, plaintiff's ability to supply his restaurant and patrons with agricultural products that he can be assured are safe, nutritious and flavorful is being, and will continue to be, harmed. Additionally, Plaintiff is personally being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

66. Plaintiff Dr. Philip Regal's principal place of business is Univ. Of Minnesota, 100 Ecology Building, 1987 Upper Buford Circle, St. Paul, MN 55108. The interests of this Plaintiff are being and will be adversely affected by Defendants' actions complained of herein.

67. Plaintiff is a professor of Ecology, Evolution and Behavior at the University of Minnesota in St. Paul, MN. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

68. Plaintiff Reverend Dr. John Reigstad resides at 1254 Eighth street, P.O. Box 286, Jesup, Iowa 50648 Plaintiff is an ordained minister in the Lutheran Church, pastor of the American Lutheran Church (ELCA) in Jesup, and Lecturer in Religion at Wartburg College, Waverly, Iowa. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein.

69. Plaintiff consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, products that contain ingredients and food additives derived from these foods, and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause umpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of the DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, (c) degradation of nutritional quality, and (d) other distortion of natural integrity. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing, and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered in a material way and pose potentially harmful impacts to his health.

70. Moreover, Plaintiff believes that the forcible transfer

of genetic material across nature's cross-breeding barriers through recombinant DNA technology for the purpose of redesigning food is a disruption of divine integrity. He further believes that, for purposes of food design, *any* artificial insertion of genetic material into an organism's DNA strand that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. He therefore views the venture to genetically reconfigure plants and animals for purposes of redesigning food as a transgression against God, especially since he views the assumptions on which it is based to be anti-theistic and the attitude with which it is carried out to be arrogant and irreverently reckless. He further believes that the alterations made to the organisms' genetic structure and cellular composition have spiritually degraded them. Thus, as a matter of religious principle, he feels obliged to avoid the purchase and consumption of these foods and any products derived from them.

71. To follow his religious convictions, plaintiff needs to be informed about foods (1) that have been genetically reconfigured through genetic engineering and (2) that contain ingredients derived from organisms that have been so reconfigured. By failing to require the comprehensive labeling of all genetically engineered foods (including substances that derive from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion, since they are fostering a situation in which it is virtually certain that he is being (and will continue to be) unwillingly and unknowingly exposed to foods he deems religiously objectionable.

72. Plaintiff Rabbi Jossi Serebryanski resides at 443 Crown Street, Brooklyn, NY 11225. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is an Orthodox Rabbi and employed as a supervisor by a kosher certifying laboratory.

73. Plaintiff believes that the forcible transfer of genetic material across nature's cross-breeding barriers for the purpose of redesigning food is a disruption of the divine plan. He bases this belief in the Hebrew scriptures and rabbinic teaching. Therefore, plaintiff views the genetic reconfiguration of plants and animals for purposes of redesigning food as spiritually degrading and a transgression against God. Thus, as a matter of religious principle, plaintiff feels obliged to avoid the purchase and consumption of these foods and any products derived from them.

74. Additionally, plaintiff follows a kosher dietary regimen, which is an important ethic of Jewish thought and practice. Accordingly, he must religiously avoid foods with food additives and ingredients derived from insects and specific kinds of animals. He believes that when genes from such prohibited species are inserted in and otherwise permitted organism, the substances produced by these genes are themselves prohibited and render that organism (and all food products derived from it) unacceptable.

75. Plaintiff consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio, products that contain ingredients and food additives derived

from these foods, and other food products that may currently be genetically engineered. To follow his religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which it is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

76. Plaintiff Sheila Slade resides at 322 Sunshine Court, Englishtown, NJ 07726. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein.

77. Plaintiff follows a kosher dietary regimen, which is an important ethic of Jewish thought and practice. Accordingly, she must avoid foods with food additives and ingredients derived from insects and specific kinds of animals. She believes that when genes from such prohibited species are inserted in and otherwise permitted organism, the substances produced by these genes are themselves prohibited and render that organism (and all food products derived from it) unacceptable.

78. Plaintiff consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio, products that contain ingredients and food additives derived from these foods, and other food products that may currently be genetically engineered. To follow her religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring her by substantially burdening her free exercise of religion. Defendants' actions have created a situation in which it is virtually certain she is being, and will continue to be, unwillingly and unknowingly exposed to foods she deems religiously objectionable.

79. Plaintiff also suffers from multiple allergies and sensitivities to uncommon foods. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of

levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality. The foods could also become allergenic to plaintiff due to introduction of novel proteins. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to her health.

80. Plaintiff Sue Speck's principal place of business is The Natural, 100 Route 23, Franklin, New Jersey. She is a member of the Eastern Orthodox Church. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein.

81. Plaintiff consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, products that contain ingredients and food additives derived from these foods, and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of the DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing, and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered in a material way and pose potentially harmful impacts to her health.

82. Moreover, Plaintiff believes that the venture to redesign the food supply through the forcible transfer of genetic material across nature's cross-breeding barriers is disrupting the divine plan and is contrary to basic principles of Eastern Orthodox Christian theology, especially since such transfers (a) are heavily dependent on the use of viruses and other pathogenic entities and (b) routinely implant viral promoters into food organisms so as to make them functioning parts of the organisms' DNA. She further believes that, for purposes of food design, any artificial insertion of genetic material into an organism's DNA strand that interrupts and permanently alters the inherent sequence of genetic information is similarly problematic, even when the inserted material is derived from the organism's own genome. Her beliefs are in part based on her perception that the above-mentioned venture, as currently conducted, is grounded in assumptions that are anti-theistic and is being carried out with an attitude that is arrogant and irreverently reckless. She further believes that the alterations made to the organisms' genetic structure and cellular composition have spiritually degraded them. Thus, as a matter of religious principle, she feels obliged to avoid the purchase and consumption of these foods and any products derived from them.

83. To follow her religious convictions, plaintiff needs to be informed about foods (1) that have been genetically reconfigured through genetic engineering and (2) that contain

ingredients derived from organisms that have been so reconfigured. By failing to require the comprehensive labeling of all genetically engineered foods (including substances that derive from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring her by substantially burdening her free exercise of religion, since they are fostering a situation in which it is virtually certain that she is being (and will continue to be) unwillingly and unknowingly exposed to foods she deems religiously objectionable.

84. Plaintiff Saul A. Stadtmauer resides at 5 West 86th Street, New York, NY 10024. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein.

85. Plaintiff is an author and former editor of *Health Alert* a national consumer newsletter. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

86. Plaintiff Ed Steinbrecher's business address is P.O. Box 46146, Los Angeles, CA 90046. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is Director of the D.O.M.E. Center, a non profit religious organization.

87. Plaintiff and many members of his organization observe vegetarianism as an important element in their religious practice. Plaintiff consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and numerous other foods that may currently be genetically engineered. Defendants' have failed to inform plaintiff about the presence of genetic material from religiously objectionable sources in otherwise acceptable foods and the presence of food products derived from organisms that were implanted with genes from religiously objectionable species. As a result, defendants' failure to require the labeling of all genetically engineered foods injures the plaintiff by substantially burdening their free exercise of religious beliefs.

88. Plaintiff Dr. Richard Strohman's principal place of business is University of California at Berkeley, Department of Molecular and Cell Biology, c/o Stanley/Donner Adm Serv Unit, 229 Stanley Hall #3206, Berkeley, CA 94720-3206. The interests of this

plaintiff are being and will be adversely affected by defendants' actions complained of herein.

89. Plaintiff is a Professor Emeritus in the Department of Molecular and Cell Biology at the University of California at Berkeley, CA. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

90. Plaintiff Rabbi Harold White's principal place of business is Office of Campus Ministry, 1 Healy Bldg., Georgetown University, Washington, DC 20007. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is a rabbi and Director of Jewish Chaplaincy and a lecturer of Religion at Georgetown University in Washington, DC.

91. Plaintiff believes that the forcible transfer of genetic material across nature's cross-breeding barriers for the purpose of redesigning food is a disruption of the divine plan. He bases this belief in the Hebrew scriptures and rabbinic teaching. He further believes that, for the purposes of food design, any artificial insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. Therefore, plaintiff views the genetic reconfiguration of plants and animals for purposes of redesigning food as a transgression against God. Thus, as a matter of religious principle, plaintiff feels obliged to separate himself as much as possible from genetic engineering by avoiding the purchase and consumption of its products.

92. Additionally, plaintiff follows a kosher dietary regimen, which is an important ethic of Jewish thought and practice. Accordingly, he must religiously avoid foods with food additives and ingredients derived from insects and specific kinds of animals. He believes that when genes from such prohibited species are inserted in and otherwise permitted organism, the substances produced by these genes are themselves prohibited and render that organism (and all food products derived from it) unacceptable.

93. Plaintiff consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio, products that contain ingredients and food additives derived

from these foods, and other food products that may currently be genetically engineered. To follow his religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which it is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

94. Plaintiff Reverend Dr. DeWitt S. Williams resides at 6368 Guilford Road, Clarksville, MD 21209. The interests of this plaintiff are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is an ordained minister in the Seventh-day Adventist Church and the director of the Church's Health Ministries Department, North American Division.

95. Plaintiff is a consumer of tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, products that contain ingredients and food additives derived from these foods, and/or other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and/or carcinogens, (b) elevation of levels of inherent toxins and/or carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing and the requirement of mandatory labeling, Plaintiff is being, and will continue to be, exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to his health.

96. Plaintiff believes that the forcible transfer of genetic material across nature's cross-breeding barriers for the purpose of redesigning food is a disruption of the divine plan.

He further believes that, for purposes of food design, any artificial insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. He therefore views the venture of genetically reconfigured plants and animals for the purpose of redesigning food as a transgression against God. Thus, as a matter of religious principle, plaintiff feels obliged to separate himself as much as possible from genetic engineering by avoiding the purchase and consumption of its products.

97. To follow his religious convictions, plaintiff needs to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff from being properly informed about the character of the food on the market and are injuring him by substantially burdening his free exercise of religion. Defendants' actions have created a situation in which plaintiff is virtually certain he is being, and will continue to be, unwillingly and unknowingly exposed to foods he deems religiously objectionable.

97. Plaintiff Beth Shalom Synagogue is located at 308 South B Street, Fairfield, IA, 52556. The interests of this plaintiff and its members are being and will be adversely affected by defendants' actions complained of herein. Plaintiff is a Jewish synagogue with a congregation of three hundred and twenty-five (325) members.

98. At its annual congregational meeting on October 15, 1996, plaintiff's members adopted a declaration finding the consumption of genetically engineered foods which contain the artificial transfer of genetic information between species that are naturally prevented from cross-breeding is in opposition to universal religious principles, rabbinic teaching and Jewish dietary law.

99. The Plaintiff's Board of Directors then passed a formal resolution attesting to the following beliefs: (1) that the forcible transfer of genetic material across nature's cross-breeding barriers for the purpose of redesigning food is a disruption of the divine plan; (2) that this understanding is based in the Hebrew scriptures and rabbinic teaching; (3) that the genetic reconfiguration of plants and animals for purposes of redesigning food is a transgression against God; (4) that, as a matter of religious principle, they feel obliged to separate themselves as much as possible from genetic engineering by avoiding the purchase and consumption of its products.

100. Additionally, the Board stated its belief that the kosher dietary regimen, which is an important ethic of Jewish thought and practice is threatened by genetic engineering. They stated that (a) devout Jews must religiously avoid foods with food additives and ingredients derived from insects and specific kinds of animals; (b) that they believe that when genes from such prohibited species are inserted in an otherwise permitted organism, the substances produced by these genes are themselves prohibited and render that organism (and all food products derived from it) unacceptable.

101. Plaintiff's members consumes tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, radicchio, products that contain ingredients and food additives derived from these foods, and other food products that may currently be genetically engineered. To follow their religious convictions, plaintiff's members need to be informed about foods that (1) have been genetically reconfigured through genetic engineering and (2) contain ingredients and food additives derived from organism that

have been so reconfigured. This information must include identification of the species from which transferred genetic material was obtained. By failing to require the comprehensive labeling of all genetically engineered foods (including substances derived from genetically modified organisms), defendants are effectively preventing plaintiff's members from being properly informed about the character of the food on the market and are injuring them by substantially burdening their free exercise of religion. Defendants' actions have created a situation in which it is virtually certain they are being, and will continue to be, unwillingly and unknowingly exposed to foods they deem religiously objectionable.

102. Plaintiff Gayatri Pariwar-Yugnirman has its offices at 8413 W. North Terrace, Niles, Illinois 60714. Plaintiff is a Hindu religious organization in the Chicago metropolitan area with a membership of approximately 1,000. The interests of this plaintiff are being adversely affected by defendants' actions complained of herein.

103. Plaintiff's members consume tomatoes, potatoes, soy products, cotton seed oil, squash, canola oil, corn, papaya, products that contain ingredients and food additives derived from these foods, and other food products that may currently be genetically engineered. Defendants' allowance of genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients can cause unpredictable changes to the characteristics of certain foods which may be difficult for consumers to detect. These changes may include unintended alterations to the function of the DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality. As a result of Defendants' allowance of genetically engineered foods into interstate commerce without food additive approval, adequate safety testing, and the requirement of mandatory labeling, Plaintiff's members are being, and will continue to be, exposed to numerous food products that are unknowingly altered in a material way and pose potentially harmful impacts to their health.

104. Plaintiff's directorate has determined that: (a) For the purpose of redesigning food, the forcible transfer of genetic material across nature's cross-breeding barriers through recombinant DNA technology is a disruption of the divine plan. (b) For purposes of food design, any artificial insertion of genetic material into an organism's DNA strand that interrupts and permanently alters the inherent sequence of genetic information is a similar disruption, even when the inserted material is derived from the organism's own genome. © The venture to reconfigure plants and animals through recombinant DNA technology for purposes of redesigning food is therefore a transgression against God, especially since the assumptions on which it is based are anti-theistic and the attitude with which it is carried out is arrogant and irreverently reckless. (d) The alterations made to the engineered organisms' genetic structure and cellular composition cause the organisms to become spiritually degraded. (e) As a matter of religious principle, the members of Gayatri Pariwar-Yugnirman can justly feel obliged to avoid the purchase and consumption of these foods and products derived from them. (f) Accordingly, it is

appropriate that the organization encourage its members to avoid genetically engineered foods and ingredients derived from them on religious grounds.

105. Plaintiff's directorate has further determined that genetic engineering poses a spiritual threat to its many members who follow a vegetarian dietary regimen as an important ethic of their religious beliefs. These individuals must religiously avoid foods with ingredients derived from insects and animals. The directorate believes that when genes from such prohibited species are inserted in an otherwise permitted organism, the substances produced by these foreign genes are themselves nonvegetarian and render that organism (and all food products derived from it) unacceptable.

106. To follow their religious convictions, Plaintiff's members need to be informed about foods (1) that have been genetically reconfigured through genetic engineering and (2) that contain ingredients derived from organisms that have been so reconfigured. This information must include identification of the species from which genetic material has been transferred. By failing to require the comprehensive labeling of all genetically engineered foods (including substances that derive from genetically modified organisms), defendants are effectively preventing Plaintiff's members from being properly informed about the character of the food on the market and are injuring them by substantially burdening their free exercise of religion, since defendants are fostering a situation in which it is virtually certain that they are being (and will continue to be) unwillingly and unknowingly exposed to foods they deem religiously objectionable.

107. Defendant Donna Shalala is sued in her official capacity as Secretary of the Department of Health Human Services with its principal office located at 200 Independence Ave., S.W., Room 615F, Washington, DC 20201. As Secretary, defendant Shalala has ultimate responsibility for the activities of the Department of Health and Human Services, including those action complained of herein.

108. Defendant Michael A. Friedman is sued in his official capacity as Lead Deputy Commissioner of the Food and Drug Administration. His principal office is located at Room 1471, 5600 Fishers Lane, Rockville, MD 20857. Lead Deputy Commissioner Friedman has ultimate responsibility for the activities of the Food and Drug Administration including those action complained of herein.

STATEMENT OF FACTS

109. Genetic engineering encompasses a number of techniques that alter the molecular or cell biology of an organism by means that are not possible under natural plant breeding conditions or processes. These techniques include recombinant DNA and RNA, cell

fusion, micro and macro encapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes.

110. Genetically engineered plants have been engineered for a variety of reasons including, *inter alia*, to alter the traits of their derived foods for processing, nutritional content, disease resistance and protection against weather conditions. The agricultural biotechnology industry has sought to alter foods through genetic engineering so that they taste better, provide more uniform aesthetics, and smell and look better. The food products resulting from these, and other, genetically engineered and material changes possess altered organoleptic properties.

111. One example of such a genetically engineered food is the FLAVR SAVR <TM> tomato which has been altered to delay fruit ripening and increase its shelf life. In addition, the FLAVR SAVR tomatoes placed in interstate commerce have exhibited a significant difference in taste from conventional tomatoes. Other genetically engineered foods also differ in texture and performance.

112. Genetic engineering modifies the performance characteristics of food. In addition to physical changes in size, shape, color and taste, genetically engineered foods have also been designed for longer shelf-life and have different functional properties such as increased solidity.

113. Genetically engineered foods require, *inter alia*, the insertion of novel genetic material, including marker genes, promoters and vectors. The inserted material disrupts the region of DNA into which it is engineered. Researchers are not able to select the exact place on plant genomes where these insertions of novel genetic material occur. In addition, a number of copies of this novel genetic material may be inserted into a plant's genome in an attempt to enhance desired transferred traits. These factors can (singly or in combination) create novel threats to the stability of the genetically engineered organism, including random application of non-transferred traits, suppression of host genes and homologous recombinations of multiple genes that may unknowingly alter the characteristics of the genetically engineered organism. The risk of these unintended changes is significantly higher in the case of genetically engineered foods than in the case of traditionally produced ones.

114. These genetic changes caused by genetic engineering are an important safety consideration for the use of their derived food. The changes may include unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) degradation of nutritional quality.

115. Genetically engineered foods may incorporate non-traditional genetic material derived from, *inter alia*, soil bacteria, plant viruses, non-food plants, insects, and animals. As a result, genetically engineered foods may express novel proteins and/or levels of specific proteins not previously found in foods. As a result, many genetically engineered

foods may contain allergenic proteins at levels that can induce serious allergenic responses.

116. Additionally, many of the marker genes used in the gene transfers of genetically engineered plants include genes that encode antibiotic resistance. These genes are additives that can affect the performance and health impacts of the food. The character gene is designed to organoleptically alter the food and the marker gene will imbue each cell with novel characteristics, such as kanymican resistance, so that confirmation of a gene transfer can be performed.

117. On May 29, 1992, defendants issued its "Statement of Policy: Foods Derived from New Plant Varieties" to address the issues of labeling and safety testing concerning genetically engineered foods. The policy determined that transferred genetic material and the resulting food products derived from genetically engineered plant varieties did not need full safety testing and were considered generally recognized as safe (GRAS). As a result, genetically engineered food producers were only encouraged to consult with the defendants concerning the potential safety and regulatory questions surrounding genetically engineered foods. Subsequently, genetically engineered food products derived from genetically engineered plants began to appear in interstate commerce without labeling, without pre-market notification to the FDA, and without other submissions and evaluations required by law.

118. In response to the policy, the defendants received over five thousand comments the vast majority of which requested that genetically engineered foods be thoroughly tested and labeled.

119. On April 28, 1993, the FDA requested additional information from the public related specifically to the labeling of foods derived from genetically engineered plants.

120. On April 17, 1994, FDA hosted a conference in Annapolis, Md., on allergen safety issues presented by transgenic foods which discussed some of the novel health threats posed by genetically engineered foods.

121. Despite the publication of its proposed policy, the second solicitation of public comment and the subsequent conference food allergy risks related to genetically engineered foods, the defendants' did not publish a final version of its 1992 Statement of Policy: Foods Derived from New Plant Varieties which addressed relevant public comments or new scientific information.

121. In June of 1996, and revised again in October 1997, defendants' did release its "Guidance on Consultation Procedures Foods Derived From New Plant Varieties" designed to guide developers of genetically engineered foods through the 1992 Statement of Policy. The guidance document indicates only that it is prudent practice for developers of genetically engineered foods to consult with the FDA prior to the introduction of genetically engineered foods into the marketplace. 122. As a result the defendants' have been operating under its proposed, May 29, 1992, Policy Statement, and undertaken

subsequent federal actions, allowing genetically engineered foods to be in interstate commerce without a proper analysis of the potential safety and health risks, without food additive petitions and without labeling. Among these foods are genetically engineered versions of the twenty most frequently consumed raw vegetable in this country, including tomatoes, corn, and potatoes.

123. Consumers have overwhelmingly stated that the information that a food has been genetically engineered is materially important to them and that all genetically engineered foods should be tested and labeled. In response to the defendants' "Statement of Policy," over 5,000 consumer comments were filed with the docket with a majority asking for the mandatory labeling of genetically engineered foods.

124. A 1997 poll released by Novartis, the agricultural biotechnology company, found that 93% of the people they surveyed felt that "bioengineered food should be labeled as such." Similarly, a February 1995 survey found that 92% of consumers think genetically engineered produced should be labeled. Other surveys have found that well over 80% of the public favors mandatory labeling of genetically engineered foods.

125. Among the numerous consumers seeking mandatory labeling of genetically engineered foods are practitioners of a wide variety of religions and religious denominations that believe that any insertion of genetic material into an organism's genome that interrupts and permanently alters the inherent sequence of genetic information is contrary to religious principle. In addition, many religious practitioners adhere to specific dietary regimens that require the avoidance of insects or animals that may be used for genetic source material in genetic engineering of certain foods. As such, many religious adherents believe that the labeling of genetically engineered foods is essential to their ability to freely exercise their religion and adhere to dietary regimens.

126. Currently, at least thirty-six genetically engineered foods derived from new plant varieties are known to be in interstate commerce. As a result of defendants' actions, these foods are not required to have any label identifying them as genetically engineered and consumers **are** already consuming some of these genetically engineered foods.

127. Because of defendants' failure to require pre-market notification or producer submitted food additive petitions and agency GRAS approval, many other genetically engineered foods could now be in interstate commerce. Millions of consumers may already be, and may in the future, consuming some of these genetically engineered foods.

128. Defendants' have not prepared or released any documentation concerning the public health, socio-economic or environmental impacts of their policy and regulatory actions on genetically engineered foods as required by NEPA.

CAUSES OF ACTION

I. FDA's "Statement of Policy: Foods Derived From New Plant Varieties.

A. Count One: FDA's Failure to Require the Labeling of Genetically Engineered Food is Arbitrary, Capricious, and a Violation of the Federal Food, Drug and Cosmetic Act.

129. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 128 *supra*.

130. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

131. Genetic engineering creates differences in the performance characteristics of all foods and the substances derived from those foods. These differences may include proteins (and in some instances additional substances) not ordinarily present in the Human food supply. These introduced proteins could cause allergic reactions in a significant portion of the population. In addition, genetically engineered foods are organoleptically altered from their natural state. As a result, all genetically engineered foods and substances derived from those foods differ in material fact from the type of product they purport to be.

132. In addition, genetic engineering poses a significant risk of causing unintended alterations to the function of DNA of the engineered organism that could cause the unwanted, unpredictable (a) presence of new toxins and carcinogens, (b) elevation of levels of inherent toxins and carcinogens, and (c) of nutritional quality. These changes could be injurious to consumer's health.

133. Finally, consumers have indicated a widespread demand for the labeling of genetically engineered foods.

134. As a result, the defendants' failure to require labeling for all genetically engineered food creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

135. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: 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.

136. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 135 *supra*.

137. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

138. A food additive is defined by 21 U.S.C. § 321(s), as any

substance the intended use of which 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 such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been already shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through the either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except such terms does not include -- . . .

139. The novel genetic material (including marker genes, promoters and vectors) used in the genetic engineering of food organisms, and the proteins and resulting substances synthesized by this genetic material, meet the statutory definition of food additives, especially since, *inter alia;* (a) they can alter the cellular function of the host organism in a range of unpredictable ways that could affect the characteristics of the resulting food; (b) each implantation of genetic material in the development of genetically engineered food entails a separate and unique safety risk; (c)there is no genetically engineered food organism for which artificially implanted genetic material has been shown through

scientific testing or procedures to be safe for its use as a functioning constituent of that organism's living cells, or that organism's DNA at the particular site of the genetic insertion.

140. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate such regulations in the case of any genetically engineered food.

141. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed genetically engineered foods to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

C. Count Three: FDA's Failure to Adequately Consider Genetic Stability and Other Potential Disruptions to Cellular Function in the "Statement of the Policy; Foods Derived From New Plant Varieties" Violates the Administrative Procedure Act.

142. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 141 *supra*.

143. Defendants "Statement of Policy; Foods Derived From New Plant Varieties" determines that virtually all transferred genetic material is "Generally Recognized As Safe" and that individual foods are therefore not subject to the submission and FDA approval of a food additive petition prior to their entrance into interstate commerce. As a result, defendants have failed to adequately address questions of food safety resulting from, *inter alia*, the well-recognized potential for unintended, unpredictable, deleterious changes to the function of the host organism's DNA caused by the random insertion of foreign genetic material. Such genetic instability is an inherent risk for every genetically engineered food.

144. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the submission of food additive petitions for all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

D. Count Four: FDA's Failure to Provide Notice and Comment During the Promulgation of the "Statement of the Policy; Foods Derived From New Plant Varieties" Violates the Administrative Procedure Act.

145. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 144 *supra*.

146. Defendants' *"Statement of the Policy; Foods Derived From New Plant Varieties"* and subsequent actions have the effect of substantive rule making and are a regulation under the Administrative Procedure Act, 5 U.S.C. § 551, *et seq*.

147. Section 553(b) - (d) of the Administrative Procedure Act requires defendants to undertake notice and comment procedures for the issuance of a substantive rule making. Defendants have failed to meet the procedural requirements of Section 553 (b) - (d). As a result, defendants' action in undertaking a rule making concerning the labeling and food additive approval of genetically engineered foods is arbitrary, capricious, an abuse of discretion, not in accordance with law and without observance of the procedure required by law under 5 U.S.C. § 706.

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

148. Plaintiffs Conroy, Epstein, Gracey, Green, Jaworowsky, Kedala, Kucynda, Serebryanski, Steinbrecher, White, Williams and Beth Shalom Synagogue incorporate by reference all allegations contained in paragraphs 1 through 147 *supra*.

149. Plaintiffs Conroy, Epstein, Gracey, Green, Jaworowsky, Kedala, Kucynda, Serebryanski, Slade, Steinbrecher, White, Williams, and Beth Shalom feel obliged to avoid consuming all genetically engineered organisms (and products derived from them) on the basis of religious belief and principle. Further, some of these plaintiffs (along with Plaintiff Slade) are religiously required to avoid foods that contain ingredients from either all or some species of animal.

150. Defendants' actions in implementing the "Statement of Policy: Foods Derived from New Plant Varieties" without mandatory labeling fails to provide means for above noted plaintiffs to follow their religious convictions that they should avoid foods and food ingredients that are derived from genetically engineered organisms. Defendants' actions further render it virtually certain that plaintiffs will be unknowingly exposed to such foods and make it extremely difficult for several of these plaintiffs to avoid genetically engineered foods that contain substances derived from prohibited species. As such, defendants' "Statement of Policy; Foods Derived from New Plant Varieties" is a neutral law which substantially burdens plaintiffs' free exercise of religion.

151. Section 3 of the Religious Freedom Restoration Act, 42 U.S.C. 2000bb-1(a) prevents the federal government from substantially burdening a person's exercise of religion even if the burden results from a rule of general applicability. Defendants' "Statement of Policy" and subsequent actions violate this statute.

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

152. Plaintiffs Conroy, Epstein, Gracey, Green, Jaworowsky, Kedala, Kucynda, Mitchell, Reigstad, Serebryanski, Speck, Steinbrecher, White, Williams, Pariwar-Yugnirman and Beth Shalom incorporate by reference all allegations contained in paragraphs 1 through 151 *supra*.

153. Plaintiffs Conroy, Epstein, Gracey, Green, Jaworowsky, Kedala, Kucynda, Serebryanski, Steinbrecher, White, Williams and Beth Shalom Synagogue feel obliged to avoid consuming all genetically engineered organisms (and products derived from them) on the basis of religious belief and principle. Further, some of these plaintiffs (along with Plaintiff Slade) are religiously required to avoid foods that contain ingredients from either all or some species of animal.

154. Defendants' actions in implementing the "Statement of Policy: Foods Derived from New Plant Varieties" without mandatory labeling fails to provide means for the above noted plaintiffs to follow their religious convictions that they should avoid foods and food ingredients that are derived from genetically engineered organisms. Defendants' actions further render it virtually certain that plaintiffs will be unknowingly exposed to such foods and makes it extremely difficult for several of these plaintiffs to avoid genetically engineered foods that contain substances derived from prohibited species. As such, defendants' "Statement of Policy; Foods Derived from New Plant Varieties" is a law which burdens plaintiffs' right to freely exercise their religion under the Free Exercise Clause of the United States Constitution.

G. Count Seven: FDA's Failure to Prepare An Environmental Assessment or an Environmental Impact Statement on Its Regulatory Actions on Genetically Engineered Foods Violates the National Environmental Policy Act (NEPA).

155. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through XX supra.

156. Section 102(2)(C) of the National Environmental Policy Act (NEPA), 42 U.S.C. § 4332(2)(C), requires each federal agency to prepare an environmental impact statement with respect to each major action of such agency that may significantly affect the quality of the Human environment.

157. The defendants have failed to prepare an adequate environmental assessment (EA) or environmental impact statement (EIS) for their regulatory actions, policies and programs on genetically engineered foods. The defendant's actions violate section 102(2)(C) of NEPA and the FDA's NEPA implementing regulations found at 21 C.F.R. Part 25.

158. Because defendants' regulatory actions on genetically engineered foods constitutes a major federal action that may significantly affect human health and the environment, the failure of the defendants to prepare an adequate EA or EIS that provides information on the impacts and risks of, and alternatives to, their regulatory actions on genetically engineered foods violates Section 102(2)(C) and (E), (F) and (G) of NEPA, 42 U.S.C. § 432(2)(C), (E), (F) and (G).

159. In light of the foregoing, defendants' failure to comply with NEPA and the applicable FDA regulations by not preparing an adequate EA or EIS under NEPA was arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §1 702 and 706.

II. FDA's Action Regarding Calgene's Flavr Savr Tomato.

A. Count One: FDA's Failure to Require the Labeling of Calgene's Flavr Savr Tomato is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

160. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 159 *supra*.

161Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

162. Genetic engineering of the Calgene's Flavr Savr Tomato creates difference in the organoleptic and performance characteristic of the tomato. These organoleptic and performance changes include, *inter alia*, delayed ripening and increased shelf life.

163. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Calgene's Flavr Savr Tomato.

164. Calgene's Flavr Savr Tomato is genetically engineered to include the antisense polygalacturonase gene from tomato, the promoter from the 35S gene from cauliflower mosaic virus, the kan sup r gene encoding the aminoglycoside 3 minutes - phosphotransferase II, and any one of the following binary vectors derived from Agrobacterium tumefaciens: pCGN1547, pCGN1548, pCGN1549, pCGN1557, pCGN1558, pCGN1559 or pCGN1578.

165. The selectable marker gene used in the Calgene's Flavr Savr Tomato is the kan sup r gene encoding the aminoglycoside 3 minutes -phosphotransferase II in each of the Calgene's Flavr Savr Tomato cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a Flavr Savr tomato is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

166. As a result, the organoleptic, performance and potential safety alterations in the Calgene's Flavr Savr Tomato, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

167. Thus, defendants' failure to require labeling for the Calgene's Flavr Savr Tomato creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

168. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of

procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Calgene's Flavr Savr Tomato Is A Violation of the Federal Food Drug and Cosmetic Act.

169. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 168 *supra*.

170. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

171. The genetic products used in the engineering of the Calgene's Flavr Savr Tomato, including the antisense polygalacturonase gene from tomato, the promoter from the 35S gene from cauliflower mosaic virus, the kan sup r gene encoding the aminoglycoside 3 minutes -phosphotransferase II and any one of the following binary vectors derived from Agrobacterium tumefaciens: pCGN1547, pCGN1548, pCGN1549, pCGN1557, pCGN1558, pCGN1559 or pCGN1578, meet the statutory definition of food additives.

172. Any substance that meets the definition of a "food additive" is presumed to be unsafe until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Calgene's Flavr Savr Tomato to be generally recognized as safe.

173. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Calgene's Flavr Savr Tomato to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

174. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Calgene's Flavr Savr Tomato, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

III. FDA's Action Regarding Asgrow Seed Co.'s Virus Resistant Squash.

A. Count One: FDA's Failure to Require the Labeling of Asgrow Seed Co.'s Virus Resistant Squash is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

175. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 174 *supra*.

176. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

177. Genetic engineering of the Asgrow Seed Co.'s Virus Resistant Squash creates difference in the organoleptic and performance characteristic of the squash. These organoleptic and performance changes include, *inter alia*, virus resistance.

178. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Asgrow Seed Co.'s Virus Resistant Squash.

179. Asgrow Seed Co.'s Virus Resistant Squash is genetically engineered to include coat protein genes of watermelon mosaic virus 2, zucchini yellow mosaic virus and cucumber mosaic virus, the 35S promoters and terminators from cauliflower mosaic virus, the nptII gene from the prokaryotic transposon Tn5, encoding the enzyme neomycin phosphotransferase II, and the Agrobacterium tumefaciens transformation system.

180. The selectable marker gene used in the Asgrow Seed Co.'s Virus Resistant Squash is the nptII gene from the prokaryotic transposon Tn5, encoding the enzyme neomycin phosphotransferase II in each of the Asgrow Seed Co.'s Virus Resistant Squash cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a squash is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

181. As a result, the organoleptic, performance and potential safety alterations in the Asgrow Seed Co.'s Virus Resistant Squash, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

182. Thus, defendants' failure to require labeling for the Asgrow Seed Co.'s Virus Resistant Squash creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. §§ 321(n), 343(a).

183. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Asgrow Seed Co.'s Virus Resistant Squash Is A Violation of the Federal Food Drug and Cosmetic Act.

184. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 183 *supra*.

185. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

186. The genetic products used in the engineering of the Asgrow Seed Co.'s Virus Resistant Squash, including coat protein genes of watermelon mosaic virus 2, zucchini yellow mosaic virus and cucumber mosaic virus, the 35S promoters and terminators from cauliflower mosaic virus, the nptII gene from the prokaryotic transposon Tn5, encoding the enzyme neomycin phosphotransferase II, and the Agrobacterium tumefaciens transformation system, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

187. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Asgrow Seed Co.'s Virus Resistant Squash to be generally recognized as safe.

188. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Asgrow Seed Co.'s Virus Resistant Squash to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

189. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Asgrow Seed Co.'s Virus Resistant Squash, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

IV. FDA's Action Regarding DNA Plant Technology's Improved Ripening Soybean

A. Count One: FDA's Failure to Require the Labeling of DNA Plant Technology's Improved Ripening Soybean is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

190. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 189 *supra*.

191. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

192. Genetic engineering of the DNA Plant Technology's Improved Ripening Soybean creates difference in the organoleptic and performance characteristic of the soybean. These organoleptic and performance changes include, *inter alia*, improved ripening.

193. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for

labels on all genetically engineered foods, including DNA Plant Technology's Improved Ripening Soybean.

194. DNA Plant Technology's Improved Ripening Soybean is genetically engineered to include a fragment of the aminocyclopropane carboxylic acid synthase gene from tomato.

195. The selectable marker gene used in the DNA Plant Technology's Improved Ripening Soybean is in each of the DNA Plant Technology's Improved Ripening Soybean cells. The production of the enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a soybean is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

196. As a result, the organoleptic, performance and potential safety alterations in the DNA Plant Technology's Improved Ripening Soybean, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

197. Thus, defendants' failure to require labeling for the DNA Plant Technology's Improved Ripening Soybean creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. §§ 321(n), 343(a).

198. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the DNA Plant Technology's Improved Ripening Soybean Is A Violation of the Federal Food Drug and Cosmetic Act.

199. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 198 *supra*.

200. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

201. The genetic products used in the engineering of the DNA Plant Technology's Improved Ripening Soybean, including a fragment of the aminocyclopropane carboxylic

acid synthase gene from tomato, meet the statutory definition of food additives under 21 U.S.C. § 321 (s).

202. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the DNA Plant Technology's Improved Ripening Soybean to be generally recognized as safe.

203. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the DNA Plant Technology's Improved Ripening Soybean to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

204. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including DNA Plant Technology's Improved Ripening Soybean, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

V. FDA's Action Regarding Monsanto Co.'s Glyphosate Tolerant Soybean

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Glyphosate Tolerant Soybean is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

205. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 204 *supra*.

206. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a

product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

207. Genetic engineering of the Monsanto Co.'s Glyphosate Tolerant Soybean creates difference in the organoleptic and performance characteristic of the soybean. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

208. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Glyphosate Tolerant Soybean.

209. Monsanto Co.'s Glyphosate Tolerant Soybean is genetically engineered to include the choloroplast transit peptide coding sequence from Petunia hybrida fused to the 5-enolpyruvylshikimate-3-phosphate synthase gene from Agrobacterium sp. strain CP4, the nopaline synthase 3 minutes terminator from Agrobacterium tumefaciens, and the 35S promoter from cauliflower mosaic virus.

210. The selectable marker gene used in the Monsanto Co.'s Glyphosate Tolerant Soybean is in each of the Monsanto Co.'s Glyphosate Tolerant Soybean cells. The production of the enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a soybean is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

211. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Glyphosate Tolerant Soybean, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

212. Thus, defendants' failure to require labeling for the Monsanto Co.'s Glyphosate Tolerant Soybean creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

213. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Glyphosate Tolerant Soybean Is A Violation of the Federal Food Drug and Cosmetic Act.

214. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 213 *supra*.

215. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

216. The genetic products used in the engineering of the Monsanto Co.'s Glyphosate Tolerant Soybean, including the choloroplast transit peptide coding sequence from Petunia hybrida fused to the 5-enolpyruvylshikimate-3-phosphate synthase gene from Agrobacterium sp. strain CP4, the nopaline synthase 3 minutes terminator from Agrobacterium. tumefaciens, and the 35S promoter from cauliflower mosaic virus, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

217. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Glyphosate Tolerant Soybean to be generally recognized as safe.

218. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Glyphosate Tolerant Soybean to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

219. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto's Glyphosate Tolerant Soybean, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

VI. FDA's Action Regarding Calgene Inc.'s Bromoxynil Tolerant Cotton.

A. Count One: FDA's Failure to Require the Labeling of Cottonseed Oil from Calgene Inc.'s Bromoxynil Tolerant Cotton is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

220. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 219 *supra*.

221. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

222. Genetic engineering of the Calgene, Inc.'s Bromoxynil Tolerant Cotton creates difference in the organoleptic and performance characteristic of cotton and cottonseed oil. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

223. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Calgene Inc.'s Bromoxynil Tolerant Cotton and cottonseed oil.

224. Calgene Inc.'s Bromoxynil Tolerant Cotton is genetically engineered to include the nitrilase gene isolated from Klebsiella ozaenae, the CryIA© gene from Bacillus thuringiensis subsp. kurstaki HD-73 (Bt), noncoding DNA sequences derived from the plant pathogens Agrobacterium tumefaciens and cauliflower mosaic virus, the nptII gene coding for the enzyme neomycin phosphotransferase, and Agrobacterium transformation system.

225. The selectable marker gene used in Calgene Inc.'s Bromoxynil Tolerant Cotton is in each of the Calgene Inc.'s Bromoxynil Tolerant Cotton cells. The production of the enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When products containing cottonseed oil are eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

226. As a result, the organoleptic, performance and potential safety alterations in the Calgene Inc.'s Bromoxynil Tolerant Cotton, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

227. Thus, defendants' failure to require labeling for cottonseed oil, and other products, from Calgene Inc.'s Bromoxynil Tolerant Cotton creates a misleading omission of material fact concerning food products and the consequences of using such foods. These

actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

228. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in Calgene Inc.'s Bromoxynil Tolerant Cotton Is A Violation of the Federal Food Drug and Cosmetic Act.

229. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 228 *supra*.

230. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

231. The genetic products used in the engineering of Calgene Inc.'s Bromoxynil Tolerant Cotton, the nitrilase gene isolated from Klebsiella ozaenae, the CryIA© gene from Bacillus thuringiensis subsp. kurstaki HD-73 (Bt), noncoding DNA sequences derived from the plant pathogens Agrobacterium tumefaciens and cauliflower mosaic virus, the nptII gene coding for the enzyme neomycin phosphotransferase, and Agrobacterium transformation system, meet the statutory definition of food additives under 21 U.S. § 321(s).

232. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in Calgene Inc.'s Bromoxynil Tolerant Cotton to be generally recognized as safe.

233. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed Calgene Inc.'s Bromoxynil Tolerant Cotton to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

234. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Calgene Inc.'s Bromoxynil Tolerant Cotton, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

VII. FDA's Action Regarding Monsanto Co.'s Improved Ripening Tomato.

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Improved Ripening Tomato is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

235. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 234 *supra*.

236. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

237. Genetic engineering of the Monsanto Co.'s Improved Ripening Tomato creates difference in the organoleptic and performance characteristic of the tomato. These organoleptic and performance changes include, *inter alia* , improved ripening.

238. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Improved Ripening Tomato.

239. Monsanto Co.'s Improved Ripening Tomato is genetically engineered to include the aminocyclopropane carboxylic acid deaminase gene from Pseudomonas chloraphis strain 6G5, the constitutive 35S promoters derived from the caulimoviruses, figwort virus and cauliflower mosaic virus, the nptII gene encoding the enzyme neomycin phosphotransferase and the Agrobacterium tumefaciens vector system.

240. The selectable marker gene used in the Monsanto Co.'s Improved Ripening Tomato is the nptII gene encoding the enzyme neomycin phosphotransferase in each of the Monsanto Co.'s Improved Ripening Tomato cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a tomato is eaten the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

241. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Improved Ripening Tomato, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

242. Thus, defendants' failure to require labeling for the Monsanto Co.'s Improved Ripening Tomato creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. §§ 321(n), 343(a).

243. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Improved Ripening Tomato Is A Violation of the Federal Food Drug and Cosmetic Act.

244. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 243 *supra*.

245. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

246. The genetic products used in the engineering of the Monsanto Co.'s Improved Ripening Tomato, including the aminocyclopropane carboxylic acid deaminase gene from Pseudomonas chloraphis strain 6G5, the constitutive 35S promoters derived from the caulimoviruses, figwort virus and cauliflower mosaic virus, the nptII gene encoding the enzyme neomycin phosphotransferase and the Agrobacterium tumefaciens vector system, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

247. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1).

Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Improved Ripening Tomato to be generally recognized as safe.

248. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Improved Ripening Tomato to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

249. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto's Improved Ripening Tomato, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

VIII. FDA's Action Regarding Monsanto Co.'s Insect Protected Potato.

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Insect Protected Potato is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

250. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 249 *supra*.

251. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

252. Genetic engineering of the Monsanto Co.'s Insect Protected Potato creates difference in the organoleptic and performance characteristic of the potato. These organoleptic and performance changes include, *inter alia*, insect resistance.

253. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Insect Protected Potato.

254. Monsanto Co.'s Insect Protected Potato is genetically engineered to include the cryIIIA gene from Bacillus thuringiensis (Bt) sp. tenebrionis, the 35S promoters from cauliflower mosaic virus and the 3' region of the nopaline synthase gene from Agrobacterium tumefaciens, the nptII gene encoding neomycin phosphotransferase II and the Agrobacterium tumefaciens transformation system.

255. The selectable marker gene used in the Monsanto Co.'s Insect Protected Potato is the nptII gene encoding neomycin phosphotransferase II in each of the Monsanto Co.'s Insect Protected Potato cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a potato is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by consumers.

256. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Insect Protected Potato, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

257. Thus, defendants' failure to require labeling for the Monsanto Co.'s Insect Protected Potato creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. §§ 321(n), 343(a).

258. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Insect Protected Potato Is A Violation of the Federal Food Drug and Cosmetic Act.

259. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 258 *supra*.

260. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

261. The genetic products used in the engineering of the Monsanto Co.'s Insect Protected Potato, including the cryIIIA gene from Bacillus thuringiensis (Bt) sp. tenebrionis, the 35S promoters from cauliflower mosaic virus and the 3' region of the nopaline synthase gene from Agrobacterium tumefaciens, the nptII gene encoding neomycin phosphotransferase II and the Agrobacterium tumefaciens transformation system, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

262. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Insect Protected Potato to be generally recognized as safe.

263. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Insect Protected Potato to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

264. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto's Insect Protected Potato, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

IX. FDA's Action Regarding Zeneca Plant Science's Delayed Softening Tomato.

A. Count One: FDA's Failure to Require the Labeling of Zeneca Plant Science's Delayed Softening Tomato is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

265. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 264 *supra*.

266. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

267. Genetic engineering of the Zeneca Plant Science's Delayed Softening Tomato creates difference in the organoleptic and performance characteristic of the tomato. These organoleptic and performance changes include, *inter alia*, delayed softening.

268. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Zeneca Plant Science's Delayed Softening Tomato.

269. Zeneca Plant Science's Delayed Softening Tomato is genetically engineered to include a fragment of the polygalacturonase gene from tomato, the nptII gene encoding neomycin phosphotransferase and the Agrobacterium tumefaciens vector system.

270. The selectable marker gene used in the Zeneca Plant Science's Delayed Softening Tomato is the nptII gene encoding the neomycin phosphotransferase enzyme in each of the Zeneca Plant Science's Delayed Softening Tomato cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a tomato is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

271. As a result, the organoleptic, performance and potential safety alterations in the Zeneca Plant Science's Delayed Softening Tomato, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

272. Thus, defendants' failure to require labeling for the Zeneca Plant Science's Delayed Softening Tomato creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. §§ 321(n), 343(a).

273. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Zeneca Plant Science's Delayed Softening Tomato Is A Violation of the Federal Food Drug and Cosmetic Act.

274. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 273 *supra*.

275. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

276. The genetic products used in the engineering of the Zeneca Plant Science's Delayed Softening Tomato, including a fragment of the polygalacturonase gene from tomato, the nptII gene encoding neomycin phosphotransferase and the Agrobacterium tumefaciens vector system, meet the statutory definition of food additives under 21 U.S.C. § 321(s)

277. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Zeneca Plant Science's Delayed Softening Tomato to be generally recognized as safe.

278. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Zeneca Plant Science's Delayed Softening Tomato to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

279. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Zeneca Plant Science's Delayed Softening Tomato, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

X. FDA's Action Regarding AgrEvo Inc.'s Glufosinate Tolerant Canola

A. Count One: FDA's Failure to Require the Labeling of AgrEvo Inc.'s Glufosinate Tolerant Canola is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

280. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 279 *supra*.

281. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

282. Genetic engineering of the AgrEvo Inc.'s Glufosinate Tolerant Canola creates difference in the organoleptic and performance characteristic of the canola. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

283. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including AgrEvo Inc.'s Glufosinate Tolerant Canola.

284. AgrEvo Inc.'s Glufosinate Tolerant Canola is genetically engineered to include the phosphinothricin acetyltransferase gene from Streptomyces viridochromogenes.

285. The selectable marker gene used in the AgrEvo Inc.'s Glufosinate Tolerant Canola is in each of the AgrEvo Inc.'s Glufosinate Tolerant Canola cells. The production of the enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When canola is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

286. As a result, the organoleptic, performance and potential safety alterations in the AgrEvo Inc.'s Glufosinate Tolerant Canola, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

287. Thus, defendants' failure to require labeling for the AgrEvo Inc.'s Glufosinate Tolerant Canola creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

288. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of

procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the AgrEvo Inc.'s Glufosinate Tolerant Canola Is A Violation of the Federal Food Drug and Cosmetic Act.

289. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 288 *supra*.

290. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

291. The genetic products used in the engineering of the AgrEvo Inc.'s Glufosinate Tolerant Canola, including the phosphinothricin acetyltransferase gene from Streptomyces viridochromogenes, meet the statutory definition of food additives under 21 U.S.C. § 321(s)

292. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the AgrEvo Inc.'s Glufosinate Tolerant Canola to be generally recognized as safe.

293. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the AgrEvo Inc.'s Glufosinate Tolerant Canola to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

294. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including AgrEvo Inc.'s Glufosinate Tolerant Canola, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XI. FDA's Action Regarding AgrEvo Inc.'s Glufosinate Tolerant Corn

A. Count One: FDA's Failure to Require the Labeling of AgrEvo Inc.'s Glufosinate Tolerant Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

295. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 294 *supra*.

296. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

297. Genetic engineering of the AgrEvo Inc.'s Glufosinate Tolerant Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

298. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including AgrEvo Inc.'s Glufosinate Tolerant Corn.

299. AgrEvo Inc.'s Glufosinate Tolerant Corn is genetically engineered to include the phosphinothricin acetyltransferase gene from Streptomyces viridochromogenes, the 35S promoter and the 35S terminator derived from cauliflower mosaic virus.

300. The selectable marker gene used in the AgrEvo Inc.'s Glufosinate Tolerant Corn is in each of the AgrEvo Inc.'s Glufosinate Tolerant Corn cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a corn is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

301. As a result, the organoleptic, performance and potential safety alterations in the AgrEvo Inc.'s Glufosinate Tolerant Corn, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

302. Thus, defendants' failure to require labeling for the AgrEvo Inc.'s Glufosinate Tolerant Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

303. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the AgrEvo Inc.'s Glufosinate Tolerant Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

304. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 303 *supra*.

305. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

306. The genetic products used in the engineering of the AgrEvo Inc.'s Glufosinate Tolerant Corn, including the phosphinothricin acetyltransferase gene from Streptomyces viridochromogenes, the 35S promoter and the 35S terminator derived from cauliflower mosaic virus, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

307. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the AgrEvo Inc.'s Glufosinate Tolerant Corn to be generally recognized as safe.

308. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the AgrEvo Inc.'s Glufosinate Tolerant Corn to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

309. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including AgrEvo Inc.'s Glufosinate Tolerant Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XII. FDA's Action Regarding Calgene Inc.'s Laurate Canola

A. Count One: FDA's Failure to Require the Labeling of Calgene Inc.'s Laurate Canola is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

310. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 309 *supra*.

311. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

312. Genetic engineering of the Calgene Inc.'s Laurate Canola creates difference in the organoleptic and performance characteristic of the canola. These organoleptic and performance changes include, *inter alia*, accumulation of the saturated fatty acid, laurate.

313. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Calgene Inc.'s Laurate Canola.

314. Calgene Inc.'s Laurate Canola is genetically engineered to include the 12:0 acyl carrier protein thioesterase gene from California bay, Umbellularia californica, the 35S promoter from cauliflower mosaic virus, tml 3 min terminator, ori pRi from Agrobacterium rhizogenes, a segment of transposable element Tn5, right and left T-DNA border sequences from Agrobacterium tumefaciens, the lac Z gene may also be present, the napin promoter and napin terminator regions associated with the TE gene, and the kanamycin resistance nptII gene.

315. The selectable marker gene used in the Calgene Inc.'s Laurate Canola is the kanamycin resistance nptII gene in each of the Calgene Inc.'s Laurate Canola cells. The product of this gene chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When canola is eaten, the presence of the gene product may reduce the therapeutic efficacy of antibiotics used by the consumer.

316. As a result, the organoleptic, performance and potential safety alterations in the Calgene Inc.'s Laurate Canola, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

317. Thus, defendants' failure to require labeling for the Calgene Inc.'s Laurate Canola creates a misleading omission of material fact concerning food products and the

consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

318. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Calgene Inc.'s Laurate Canola Is A Violation of the Federal Food Drug and Cosmetic Act.

319. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 318 *supra*.

320. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

321. The genetic products used in the engineering of the Calgene Inc.'s Laurate Canola, including the 12:0 acyl carrier protein thioesterase gene from California bay, Umbellularia californica, the 35S promoter from cauliflower mosaic virus, tml 3 min terminator, ori pRi from Agrobacterium rhizogenes, segment of transposable element Tn5, right and left T-DNA border sequences from Agrobacterium tumefaciens, the lac Z gene may also be present, the napin promoter and napin terminator regions associated with the TE gene, and the kanamycin resistance nptII gene, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

322. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Calgene Inc.'s Laurate Canola to be generally recognized as safe.

323. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Calgene Inc.'s Laurate Canola to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants

have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

324. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Calgene Inc.'s Larate Canola, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XIII. FDA's Action Regarding Ciba-Geigy Corp.'s Insect Protected Corn.

A. Count One: FDA's Failure to Require the Labeling of Ciba-Geigy Corp.'s Insect Protected Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

325. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 324 *supra*.

326. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

327. Genetic engineering of the Ciba-Geigy Corp.'s Insect Protected Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, insect resistance.

328. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Ciba-Geigy Corp.'s Insect Protected Corn.

329. Ciba-Geigy Corp.'s Insect Protected Corn is genetically engineered to include the cryIA(b) gene from Bacillus thuringiensis kurstaki, the 35S promoter, the 35S terminator from the cauliflower mosaic virus, the gene encoding the enzyme phosphinothricin acetyltransferase.

330. The selectable marker gene used in the Ciba-Geigy Corp.'s Insect Protected Corn is the gene encoding the enzyme phosphinothricin acetyltransferase in each of the Ciba-Geigy Corp.'s Insect Protected Corn cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When corn is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

331. As a result, the organoleptic, performance and potential safety alterations in the Ciba-Geigy Corp.'s Insect Protected Corn, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

332. Thus, defendants' failure to require labeling for the Ciba-Geigy Corp.'s Insect Protected Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

333. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Ciba-Geigy Corp.'s Insect Protected Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

334. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 333 *supra*.

335. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

336. The genetic products used in the engineering of the Ciba-Geigy Corp.'s Insect Protected Corn, including the cryIA(b) gene from Bacillus thuringiensis kurstaki, the 35S promoter, the 35S terminator from the cauliflower mosaic virus, and the gene encoding the enzyme phosphinothricin acetyltransferase, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

337. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation

prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Ciba-Geigy Corp.'s Insect Protected Corn to be generally recognized as safe.

338. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Ciba-Geigy Corp.'s Insect Protected Corn to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

339. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Ciba-Geigy Corp.'s Insect Protected Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XIV. FDA's Action Regarding Monsanto Co.'s Glyphosate Tolerant Cotton

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Glyphosate Tolerant Cotton is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

340. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 339 *supra*.

341. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

342. Genetic engineering of the Monsanto Co.'s Glyphosate Tolerant Cotton creates difference in the organoleptic and performance characteristic of the cotton and cottonseed oil. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

343. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Glyphosate Tolerant Cotton.

344. Monsanto Co.'s Glyphosate Tolerant Cotton is genetically engineered to include the enolpyrovylshikimate-3-phosphate synthase gene from Agrobacterium sp. strain CP4, the 35S promoter derived from cauliflower mosaic virus, the nptII gene, which encodes neomycin phosphotransferase II, the aad gene, which encodes the bacterial selectable marker 3'(9)-O-aminoglycoside adenyltransferase and the Agrobacterium tumefaciens transformation system.

345. The selectable marker genes used in the Monsanto Co.'s Glyphosate Tolerant Cotton are the nptII gene, which encodes neomycin phosphotransferase II, and the aad gene, which encodes the bacterial selectable marker 3'(9)-O-aminoglycoside adenyltransferase in each of the Monsanto Co.'s Glyphosate Tolerant Cotton cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When cottonseed oil is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

346. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Glyphosate Tolerant Cotton, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

347. Thus, defendants' failure to require labeling for the Monsanto Co.'s Glyphosate Tolerant Cotton creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

348. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Glyphosate Tolerant Cotton Is A Violation of the Federal Food Drug and Cosmetic Act.

349. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 348 *supra*.

350. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

351. The genetic products used in the engineering of the Monsanto Co.'s Glyphosate Tolerant Cotton, including the enolpyrovylshikimate-3-phosphate synthase gene from Agrobacterium sp. strain CP4, the 35S promoter derived from cauliflower mosaic virus, the nptII gene, which encodes neomycin phosphotransferase II, and the aad gene, which encodes the bacterial selectable marker 3'(9)-O-aminoglycoside adenyltransferase and the Agrobacterium tumefaciens transformation system, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

352. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Glyphosate Tolerant Cotton to be generally recognized as safe.

353. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Glyphosate Tolerant Cotton to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

354. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto's Glyphosate Tolerant Cotton, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XV. FDA's Action Regarding Monsanto Co.'s Glyphosate Tolerant Canola

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Glyphosate Tolerant Canola is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

355. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 354 *supra*.

356. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

357. Genetic engineering of the Monsanto Co.'s Glyphosate Tolerant Canola creates difference in the organoleptic and performance characteristic of the canola and canola oil. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

358. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Glyphosate Tolerant Canola.

359. Monsanto Co.'s Glyphosate Tolerant Canola is genetically engineered to include the enolpyruvylshikimate-3-phosphate synthase gene from Agrobacterium sp. strain CP4.

360. The selectable marker gene used in the Monsanto Co.'s Glyphosate Tolerant Canola is in each of the Monsanto Co.'s Glyphosate Tolerant Canola cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When canola and canola oil is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

361. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Glyphosate Tolerant Canola, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

362. Thus, defendants' failure to require labeling for the Monsanto Co.'s Glyphosate Tolerant Canola creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

363. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Glyphosate Tolerant Canola Is A Violation of the Federal Food Drug and Cosmetic Act.

364. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 363 *supra*.

365. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

366. The genetic products used in the engineering of the Monsanto Co.'s Glyphosate Tolerant Canola, including the enolpyruvylshikimate-3-phosphate synthase gene from Agrobacterium sp. strain CP4, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

367. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Glyphosate Tolerant Canola to be generally recognized as safe.

368. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Glyphosate Tolerant Canola to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

369. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto Co.'s Glyphosate Tolerant Canola, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XVI. FDA's Action Regarding Monsanto Co.'s Insect Protected Cotton

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Insect Protected Cotton is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

370. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 369 *supra*.

371. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

372. Genetic engineering of the Monsanto Co.'s Insect Protected Cotton creates difference in the organoleptic and performance characteristic of the cotton and cottonseed oil. These organoleptic and performance changes include, *inter alia*, insect resistance.

373. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Insect Protected Cotton.

374. Monsanto Co.'s Insect Protected Cotton is genetically engineered to include the cryIA© from Bacillus thuringiensis (Bt) subsp. kurstaki, and the nptII gene which encodes neomycin phosphotransferase II.

375. The selectable marker gene used in the Monsanto Co.'s Insect Protected Cotton is the nptII gene which encodes neomycin phosphotransferase II in each of the Monsanto Co.'s Insect Protected Cotton cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a cotton and cottonseed oil is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

376. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Insect Protected Cotton, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

377. Thus, defendants' failure to require labeling for the Monsanto Co.'s Insect Protected Cotton creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

378. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Insect Protected Cotton Is A Violation of the Federal Food Drug and Cosmetic Act.

379. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 378 *supra*.

380. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

381. The genetic products used in the engineering of the Monsanto Co.'s Insect Protected Cotton, including the cryIA© from Bacillus thuringiensis (Bt) subsp. kurstaki, and the nptII gene which encodes neomycin phosphotransferase II, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

382. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Insect Protected Cotton to be generally recognized as safe.

383. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Insect Protected Cotton to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

384. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto Co.'s Insect Protected Cotton, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XVII. FDA's Action Regarding Agritope Inc.'s Modified Fruit Ripening Tomato

A. Count One: FDA's Failure to Require the Labeling of Agritope Inc.'s Modified Fruit Ripening Tomato is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

385. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 384 *supra*.

386. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

387. Genetic engineering of the Agritope Inc.'s Modified Fruit Ripening Tomato creates difference in the organoleptic and performance characteristic of the tomato. These organoleptic and performance changes include, *inter alia*, modified fruit ripening. 388. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Agritope Inc.'s Modified Fruit Ripening Tomato.

389. Agritope Inc.'s Modified Fruit Ripening Tomato is genetically engineered to include the S-adenosylmethionine hydrolase gene from E. coli bacteriophage T3, the untranslated 3' region of the nopaline synthase gene from Agrobacterium tumefaciens, the modified E8 gene promoter from tomatoes, the nptII gene from prokaryotic transposon Tn5 encoding neomycin phosphotransferase II and the Agrobacterium tumefaciens vector system.

390. The selectable marker gene used in the Agritope Inc.'s Modified Fruit Ripening Tomato is the nptII gene from prokaryotic transposon Tn5 encoding the neomycin phosphotransferase II enzyme in each of the Agritope Inc.'s Modified Fruit Ripening Tomato cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a tomato is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

391. As a result, the organoleptic, performance and potential safety alterations in the Agritope Inc.'s Modified Fruit Ripening Tomato, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

392. Thus, defendants' failure to require labeling for the Agritope Inc.'s Modified Fruit Ripening Tomato creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

393. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Agritope Inc.'s Modified Fruit Ripening Tomato Is A Violation of the Federal Food Drug and Cosmetic Act.

394. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 393 *supra*.

395. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

396. The genetic products used in the engineering of the Agritope Inc.'s Modified Fruit Ripening Tomato, including the S-adenosylmethionine hydrolase gene from E. coli bacteriophage T3, the untranslated 3' region of the nopaline synthase gene from Agrobacterium tumefaciens, the modified E8 gene promoter from tomatoes, the nptII gene from prokaryotic transposon Tn5 encoding neomycin phosphotransferase II and the Agrobacterium tumefaciens vector system, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

397. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Agritope Inc.'s Modified Fruit Ripening Tomato to be generally recognized as safe.

398. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Agritope Inc.'s Modified Fruit Ripening Tomato to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

399. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Agritope Inc.'s Modified Fruit Ripening Tomato, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XVIII. FDA's Action Regarding Dekalb Genetics Corp.'s Glufosinate Tolerant Corn

A. Count One: FDA's Failure to Require the Labeling of Dekalb Genetics Corp.'s Glufosinate Tolerant Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

400. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 399 *supra*.

401. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

402. Genetic engineering of the Dekalb Genetics Corp.'s Glufosinate Tolerant Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

403. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Dekalb Genetics Corp.'s Glufosinate Tolerant Corn.

404. Dekalb Genetics Corp.'s Glufosinate Tolerant Corn is genetically engineered to include the phosphinothricin acetyl transferase gene from Streptomyces hygroscopicus, the 35S promoter derived from cauliflower mosaic virus and the Agrobacterium tumefaciens transcript 7 (Tr 7) 3' regulatory region.

405. The selectable marker gene used in the Dekalb Genetics Corp.'s Glufosinate Tolerant Corn is in each of the Dekalb Genetics Corp.'s Glufosinate Tolerant Corn cells. The production of the enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a corn is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

406. As a result, the organoleptic, performance and potential safety alterations in the Dekalb Genetics Corp.'s Glufosinate Tolerant Corn, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

407. Thus, defendants' failure to require labeling for the Dekalb Genetics Corp.'s Glufosinate Tolerant Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

408. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Dekalb Genetics Corp.'s Glufosinate Tolerant Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

409. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 408 *supra*.

410. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

411. The genetic products used in the engineering of the Dekalb Genetics Corp.'s Glufosinate Tolerant Corn, including the phosphinothricin acetyl transferase gene from Streptomyces hygroscopicus, the 35S promoter derived from cauliflower mosaic virus

and the Agrobacterium tumefaciens transcript 7 (Tr 7) 3' regulatory region, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

412. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Dekalb Genetics Corp.'s Glufosinate Tolerant Corn to be generally recognized as safe.

413. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Dekalb Genetics Corp.'s Glufosinate Tolerant Corn to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

414. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Dekalb Genetics Corp.'s Glufosinate Tolerant Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XIX. FDA's Action Regarding Dupont's Sulfonylurea Tolerant Cotton

A. Count One: FDA's Failure to Require the Labeling of Dupont's Sulfonylurea Tolerant Cotton is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

415. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 414 *supra*.

416. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a

product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

417. Genetic engineering of the Dupont's Sulfonylurea Tolerant Cotton creates difference in the organoleptic and performance characteristic of the cotton and cottonseed oil. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

418. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Dupont's Sulfonylurea Tolerant Cotton.

419. Dupont's Sulfonylurea Tolerant Cotton is genetically engineered to include the acetolactate synthase gene from tobacco, Nicotiana tabacum cv. Xanthi and the Agrobacterium tumefaciens transformation system.

420. The selectable marker gene used in the Dupont's Sulfonylurea Tolerant Cotton is in each of the Dupont's Sulfonylurea Tolerant Cotton cells. The production of the enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When cottonseed oil is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

421. As a result, the organoleptic, performance and potential safety alterations in the Dupont's Sulfonylurea Tolerant Cotton, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

422. Thus, defendants' failure to require labeling for the Dupont's Sulfonylurea Tolerant Cotton creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

423. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Dupont's Sulfonylurea Tolerant Cotton Is A Violation of the Federal Food Drug and Cosmetic Act.

424. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 423 *supra*.

425. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

426The genetic products used in the engineering of the Dupont's Sulfonylurea Tolerant Cotton, including the acetolactate synthase gene from tobacco, Nicotiana tabacum cv. Xanthi and the Agrobacterium tumefaciens transformation system, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

427. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Dupont's Sulfonylurea Tolerant Cotton to be generally recognized as safe.

428. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Dupont's Sulfonylurea Tolerant Cotton to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

429. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Dupont's Sulfonylurea Tolerant Cotton, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XX. FDA's Action Regarding Monsanto Co.'s Insect Protected Potato

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Insect Protected Potato is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

430. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 429 *supra*.

431. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

432. Genetic engineering of the Monsanto Co.'s Insect Protected Potato creates difference in the organoleptic and performance characteristic of the potato. These organoleptic and performance changes include, *inter alia*, insect resistance.

433. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Insect Protected Potato.

434. Monsanto Co.'s Insect Protected Potato is genetically engineered to include the cryIIIA gene from Bacillus thuringiensis, the 35S promoters from the tobacco mosaic virus and the 3' region of the nopaline synthase gene from Agrobacterium tumefaciens, the nptII gene from the prokaryotic transposon Tn5 and the Agrobacterium tumefaciens transformation system.

435. The selectable marker gene used in the Monsanto Co.'s Insect Protected Potato is the nptII gene from the prokaryotic transposon Tn5 in each of the Monsanto Co.'s Insect Protected Potato cells. The enzyme gene product chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a potato is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

436. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Insect Protected Potato, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

437. Thus, defendants' failure to require labeling for the Monsanto Co.'s Insect Protected Potato creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

438. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Insect Protected Potato Is A Violation of the Federal Food Drug and Cosmetic Act.

439. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 438 *supra*.

440. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

441. The genetic products used in the engineering of the Monsanto Co.'s Insect Protected Potato, including the cryIIIA gene from Bacillus thuringiensis, the 35S promoters from the tobacco mosaic virus, the 3' region of the nopaline synthase gene from Agrobacterium tumefaciens, the nptII gene from the prokaryotic transposon Tn5 and the Agrobacterium tumefaciens transformation system, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

442. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Insect Protected Potato to be generally recognized as safe.

443. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Insect Protected Potato to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

444. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto Co.'s Insect Protected Potato, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXI. FDA's Action Regarding Monsanto Co.'s Insect Protected Corn

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Insect Protected Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

445. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 444 *supra*.

446. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

447. Genetic engineering of the Monsanto Co.'s Insect Protected Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, insect resistance.

448. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Insect Protected Corn.

449. Monsanto Co.'s Insect Protected Corn is genetically engineered to include the cryIA(b) gene from Bacillus thuringiensis subsp. kurstaki, the CP4 EPSPS protein from Agrobacterium sp. strain CP4, the intron from the corn hsp70 gene and by gene sequences from the plant pathogens Agrobacterium tumefaciens and cauliflower mosaic virus, the cryIA(b) gene, the gox gene, and the nptII selectable marker gene is present in the subject corn line under control of a bacterial promoter.

450. The selectable marker gene used in the Monsanto Co.'s Insect Protected Corn is the cryIA(b) gene. the gox gene. the nptII selectable marker gene is present in the subject corn line under control of a bacterial promoter in each of the Monsanto Co.'s Insect Protected Corn cells. The production of this enzyme chemically inactivates many antibiotics including kanamycin, neomycin or geneticin. When a corn is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

451. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Insect Protected Corn, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

452. Thus, defendants' failure to require labeling for the Monsanto Co.'s Insect Protected Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

453. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Insect Protected Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

454. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 453 *supra*.

455. The "Food Additive Amendment" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

456. The genetic products used in the engineering of the Monsanto Co.'s Insect Protected Corn, including the cryIA(b) gene from Bacillus thuringiensis subsp. kurstaki, the CP4 EPSPS protein from Agrobacterium sp. strain CP4, the intron from the corn hsp70 gene and by gene sequences from the plant pathogens Agrobacterium tumefaciens and cauliflower mosaic virus, the cryIA(b) gene. the gox gene. the nptII selectable marker gene is present in the subject corn line under control of a bacterial promoter, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

457. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Insect Protected Corn to be generally recognized as safe.

458. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Insect Protected Corn to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

459. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto Co.'s Insect Protected Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXII. FDA's Action Regarding Monsanto Co.'s Insect Protected Corn

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Insect Protected Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

460. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 459 *supra*.

461. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

462. Genetic engineering of the Monsanto Co.'s Insect Protected Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, insect resistance.

463. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Insect Protected Corn.

464. Monsanto Co.'s Insect Protected Corn is genetically engineered to include the cryIA(b) gene from Bacillus thuringiensis subsp. kurstaki, the enhanced 35S promoter derived from cauliflower mosaic virus, and the gene encoding selectable marker enzyme 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS).

465. The selectable marker gene used in the Monsanto Co.'s Insect Protected Corn is the gene encoding the selectable marker enzyme 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) in each of the Monsanto Co.'s Insect Protected Corn cells. When the corn is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

466. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Insect Protected Corn, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

467. Thus, defendants' failure to require labeling for the Monsanto Co.'s Insect Protected Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

468. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Insect Protected Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

469. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 468 *supra*.

470. The "Food Additive Amendment" to the FFDCA, 21 establish a premarket approval requirement for all "food additives" known as a food additive petition.

471. The genetic products used in the engineering of the Monsanto Co.'s Insect Protected Corn, including the cryIA(b) gene from Bacillus thuringiensis subsp. kurstaki, the enhanced 35S promoter derived from cauliflower mosaic virus, and the gene encoding

selectable marker enzyme 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS), meet the statutory definition of food additives under 21 U.S.C. § 321(s).

472. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Insect Protected Corn to be generally recognized as safe.

473. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Insect Protected Corn to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

474. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto Co.'s Insect Protected Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXIII. FDA's Action Regarding Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

475. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 474 *supra*.

476. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information

concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

477. Genetic engineering of the Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, herbicide tolerance and insect resistance.

478. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn.

479. Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn is genetically engineered to include the enolpyruvylshikimate-3-phosphate synthase gene from Agrobacterium sp. strain CP4 and the glyphosate oxidoreductase gene from Ohrobactrum anthropi in the glyphosate tolerant lines, the CryIA(b) gene from Bacillus thuringiensis subsp. kurstaki in lines that are also insect protected, the enhanced 35S promoter derived from cauliflower mosaic virus.

480. The selectable marker gene used in the Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn is in each of the Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn cells. When the corn is eaten the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

481. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

482. Thus, defendants' failure to require labeling for the Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. §§ 321(n), 343(a).

483. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

484. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 483 *supra*.

485. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives"

486. The genetic products used in the engineering of the Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn, including the enolpyruvylshikimate-3-phosphate synthase gene from Agrobacterium sp. strain CP4 and the glyphosate oxidoreductase gene from Ohrobactrum anthropi in the glyphosate tolerant lines, the CryIA(b) gene from Bacillus thuringiensis subsp. kurstaki in lines that are also insect protected, and the enhanced 35S promoter derived from cauliflower mosaic virus, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

487. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn to be generally recognized as safe.

488. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

489. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto Co.'s Glyphosate Tolerant/Insect Protected Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXIV. FDA's Action Regarding Northrup King's Insect Protected Corn

A. Count One: FDA's Failure to Require the Labeling of Northrup King's Insect Protected Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

490. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 489 *supra*.

491. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

492. Genetic engineering of the Northrup King's Insect Protected Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, insect resistance.

493. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Northrup King's Insect Protected Corn.

494. Northrup King's Insect Protected Corn is genetically engineered to include the cryIA(b) gene from Bacillus thuringiensis (Bt) subsp. kurstaki, the 35S promoter derived from cauliflower mosaic virus and a NOS terminator derived from the nopaline gene of Agrobacterium tumefaciens, and the pat gene isolated from Streptomyces viridochromogenes that encodes the selectable marker, phophinothricin-N-acetyltransferase (PAT) enzyme.

495. The selectable marker gene used in the Northrup King's Insect Protected Corn is the pat gene isolated from Streptomyces viridochromogenes that encodes the selectable marker, phophinothricin-N-acetyltransferase (PAT) enzyme in each of the Northrup King's Insect Protected Corn cells. When the corn is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

496. As a result, the organoleptic, performance and potential safety alterations in the Northrup King's Insect Protected Corn, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

497. Thus, defendants' failure to require labeling for the Northrup King's Insect Protected Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

498. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Northrup King's Insect Protected Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

499. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 498 *supra*.

500. The "Food Additive Amendment" to the FFDCA, 21 establish a premarket approval requirement for all "food additives" known as a food additive petition.

501The genetic products used in the engineering of the Northrup King's Insect Protected Corn, including the cryIA(b) gene from Bacillus thuringiensis (Bt) subsp. kurstaki, the 35S promoter derived from cauliflower mosaic virus and a NOS terminator derived from the nopaline gene of Agrobacterium tumefaciens, and the pat gene isolated from Streptomyces viridochromogenes that encodes the selectable marker, phophinothricin-N-acetyltransferase (PAT) enzyme, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

502. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Northrup King's Insect Protected Corn to be generally recognized as safe.

503. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Northrup King's Insect Protected Corn to be introduced into interstate commerce in the absence of food additive approval. As a result,

defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

504. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Northrup King's Insect Protected Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXV. FDA's Action Regarding Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape

A. Count One: FDA's Failure to Require the Labeling of Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

505. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 504 *supra*.

506. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

507. Genetic engineering of the Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape creates difference in the organoleptic and performance characteristic of canola oil. These organoleptic and performance changes include, *inter alia*, male sterility.

508. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape.

509. Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape is genetically engineered to include the barnase ribonuclease gene from Bacillus amyloliquefaciens in the male sterile oilseed , the barstar gene from Bacillus amyloliquefaciens in the fertility

restorer lines, the P35S promoter derived from the cauliflower mosaic virus and 3' not sequence from Agrobacterium tumefaciens, and the bar gene isolated from the bacterium Streptomyces hygroscopicius.

510. The selectable marker gene used in the Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape is the bar gene isolated from the bacterium Streptomyces hygroscopicius in each of the Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape cells. When canola oil is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

511. As a result, the organoleptic, performance and potential safety alterations in the Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

512. Thus, defendants' failure to require labeling for the Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

513. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape Is A Violation of the Federal Food Drug and Cosmetic Act.

514. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 513 *supra*.

515. The "Food Additive Amendment" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

516. The genetic products used in the engineering of the Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape, including the barnase ribonuclease gene from Bacillus amyloliquefaciens in the male sterile oilseed , the barstar gene from Bacillus amyloliquefaciens in the fertility restorer lines, the P35S promoter derived from the cauliflower mosaic virus and 3' not sequence from Agrobacterium tumefaciens, and the

bar gene isolated from the bacterium Streptomyces hygroscopicius, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

517. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape to be generally recognized as safe.

518. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Plant Genetic Systems's Male Sterile/Fertility Restorer Oilseed Rape to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2). 519. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Plant Genetic Systems' Male Sterile/Fertility Restorer Oilseed Rape, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXVI. FDA's Action Regarding Plant Genetic Systems's Male Sterile Corn

A. Count One: FDA's Failure to Require the Labeling of Plant Genetic Systems's Male Sterile Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

520. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 519 *supra*.

521. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

522. Genetic engineering of the Plant Genetic Systems's Male Sterile Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, male sterility.

523. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Plant Genetic Systems's Male Sterile Corn.

524. Plant Genetic Systems's Male Sterile Corn is genetically engineered to include the barnase gene from Bacillus amyloliquefaciens, and the bar gene from Streptomyces.

525. The selectable marker gene used in the Plant Genetic Systems's Male Sterile Corn is in each of the Plant Genetic Systems's Male Sterile Corn cells. When the corn is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

526. As a result, the organoleptic, performance and potential safety alterations in the Plant Genetic Systems's Male Sterile Corn, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

527. Thus, defendants' failure to require labeling for the Plant Genetic Systems's Male Sterile Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

528. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Plant Genetic Systems's Male Sterile Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

529. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 528 *supra*.

530. The "Food Additive Amendment" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

531. The genetic products used in the engineering of the Plant Genetic Systems's Male Sterile Corn, including the barnase gene from Bacillus amyloliquefaciens, and the bar gene from Streptomyces, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

532. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Plant Genetic Systems's Male Sterile Corn to be generally recognized as safe.

533. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Plant Genetic Systems's Male Sterile Corn to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

534. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Plant Genetic Systems's Male Sterile Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXVII. FDA's Action Regarding Dekalb Genetics Corp.'s Insect Protected Corn

A. Count One: FDA's Failure to Require the Labeling of Dekalb Genetics Corp.'s Insect Protected Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

535. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 534 *supra*.

536. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

537. Genetic engineering of the Dekalb Genetics Corp.'s Insect Protected Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, insect resistance.

538. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Dekalb Genetics Corp.'s Insect Protected Corn.

539. Dekalb Genetics Corp.'s Insect Protected Corn is genetically engineered to include the cryIA© gene from Bacillus thuringiensis (Bt), the bar gene isolated rom Streptomyces hygroscopicus that encodes a phosphinothricin acetyltransferase (PAT) enzyme, which inactivates glufosinate, and gene control sequences derived from cauliflower mosaic virus and Agrobacterium tumefaciens.

540. The selectable marker gene used in the Dekalb Genetics Corp.'s Insect Protected Corn is in each of the Dekalb Genetics Corp.'s Insect Protected Corn cells. When the corn is eaten, the presence of this enzyme may reduce the therapeutic efficacy of antibiotics used by the consumer.

541. As a result, the organoleptic, performance and potential safety alterations in the Dekalb Genetics Corp.'s Insect Protected Corn, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

542. Thus, defendants' failure to require labeling for the Dekalb Genetics Corp.'s Insect Protected Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

543. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Dekalb Genetics Corp.'s Insect Protected Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

544. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 543 *supra*.

545. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

546. The genetic products used in the engineering of the Dekalb Genetics Corp.'s Insect Protected Corn, including the cryIA© gene from Bacillus thuringiensis (Bt), the bar gene isolated from Streptomyces hygroscopicus that encodes a phosphinothricin acetyltransferase (PAT) enzyme, which inactivates glufosinate, and gene control sequences derived from cauliflower mosaic virus and Agrobacterium tumefaciens, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

547. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Dekalb Genetics Corp.'s Insect Protected Corn to be generally recognized as safe.

548. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Dekalb Genetics Corp.'s Insect Protected Corn to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

549. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Dekalb Genetics Corp.'s Insect Protected Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXVIII. FDA's Action Regarding Dupont's High Oleic Acid Soybean

A. Count One: FDA's Failure to Require the Labeling of Dupont's High Oleic Acid Soybean is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

550. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 549 *supra*.

551. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

552. Genetic engineering of the Dupont's High Oleic Acid Soybean creates difference in the organoleptic and performance characteristic of the soybean. These organoleptic and performance changes include, *inter alia*, high oleic acid production.

553. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Dupont's High Oleic Acid Soybean.

554. Dupont's High Oleic Acid Soybean is genetically engineered to include sequences mediating the sense suppression GmFad2-1 gene which encodes a delta-12 desaturase enzyme, gene sequences derived from Agrobacterium tumefaciens and cauliflower mosaic virus, the GUS and Amp marker genes.

555. The selectable marker gene used in the Dupont's High Oleic Acid Soybean is the GUS and Amp marker genes in each of the Dupont's High Oleic Acid Soybean cells. When these soybeans are eaten, the presence of these genes may reduce the therapeutic efficacy of antibiotics used by the consumer.

556. As a result, the organoleptic, performance and potential safety alterations in the Dupont's High Oleic Acid Soybean, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

557. Thus, defendants' failure to require labeling for the Dupont's High Oleic Acid Soybean creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

558. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Dupont's High Oleic Acid Soybean Is A Violation of the Federal Food Drug and Cosmetic Act.

559. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 558 *supra*.

560. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

561. The genetic products used in the engineering of the Dupont's High Oleic Acid Soybean, including sequences mediating the sense suppression GmFad2-1 gene which encodes a delta-12 desaturase enzyme, gene sequences derived from Agrobacterium tumefaciens and cauliflower mosaic virus, and the GUS and Amp marker genes, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

562. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Dupont's High Oleic Acid Soybean to be generally recognized as safe.

563. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Dupont's High Oleic Acid Soybean to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

564. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Dupont's High Oleic Acid Soybean, is arbitrary, capricious, an abuse of discretion and otherwise

not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXIX. FDA's Action Regarding Cornell University and University of Hawaii's Virus Resistant Papaya

A. Count One: FDA's Failure to Require the Labeling of Cornell University's Virus Resistant Papaya is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

565. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 564 *supra*.

566. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

567. Genetic engineering of the Cornell University's Virus Resistant Papaya creates difference in the organoleptic and performance characteristic of the papaya. These organoleptic and performance changes include, *inter alia*, virus resistance.

568. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Cornell University's Virus Resistant Papaya.

569. Cornell University's Virus Resistant Papaya is genetically engineered to express, *inter alia*, the coat protein gene from papaya ringspot virus gene strain HA 5-1 and gene control sequences derived from Agrobacterium tumefaciens and 35S promoter and terminator cauliflower mosaic virus, the GUS and nptII selectable marker genes.

570. The selectable marker genes GUS and npt II used in the Cornell University's Virus Resistant Papaya are each of the Cornell University's Virus Resistant Papaya cells. When

the papaya is eaten, the presence of these genes may reduce the therapeutic efficacy of antibiotics used by the consumer.

571. As a result, the organoleptic, performance and potential safety alterations in the Cornell University's Virus Resistant Papaya, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

572. Thus, defendants' failure to require labeling for the Cornell University's Virus Resistant Papaya creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

573. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Cornell University's Virus Resistant Papaya Is A Violation of the Federal Food Drug and Cosmetic Act.

574. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 573 *supra*.

575. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

576. The genetic products used in the engineering of the Cornell University's Virus Resistant Papaya, including sequences expressing the coat protein gene from papaya ringspot virus gene strain HA 5-1 and gene control sequences derived from Agrobacterium tumefaciens and 35S promoter and terminator cauliflower mosaic virus, and the GUS and nptII marker genes, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

577. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Cornell University's Virus Resistant Papaya to be generally recognized as safe.

578. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Cornell University's Virus Resistant Papaya to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

579. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Cornell University's Virus Resistant Papaya, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXX. FDA's Action Regarding Bejo Zaden BV's Male Sterile Radicchio Rosso.

A. Count One: FDA's Failure to Require the Labeling of Bejo Zaden BV's Male Sterile Radicchio Rosso is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

580. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 579 *supra*.

581. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

582. Genetic engineering of the Bejo Zaden BV's Male Sterile Radicchio creates difference in the organoleptic and performance characteristic of radicchio. These organoleptic and performance changes include, *inter alia*, herbicide tolerance and male sterility.

583. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Bejo Zaden BV's Male Sterile Radicchio Rosso.

584. Bejo Zaden BV's Male Sterile Radicchio Rosso is genetically engineered to include sequences mediating the barnase gene from Bacillus amyloliquefaciens, the bar gene isolated from Streptomyces hygroscopius which encodes a phosphinothricin acetyltransferase enzyme, gene sequences derived from Agrobacterium tumefaciens, and the nptII selectable marker gene.

585. The selectable marker gene used in the Bejo Zaden BV's Male Sterile Radicchio Rosso is the nptII marker gene in each of the radicchio's cells. When the radicchio is eaten, the presence of these genes may reduce the therapeutic efficacy of antibiotics used by the consumer.

586. As a result, the organoleptic, performance and potential safety alterations in the Bejo Zaden BV's Male Sterile Radicchio Rosso, its genetically engineered design is a material fact under 21 U.S.C. § 321(n).

587. Thus, defendants' failure to require labeling for the Bejo Zaden BV's Male Sterile Radicchio Rosso creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

588. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Bejo Zaden BV's Male Sterile Radicchio Rosso Is A Violation of the Federal Food Drug and Cosmetic Act.

589. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 588 *supra*.

590. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

592. The genetic products used in the engineering of the Bejo Zaden BV's Male Sterile Radicchio Rosso, including sequences mediating the barnase gene from Bacillus amyloliquefaciens, the bar gene isolated from Streptomyces hygroscopius which encodes a phosphinothricin acetyltransferase enzyme, gene sequences derived from Agrobacterium tumefaciens, and the nptII selectable marker gene, meet the statutory definition of food additives under 21 U.S.C. § 321(s).

593. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. § 348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Bejo Zaden BV's Male Sterile Radicchio Rosso to be generally recognized as safe.

594. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Bejo Zaden BV's Male Sterile Radicchio Rosso to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

594. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Bejo Zaden BV's Male Sterile Radicchio Rosso, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXXI. FDA's Action Regarding Seminis Vegetable Seeds' Virus Resistant Squash.

A. Count One: FDA's Failure to Require the Labeling of Seminis Vegetable Seeds' Virus Resistant Squash is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

595. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 594 *supra*.

596. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

597. Genetic engineering of the Seminis Vegetable Seeds' Virus Resistant Squash creates difference in the organoleptic and performance characteristic of the squash. These organoleptic and performance changes include, *inter alia*, virus resistance.

598. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Seminis Vegetable Seeds' Virus Resistant Squash.

599. Seminis Vegetable Seeds' Virus Resistant is genetically engineered to include, *inter alia*, sequences mediating the coat protein genes of cucumber mosiac virus, zucchini yellow mosaic virus, and watermelon mosaic virus, as well as marker genes.

600. The selectable marker gene used in the Seminis Vegetable Seeds' Virus Resistant may reduce the therapeutic efficacy of antibiotics used by the consumer.

601. As a result, the organoleptic, performance and potential safety alterations in the Seminis Vegetable Seeds' Virus Resistant Squash's genetically engineered design is a material fact under 21 U.S.C. § 321(n).

602. Thus, defendants' failure to require labeling for the Seminis Vegetable Seeds' Virus Resistant Squash creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

603. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Seminis Vegetable Seeds' Virus Resistant Is A Violation of the Federal Food Drug and Cosmetic Act.

604. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 603 *supra*.

605. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

606. The novel genetic material, marker genes, vectors used in the genetic engineering of Seminis Vegetable Seeds' Virus Resistant Squash and the proteins synthesized by these transgenes and other substances meet the statutory definition of food under 21 U.S.C. § 321(s).

607. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. §348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. §348(a)(2); 21 C.F.R. §5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Seminis Vegetable Seeds' Virus Resistant to be generally recognized as safe.

608. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Seminis Vegetable Seeds' Virus Resistant Squash to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

608. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Seminis Vegetable Seeds' Virus Resistant Squash, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXXII. FDA's Action Regarding Calgene's Bromonoxynil Tolerant/Insect Protected Cotton.

A. Count One: FDA's Failure to Require the Labeling of Calgene's Bromonoxynil Tolerant/Insect Protected Cotton is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

609. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 608 *supra*.

610. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

611. Genetic engineering of the Calgene's Bromonoxynil Tolerant/Insect Protected Cotton creates difference in the organoleptic and performance characteristic of the cotton and cottonseed oil. These organoleptic and performance changes include, *inter alia*, herbicide tolerance and insect resistance.

612. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Calgene's Bromonoxynil Tolerant/Insect Protected Cotton.

613. Calgene's Bromonoxynil Tolerant/Insect Protected Cotton is genetically engineered to include, *inter alia*, sequences of the Nitrilase gene from Klebsiella pneumoniae and the cryIA© gene from Bacillus thuringiensis subsp. kurstaki,as well as, marker genes.

614. The selectable marker gene used in the Calgene's Bromonoxynil Tolerant/Insect Protected Cotton may reduce the therapeutic efficacy of antibiotics used by the consumer.

615. As a result, the organoleptic, performance and potential safety alterations in the Calgene's Bromonoxynil Tolerant/Insect Protected Cotton's genetically engineered design is a material fact under 21 U.S.C. § 321(n).

616. Thus, defendants' failure to require labeling for the Calgene's Bromonoxynil Tolerant/Insect Protected Cotton creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

617. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Calgene's Bromonoxynil Tolerant/Insect Protected Cotton Is A Violation of the Federal Food Drug and Cosmetic Act.

618. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 617 *supra*.

619. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

620. The novel genetic material, marker genes, vectors used in the genetic engineering of Calgene's Bromonoxynil Tolerant/Insect Protected Cotton and the proteins synthesized by these transgenes and other substances meet the statutory definition of food under 21 U.S.C. § 321(s).

621. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. §348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. §348(a)(2); 21 C.F.R. §5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Calgene's Bromonoxynil Tolerant/Insect Protected Cotton to be generally recognized as safe.

622. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Calgene's Bromonoxynil Tolerant/Insect Protected Cotton to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

622. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Calgene's Bromonoxynil Tolerant/Insect Protected Cotton, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXXIII. FDA's Action Regarding Calgene's Insect Protected Tomato.

A. Count One: FDA's Failure to Require the Labeling of Calgene's Insect Protected Tomato is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

623. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 622 *supra*.

624. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

625. Genetic engineering of the Calgene's Insect Protected Tomato creates difference in the organoleptic and performance characteristic of the tomato. These organoleptic and performance changes include, *inter alia*, insect resistance.

626. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Calgene's Insect Protected Tomato.

627. Calgene's Insect Protected Tomato is genetically engineered to include, *inter alia*, sequences of the cryIA© gene from Bacillus thuringiensis subsp. kurstaki,as well as, marker genes.

628. The selectable marker gene used in the Calgene's Insect Protected Tomato may reduce the therapeutic efficacy of antibiotics used by the consumer.

629. As a result, the organoleptic, performance and potential safety alterations in the Calgene's Insect Protected Tomato's genetically engineered design is a material fact under 21 U.S.C. § 321(n).

630. Thus, defendants' failure to require labeling for the Calgene's Insect Protected Tomato creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

631. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of

procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Calgene's Insect Protected Tomato Is A Violation of the Federal Food Drug and Cosmetic Act.

632. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 631 *supra*.

633. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

634. The novel genetic material, marker genes, vectors used in the genetic engineering of Calgene's Insect Protected Tomato and the proteins synthesized by these transgenes and other substances meet the statutory definition of food under 21 U.S.C. § 321(s).

635. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. §348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. §348(a)(2); 21 C.F.R. §5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Calgene's Insect Protected Tomato to be generally recognized as safe.

636. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Calgene's Insect Protected Tomato to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

636. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Calgene's Insect Protected Tomato, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXXIV. FDA's Action Regarding the University of Saskatchewan's Sulfonylurea Tolerant Flax.

A. Count One: FDA's Failure to Require the Labeling of the University of Saskatchewan's Sulfonylurea Tolerant Flax is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

637. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 636 *supra*.

638. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

639. Genetic engineering of the University of Saskatchewan's Sulfonylurea Tolerant Flax creates difference in the organoleptic and performance characteristic of the flax and flax seed. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

640. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including the University of Saskatchewan's Sulfonylurea Tolerant Flax.

641. The University of Saskatchewan's Sulfonylurea Tolerant Flax is genetically engineered to include, *inter alia*, sequences of the acetolactate synthase gene from Arabidopsis,as well as, marker genes.

642. The selectable marker gene used in the University of Saskatchewan's Sulfonylurea Tolerant Flax may reduce the therapeutic efficacy of antibiotics used by the consumer.

643. As a result, the organoleptic, performance and potential safety alterations in the University of Saskatchewan's Sulfonylurea Tolerant Flax's genetically engineered design is a material fact under 21 U.S.C. § 321(n).

644. Thus, defendants' failure to require labeling for the University of Saskatchewan's Sulfonylurea Tolerant Flax creates a misleading omission of material fact concerning

food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

645. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the University of Saskatchewan's Sulfonylurea Tolerant Flax Is A Violation of the Federal Food Drug and Cosmetic Act.

646. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 645 *supra*.

647. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

648. The novel genetic material, marker genes, vectors used in the genetic engineering of the University of Saskatchewan's Sulfonylurea Tolerant Flax and the proteins synthesized by these transgenes and other substances meet the statutory definition of food under 21 U.S.C. § 321(s).

649. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. §348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. §348(a)(2); 21 C.F.R. §5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the University of Saskatchewan's Sulfonylurea Tolerant Flax to be generally recognized as safe.

650. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the University of Saskatchewan's Sulfonylurea Tolerant Flax to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

651. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including the

University of Saskatchewan's Sulfonylurea Tolerant Flax, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXXV. FDA's Action Regarding Agrevo, Inc.'s Glufosinate Tolerant Corn.

A. Count One: FDA's Failure to Require the Labeling of Agrevo, Inc.'s Glufosinate Tolerant Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

652. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 651 *supra*.

653. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

654. Genetic engineering of the Agrevo, Inc.'s Glufosinate Tolerant Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, insect resistance.

655. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Agrevo, Inc.'s Glufosinate Tolerant Corn.

656. Agrevo, Inc.'s Glufosinate Tolerant Corn is genetically engineered to include, *inter alia*, sequences of the phosphinothricin acetyltransferase gene Strptomyces viridochromogenes,as well as, marker genes.

657. The selectable marker gene used in the Agrevo, Inc.'s Glufosinate Tolerant Corn may reduce the therapeutic efficacy of antibiotics used by the consumer.

658. As a result, the organoleptic, performance and potential safety alterations in the Agrevo, Inc.'s Glufosinate Tolerant Corn's genetically engineered design is a material fact under 21 U.S.C. § 321(n).

659. Thus, defendants' failure to require labeling for the Agrevo, Inc.'s Glufosinate Tolerant Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

660. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Agrevo, Inc.'s Glufosinate Tolerant Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

661. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 660 *supra*.

662. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

663. The novel genetic material, marker genes, vectors used in the genetic engineering of Agrevo, Inc.'s Glufosinate Tolerant Corn and the proteins synthesized by these transgenes and other substances meet the statutory definition of food under 21 U.S.C. § 321(s).

664. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. §348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. §348(a)(2); 21 C.F.R. §5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Agrevo, Inc.'s Glufosinate Tolerant Corn to be generally recognized as safe.

665. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Agrevo, Inc.'s Glufosinate Tolerant Corn to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

666. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Agrevo, Inc.'s Glufosinate Tolerant Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXXVI. FDA's Action Regarding Monsanto Co.'s Glyphosate Tolerant Corn

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Glyphosate Tolerant Corn is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

667. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 666 *supra*.

668. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

669. Genetic engineering of the Monsanto Co.'s Glyphosate Tolerant Corn creates difference in the organoleptic and performance characteristic of the corn. These organoleptic and performance changes include, *inter alia*, herbicide tolerance.

670. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Glyphosate Tolerant Corn.

671. Monsanto Co.'s Glyphosate Tolerant Corn is genetically engineered to include, *inter alia*, sequences of the enolpyruvylshikimate-3-phosphate synthase gene from Abrobacterium sp. strain CP4,as well as, marker genes.

672. The selectable marker gene used in the Monsanto Co.'s Glyphosate Tolerant Corn may reduce the therapeutic efficacy of antibiotics used by the consumer.

673. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Glyphosate Tolerant Corn's genetically engineered design is a material fact under 21 U.S.C. § 321(n).

674. Thus, defendants' failure to require labeling for the Monsanto Co.'s Glyphosate Tolerant Corn creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

675. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Glyphosate Tolerant Corn Is A Violation of the Federal Food Drug and Cosmetic Act.

676. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 675 *supra*.

677. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

678. The novel genetic material, marker genes, vectors used in the genetic engineering of Monsanto Co.'s Glyphosate Tolerant Corn and the proteins synthesized by these transgenes and other substances meet the statutory definition of food under 21 U.S.C. § 321(s).

679. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. §348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. §348(a)(2); 21 C.F.R. §5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Glyphosate Tolerant Corn to be generally recognized as safe.

680. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Glyphosate Tolerant Corn to be

introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

681. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto Co.'s Glyphosate Tolerant Corn, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

XXXVII. FDA's Action Regarding Monsanto Co.'s Insect and Virus Protected Potato

A. Count One: FDA's Failure to Require the Labeling of Monsanto Co.'s Insect and Virus Protected Potato is Arbitrary, Capricious, Not in Accordance With Law and a Violation of the Federal Food, Drug and Cosmetic Act.

682. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 681 *supra*.

683. Section 201(n) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §321(n), mandates the FDA to require affirmative labeling on all foods with information concerning material facts. Failure to communicate materials facts to consumers on a product label, or by specific labeling, is misleading and renders a product misbranded under section 403(a) of the FFDCA, 21 U.S.C. § 343(a).

684. Genetic engineering of the Monsanto Co.'s Insect and Virus Protected Potato creates difference in the organoleptic and performance characteristic of the potato. These organoleptic and performance changes include, *inter alia*, insect and virus resistance.

685. Consumers have overwhelmingly stated a need for providing information that a food has been genetically engineered to prevent consumer deception and a preference for labels on all genetically engineered foods, including Monsanto Co.'s Insect and Virus Protected Potato.

686. Monsanto Co.'s Insect and Virus Protected Potato is genetically engineered to include, *inter alia*, sequences of the cryIIIA gene from Bacillus thuringiensis sp. tenebrionis and the potato leafroll virus replicase gene, as well as, marker genes.

687. The selectable marker gene used in the Monsanto Co.'s Insect and Virus Protected Potato may reduce the therapeutic efficacy of antibiotics used by the consumer.

688. As a result, the organoleptic, performance and potential safety alterations in the Monsanto Co.'s Insect and Virus Protected Potato's genetically engineered design is a material fact under 21 U.S.C. § 321(n).

689. Thus, defendants' failure to require labeling for the Monsanto Co.'s Insect and Virus Protected Potato creates a misleading omission of material fact concerning food products and the consequences of using such foods. These actions are in violation of sections 201(n) and 403(a) of the FFDCA, 21 U.S.C. § 321(n), 343(a).

690. In light of the foregoing, defendants' failure to comply with the FFDCA by not requiring the labeling of all genetically engineered foods is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

B. Count Two: FDA's Failure to Require the Submission of Food Additive Petitions for all Genetic Alterations in the Monsanto Co.'s Insect and Virus Protected Potato Is A Violation of the Federal Food Drug and Cosmetic Act.

691. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 690 *supra*.

692. The "Food Additive Amendments" to the FFDCA establish a premarket approval requirement for all "food additives" known as a food additive petition.

693. The novel genetic material, marker genes, vectors used in the genetic engineering of Monsanto Co.'s Insect and Virus Protected Potato and the proteins synthesized by these transgenes and other substances meet the statutory definition of food under 21 U.S.C. § 321(s).

694. Any substance that meets the definition of a "food additive" is presumed to be unsafe under 21 U.S.C. §348 until the defendants have promulgated a regulation prescribing conditions assuring safe use. 21 U.S.C. §348(a)(2); 21 C.F.R. §5.10(a)(1). Defendants have failed to promulgate regulations finding products used in the Monsanto Co.'s Insect and Virus Protected Potato to be generally recognized as safe.

695. The FFDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any adulterated food. Section 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C), defines adulterated foods as those which bear or contain any food additive which is unsafe. Defendants have allowed the Monsanto Co.'s Insect and Virus Protected Potato to be introduced into interstate commerce in the absence of food additive approval. As a result, defendants have allowed adulterated food in violation of 21 U.S.C. § 342 (a)(2)(C) and 21 U.S.C. § 348(a)(2).

696. In light of the foregoing, defendants' failure to comply with the FFDCA by not approving food additive petitions for all genetically engineered foods, including Monsanto Co.'s Insect and Virus Protected Potato, is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and without observance of procedures required by law, in violation of the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

RELIEF REQUESTED

WHEREFORE, plaintiffs respectfully request that this Court enter an Order:

(1). Declaring that:

(a). Defendants' actions authorizing, allowing, and approving any and all genetically engineered foods without requiring affirmative labeling was, and is, arbitrary, capricious, an abuse of discretion, not in accordance with law, and without observance of procedures required by law.

(b). Defendants' actions authorizing, allowing, and approving any and all genetically engineered foods without completion of food additive petitions for the novel genetic material, marker genes, and vectors used in the genetic engineering of food derived from new plant varieties and the protein synthesized by these transgenes was, and is, arbitrary, capricious, an abuse of discretion, not in accordance with law, and without observance of procedures required by law.

(2). Direct the defendants to:

(a). Immediately suspend all federal approval of genetically engineered foods, unless and until this Court has satisfactory assurances, that the defendants have complied with the labeling requirements of the Federal Food, Drug and Cosmetic Act;

(b). Immediately require all genetically engineered foods already approved by the defendants, or in any other way, already available on the market for consumer purchase and consumption, be labeled in compliance with the requirements of the Federal Food, Drug and Cosmetic Act;

(c). Immediately suspend all federal approval of genetically engineered foods, unless and until this court has satisfactory assurances, that the defendants have complied with the

requirements of the Food Additive Amendments of the Federal Food, Drug and Cosmetic Act including, *inter alia*, mandating the submission of food additive petitions for all genetically engineered food;

(d). Immediately suspend all federal approval of genetically engineered foods, unless and until this court has satisfactory assurances, that the defendants have complied with the requirements of the Religious Freedom Restoration Act and the Free Exercise Clause of the United States Constitution;

(3). Retain jurisdiction of this action to ensure compliance with its decree;

(4). Award plaintiffs attorney's fees and all other reasonable expense occurred in pursuit of this action; and

(5). Grant such other relief as the Court deems just and proper.

Respectfully submitted,

Joseph Mendelson, III

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DATED: September 14, 1998

CERTIFICATE OF SERVICE

I hereby certify that a copy of Plaintiffs' First Amended Complaint For Declaratory and Injunctive Relief, and all materials in support thereof, was served this 14th day of September 1998, by hand delivery to:

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