

**CITIZEN PETITION BEFORE THE  
UNITED STATES FOOD AND DRUG ADMINISTRATION**

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**CENTER FOR FOOD SAFETY** )  
660 Pennsylvania Ave, SE, Suite 302 )  
Washington, DC 20003, )  
*et al.*, )  
Petitioners, )  
v. )  
***Filed With:*** )  
Food and Drug Administration )  
Division of Dockets & Management )  
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U.S. Department of Health and Human )  
200 Independence Avenue, S.W. )  
Washington, D.C. 20201 )

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Docket Number \_\_\_\_\_

**PETITION SEEKING MANDATORY LABELING  
FOR GENETICALLY ENGINEERED FOODS**

Genetic engineering results in changes to foods at the molecular level that have never occurred in traditional varieties. These changes are determinative of consumers' food purchases and not readily apparent. Thus, the absence of mandatory labeling disclosures for GE foods is misleading to consumers. FDA's failure to require labeling for GE foods is an abdication of its statutory mandate to require labeling for foods that are "misbranded" because they are misleading.<sup>i</sup>

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,<sup>ii</sup> the Administrative Procedure Act,<sup>iii</sup> and the Food and Drug Administration's ("FDA") implementing regulations,<sup>iv</sup> petitioners respectfully request that FDA require that foods that are genetically engineered organisms, or contain ingredients derived from genetically engineered organisms—collectively referred to as "GE foods"—be labeled under the Federal Food Drug and Cosmetic Act ("FFDCA").<sup>v</sup> The requested actions are necessary to prevent economic fraud, and to protect consumers who are deceived by thinking the absence of labeling means the absence of GE foods. In addition, this action requests that FDA revisit its interpretation of "material" facts in light of intervening evidence since the agency enacted its "Statement of Policy: Foods Derived from New Plant Varieties" in 1992. By failing to label GE foods, FDA has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [and has] offered [] explanation[s] for its decision[s] that run[] counter to the evidence before the agency."<sup>vi</sup> Accordingly, based on the evidence and justifications in this petition, failure by FDA to take the requested actions would be arbitrary, capricious, and contrary to law.<sup>vii</sup>

**ACTIONS REQUESTED**

Petitioners seek the following:

1. Rescission of FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieties,<sup>viii</sup> and issuance of a new policy declaring that a production process is "material" under FFDCA section 201(n) if it results in a change to a food at the molecular or genetic level because a significant share of consumers would find it relevant to their purchasing decisions.
2. Issuance of new regulations under 21 C.F.R. § 101 requiring labeling for all foods produced using genetic engineering. Such regulations shall include the following:
  - a. Definitions
    - i. "Genetic engineering" means a process that alters an organism at the molecular or cellular level by means that are not possible under natural conditions or processes. Such means include, but are not limited to, recombinant DNA and RNA techniques, cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling,

introducing a foreign gene, and changing the position of genes. Genetic engineering does not include modification that consists exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

- ii. “Genetically engineered food” means a food:
  - 1) that is, or that is derived from, an organism that is produced through the intentional use of a process described in (i);
  - 2) that is, or that is derived from, the progeny of intended sexual or asexual reproduction (or both) of one or more organisms that is (are) the product of a process described in (i); or
  - 3) that contains ingredients derived from organisms as described in (1) or (2).
- b. A packaged genetically engineered food shall be considered misbranded, unless its nutritional information panel indicates which ingredients are genetically engineered as follows:
  - i. An asterisk appearing after each genetically engineered ingredient
  - ii. Directly below the list of ingredients, in bold typeface not less than twice the size of the typeface in the ingredients list, a notice as follows: “**\*GENETICALLY ENGINEERED**”
- c. Any genetically engineered food shall be considered misbranded, unless it contains a label that provides notices in accordance with the following:
  - i. A notice as follows: “GENETICALLY ENGINEERED”
  - ii. A notice as follows: “UNITED STATES GOVERNMENT NOTICE: THIS PRODUCT WAS PRODUCED USING GENETIC ENGINEERING”
  - iii. The notice required in clause (i) must immediately precede the notice required in clause (ii) and must be no less than twice the size of the notice required in (ii).
  - iv. The notice required in clause (ii) must be the same size as would apply if the notice provided nutritional information.

## PETITIONERS

Petitioner, **Center for Food Safety (CFS)**, is a nonprofit organization based in Washington, D.C. Since the organization's founding in 1997 CFS has sought to ameliorate the adverse impacts of industrial farming and food production systems on human health, animal welfare, and the environment. CFS has over 200,000 members in almost every state across the country. CFS seeks to protect human health and the environment by advocating thorough, science-based safety testing of GE products prior to any marketing; cultivation of GE crops in a manner that minimizes any risk of contaminating conventional food supplies or the environment, and that minimizes negative impacts such as increased use of pesticides and evolution of resistant weeds. CFS also seeks to provide consumers with a means of identifying GE foods on the market and to encourage full public participation in defining the issues presented by GE crops. Finally, a foundational part of CFS' mission is to further the public's fundamental right to know what is in their food.

To achieve its goals, CFS disseminates to government agencies, members of Congress, and the general public a wide array of educational and informational materials addressing the introduction of GE crops into the environment and food supply. CFS also sends out action alerts to its True Food Network; these action alerts generate public involvement, education, and engagement with governmental officials on issues related to genetic engineering and other issues affecting a sustainable food system.

Petitioner, **Amy's Kitchen**, P.O. Box 449, Petaluma, CA, 94952, is a privately held corporation which began operation in 1987, with the purpose of making healthy, organic, and easy-to-prepare frozen food. Owned and run by Andy and Rachel Berliner, employs over 1,500 people and operates processing plants located in Santa Rosa, California and White City, Oregon.

Petitioner, **Annie's Homegrown**, 1610 Fifth Street, Berkeley, CA 94710, is a producer of natural and/or organic pastas, meals and snacks.

Petitioner, **Beyond Pesticides**, located at 701 E Street, SE, Suite 200, Washington, DC 20003, is a Washington, D.C.-based nonprofit corporation that promotes safe air, water, food, and a healthy environment by working to encourage a transition away from the use of toxic pesticides. Beyond Pesticides' public education contributes to a significant reduction in unnecessary pesticide use, thus improving protection of public health and the environment.

Petitioner, **Center for Environmental Health (CEH)**, located at 2201 Broadway, Suite 302, Oakland, CA, 94612, is a California nonprofit organization dedicated to protecting the public from environmental and consumer health hazards. CEH is committed to environmental justice, reducing the use of toxic chemicals and practices, supporting communities in their quest for a safer environment, and corporate accountability.

Petitioner, **Consumer Reports (CR)**, located at 101 Truman Avenue, Yonkers, NY 10703-1057, is the world's largest independent product-testing organization. Using its more than 50 labs, an auto test center, and a survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million

subscribers to its magazine, website, and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Petitioner, **CROPP Cooperative (Organic Valley)**, located at 1 Organic Way, LaFarge, WI 54639, is the nation's largest, independent cooperative of organic family farmers marketing its members' organic dairy, soy, eggs and produce (in season). Organic Valley has 1643 farmer-owners located in 32 states and one Canadian province who specialize in sustainable, organic agriculture practices.

Petitioner, **Environmental Working Group (EWG)**, located at 1436 U Street. NW, Suite 100, Washington, DC 20009, is a 501(c)(3) nonprofit corporation dedicated to using the power of public information to protect public health and the environment. EWG works to replace federal policies—including government subsidies that damage the environment and natural resources—with policies that invest in conservation and sustainable development.

Petitioner, **Food & Water Watch (FWW)**, located at 1616 P Street, NW Suite 300 Washington, DC 20036, is a Washington, D.C.-based nonprofit corporation and consumer rights group which focuses on corporate and government accountability relating to food, water, and fishing. FWW works to ensure the food, water and fish people consume is safe, accessible and sustainably produced.

Petitioner, **Horizon Organic**, located at 12002 Airport Way, Broomfield, CO 80021, is a USDA National Organic Program-certified dairy company that is one of the largest suppliers of organic milk in all of North America.

Petitioner, **The Midwest Organic and Sustainable Education Service (MOSES)**, P.O. Box 339, Spring Valley, WI 54767, is a 501(c)(3) nonprofit corporation and education-outreach organization working to promote sustainable and organic agriculture. MOSES serves farmers striving to produce high-quality, healthful food using organic and sustainable techniques.

Petitioner, **The National Cooperative Grocers Association (NCGA)**, located at 14 S Linn Street, Iowa City, IA 52240, is a business services cooperative for natural food co-ops located throughout the United States. NCGA helps unify natural food co-ops in order to optimize operational and marketing resources, strengthen purchasing power, and ultimately offer more value to natural food co-op owners and shoppers everywhere.

Petitioner, **The National Family Farm Coalition (NFFC)**, located at 110 Maryland Ave. N.E., Suite 307, Washington, D.C. 20002, is a non-profit 501(c)(3) organization that serves as a national link for grassroots organizations working on family farm issues. NFFC represents 24 grassroots organizations in 32 states. The mission of NFFC is to unite and strengthen the voices and actions of its diverse grassroots members to demand viable livelihoods for family farmers, fishers, and workers, safe and healthy food for everyone, and economically and environmentally sound rural communities.

Petitioner, **Northeast Organic Dairy Producers Alliance (NODPA)**, located at 30 Keets Rd., Deerfield, MA 01342, is the largest grassroots farmer organizations in the country and is dedicated to organic dairy farmers' interests, peer mentoring and communication between producers. NODPA's mission is to enable organic dairy family farmers, situated across an extensive area, to have informed discussion about matters critical to the well-being of the organic dairy industry.

Petitioner, **The Northeast Organic Farming Association (NOFA)**, P.O. Box 164, Stevenson, CT 06491, is a nonprofit organization of over 5,000 farmers, gardeners, landscape professionals and consumers working to promote healthy food, organic farming practices and a cleaner environment. NOFA has chapters in Connecticut, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island and Vermont.

Petitioner, **The National Organic Coalition (NOC)** is a national alliance of organizations working to provide a political voice for farmers, ranchers, environmentalists, consumers and progressive industry members involved in organic agriculture. The coalition operates under the central principle that protecting the stringency and integrity of the national organic standards is necessary to ensure the long-term environmental and economic viability of organic farming.

Petitioner, **Organic Seed Alliance (OSA)**, P.O. Box 772, Port Townsend, WA 98368, is a Port Townsend, WA-based nonprofit corporation, founded in 1975 as Abundant Life Seed Foundation, with a name change to Organic Seed Alliance in 2003. OSA promotes the ethical development and stewardship of the genetic resources of agricultural seed, and accomplishes its goals through collaborative education and research programs with organic farmers and other seed professionals.

Petitioner, **The Organic Seed Growers and Trade Association (OSGATA)**, P.O. Box 512 Montrose CO 81402, develops, protects and promotes the organic seed trade and its growers, and assures that the organic community has access to excellent quality organic seed, free of contaminants and adapted to the diverse needs of local organic agriculture. OSGATA accomplishes these goals by, *inter alia*, ensuring the right to true choice in the marketplace for farmers and consumers.

Petitioner, **Organic Trade Association (OTA)**, located at 28 Vernon Street Suite 413, Brattleboro VT 05301, is the membership-based business association for the organic industry in North America. OTA's mission is to promote and protect organic trade to benefit the environment, farmers, the public, and the economy. OTA envisions organic products becoming a significant part of everyday life, enhancing people's lives and the environment. OTA represents businesses across the organic supply chain and addresses all things organic, including food, fiber/textiles, personal care products, and new sectors as they develop. Over sixty percent of OTA trade members are small businesses.

Petitioner, **Organically Grown Company (OGC)**, located at 1800B Prairie Rd., Eugene, OR 97402, is the largest wholesaler of organic produce in the Pacific Northwest with Eugene and

Portland, OR and Kent, WA locations. OGC promotes health through organic agriculture as a leading sustainable system.

Petitioner, **The Rural Advancement Foundation International (RAFI) – USA** is a private nonprofit organization located at 274 Pittsboro Elementary School Road, Pittsboro, NC 27312. By working with a variety of farm, community, university and government groups, RAFI – USA promotes sustainability, equity and diversity in agriculture through policy changes, practical assistance, market opportunities, and access to financial and technical resources.

Petitioner, **Save New Mexico Seeds** is a New Mexico-based nonprofit organization that aims to protect farmers from transgenic contamination of their seed from genetically engineered crops.

Petitioner, **Stonyfield Farm**, located at 10 Burton Drive, Londonderry, NH, 03053, is the world’s leading organic yogurt company. Its certified organic yogurt, smoothies, milk, cultured soy, frozen yogurt and ice cream are distributed nationally. The company advocates that healthy food can only come from a healthy planet. Its use of organic ingredients helps keep over 200,000 farm acres free of toxic, persistent pesticides and chemical fertilizers known to contaminate soil, drinking water and food. To help reduce climate change, Stonyfield offsets all of the CO2 emissions generated from its facility energy use. The company also started a nonprofit called Climate Counts ([climatecounts.org](http://climatecounts.org)) which shows people how they can help fight climate change by the way they shop and invest. Stonyfield also donates 10% of its profits to efforts that help protect and restore the Earth.

## STATEMENT OF GROUNDS

### I. INTRODUCTION

FDA’s outdated regulatory regime for food labeling is woefully inadequate. FDA is still using 19<sup>th</sup> century ideas to regulate 21<sup>st</sup> century foods, focusing only on traits that consumers can detect with their senses. But modern public preferences and purchasing decisions are based not only on sensory perceptions, but also on concerns related to latent or unknown health risks, animal welfare, faith, political concerns, social justice, and environmental impacts.

In addition to genetic engineering, other novel and unnatural food production technologies are either on the horizon or are currently in use, many completely unbeknownst to consumers. The use of these novel food technologies on a commercial scale has so far slipped underneath FDA’s current threshold for “materiality” because they make silent, genetic, and molecular changes to food that are not capable of being detected by human senses. As the use of these and future food production technologies proliferates, consumers know less and less about the food they put in their bodies.

The power and duty to modernize the oversight of food lies with FDA. Under FFDCA,<sup>ix</sup> FDA’s authority to require labeling based on production processes goes well beyond the agency’s antiquated definition of “material” facts. FFDCA authorizes FDA to require labeling

for GE foods in order to prevent consumer deception. As discussed *infra*, in the past FDA itself has mandated labeling based on production processes. Failure to require labeling of GE foods conflicts with this past FDA precedent and creates the appearance that FDA has altered its past policies to benefit the biotechnology industry, not the public.

For the reasons explained below, Petitioners respectfully submit that FDA has not just the statutory authority, but also the duty to require that products of novel food technologies, particularly genetic engineering, be labeled differently from their conventional counterparts. Accordingly, FDA's failure to take the requested action would be arbitrary, capricious, and contrary to law.<sup>x</sup>

## **II. STATEMENT OF LAW**

Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*

Food and Drug Administration, 21 C.F.R. part 101, *et seq.*

## **III. PROCEDURAL HISTORY AND STATEMENT OF FACTS**

### **A. FDA's 1992 Policy On Genetically Engineered Foods**

On May 29, 1992, FDA published a "policy statement" establishing a regulatory framework for foods created through genetic engineering technology.<sup>xi</sup> The 1992 Policy allows, *inter alia*, genetically engineered foods to be marketed without labeling. This policy was based on FDA's determination that genetically engineered foods are substantially equivalent to foods produced through conventional methods:

The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.<sup>xii</sup>

Thus, FDA adopted the policy that the fact that a food was genetically engineered was not, in itself, a "material" fact under FFDCa section 201(n).

FDA received nearly 6,500 comments on its 1992 Policy. An agency analysis of those comments concluded that more than 98% of the public commenters opposed the policy. Moreover, about 80% of the commenters demanded mandatory labeling of genetically engineered foods, and a significant number questioned the safety and environmental impacts of these novel foods and crops.<sup>xiii</sup> Despite the public outcry and consistent, ongoing public concern about GE foods,<sup>xiv</sup> FDA never issued a response to those comments. Nor has the agency ever completed or released any documentation assessing the human health, environmental, and socio-economic impacts of the commercialization of unlabeled and untested genetically engineered foods, although FDA staff recommended that such an analysis be performed. The combination

of FDA’s failure to mandate pre-market safety testing and its permissive labeling policy has meant that silent changes to our food supply are tested on the public without their knowledge.

## **B. Genetic Engineering Is Radically Different From Conventional Food Production**

The 1992 Policy contained no scientific studies or data to support the assumption that genetically engineered foods were substantially equivalent to conventional foods.<sup>xv</sup> It was a political, not scientific, decision. In fact, scientists within FDA and outside the agency agreed that there are profound differences between genetically engineered foods and those produced through traditional breeding.<sup>xvi</sup>

As a general rule, conventional breeding develops new plant varieties by the process of *selection* and seeks to achieve expression of genetic material that is already present in the species. Conventional breeding employs processes that occur in nature, such as sexual and asexual reproduction. The product of conventional breeding emphasizes certain characteristics, but these characteristics are not new to the species. Rather, they have been present for millennia within the genetic potential of the species.<sup>xvii</sup>

Genetic engineering, by contrast, works primarily through **insertion** of foreign genetic material, followed up by selection. Gene transfer occurs by artificial means—through a gene “gun,” a bacterial vector, or chemical or electrical treatment—without regard for natural species boundaries. Biotechnicians use promoters derived from genetic parasites, such as viruses, that have been designed to breach species barriers, in order to ensure that the right amount of the desired gene product will be produced at the right time. Neither vectors nor promoters are needed in traditional breeding.<sup>xviii</sup> As FDA scientists have explained, genetic engineering allows

for the possibility of transferring to any organism a gene from any other organism or from a synthetic source (i.e., an enzyme composed of several domains of unrelated proteins). This potential is beyond the realm of possibility of standard breeding practice. **The food safety of organisms derived from recombinant DNA technologies do not have the history of the safe use that has come to be associated with organisms derived by standard breeding practices.**<sup>xix</sup>

Scientists may even insert custom-designed genes that do not exist in nature, producing a synthetic life form.<sup>xx</sup> One FDA expert summed up the novel nature of these foods: “We should also keep in mind that plant genetic engineering is an entirely new adventure with potentially new effects.”<sup>xxi</sup>

FDA scientists further warned that the artificial insertion of DNA into plants, a technique unique to genetic engineering, could cause a variety of significant problems with plant foods including an increase in levels of known toxicants, the appearance of new toxicants or new allergens, loss of nutrients, poor growth, and higher concentrations of herbicides and pesticides.<sup>xxii</sup> Scientists also caution that genetically engineered foods may cause antibiotic resistance.<sup>xxiii</sup>

#### IV. ARGUMENT

##### A. FFDCCA Prohibits The Marketing And Sale Of Unlabeled GE Foods: They Are Misbranded Because They Are “Misleading In *Any Particular*”

For decades, FDA has focused its determination of whether a label is misleading because of an omitted fact on the question of whether the fact is “material,” neglecting the remainder of FFDCCA section 201(n). However, under FFDCCA, whether omitted facts are “material” is not the only basis upon which FDA must consider whether labels are misleading. FFDCCA prohibits the marketing or sale of foods if the “labeling is false or misleading **in any particular.**”<sup>xxiv</sup> The statute continues:

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

The requirement that FDA “shall” take “other things” into account demonstrates that the considerations listed in the statute are not an exhaustive list. Rather, FDA’s ongoing duty is to holistically examine food labels to determine whether they are misleading “in **any particular.**”

Food labels that do not disclose the fact that the food was produced using genetic engineering or contains ingredients from GE organisms are misleading to consumers, regardless of whether or not genetic engineering meets FDA’s 1992 extra-statutory definition of a “material” fact. Consumers are misled when food labels do not differentiate foods with known health properties from novel foods with unknown health consequences. Unlike time-tested conventional food varieties, which have had centuries to manifest long-term health impacts, the scientific community and our government are still uncovering new and significant information about the human health and environmental impacts of GE foods. In many cases, this new information contradicts the biotechnology industry’s and FDA’s prior assumptions and assurances about the health properties and risks of GE foods.<sup>xxvi</sup>

In a recent example, an independent Canadian study found that a toxin from soil bacterium Bt (*Bacillus thuringiensis*), which has been engineered into Bt corn was present in the bloodstream of 93% of pregnant women, as well as in 80% of their fetal cord blood.<sup>xxvii</sup> These findings cast grave doubt on the biotechnology industry’s assurances—accepted at face value by federal agencies, including FDA—that the genetically engineered Bt toxin would be broken down by human digestive systems before entering the bloodstream. This Canadian study not only underscores the scientific uncertainty surrounding the health impacts of GE crops, but also

casts doubt on the wisdom of federal agencies' practice of relying excessively on crop developers' own safety assessments rather than on independent studies.

In another example, the U.S. Court of Appeals for the Sixth Circuit last year recognized that record evidence demonstrated a compositional difference between milk from cows treated with the genetically engineered growth hormone rbST and milk from untreated cows.<sup>xxviii</sup> This finding, supported by independent, peer-reviewed scientific studies, contradicted FDA's long-standing position that there was no compositional difference between milk produced with rbST and other milk.<sup>xxix</sup> Moreover, the court made clear that a compositional difference did not have to be **certain** in order to support different labeling; rather, the two milk products may be distinguished by the fact that the absence of rbST is **demonstrably true** in milk from untreated cows, whereas the absence of rbST in milk from treated cows has **not been verified** because of the limitations of current testing methods.<sup>xxx</sup>

Consumers and the public are misled by companies' failure to disclose a difference similar to the one recognized by the U.S. Court of Appeals in *IDFA v. Boggs*: namely, that time-tested, conventionally produced foods **demonstrably** have a history of safe use, whereas their GE counterparts uniformly lack the same history of safe use. This difference is compounded by the fact that FDA, the agency most often cited as vouching for the safety of GE foods, has never conducted a single safety assessment for them, does not affirm their safety, and in fact explicitly places responsibility for their safety in the hands of biotechnology companies. FDA instead uses what it calls a "voluntary consultation" process. Companies that develop a GE crop are encouraged, but not required, to share the conclusions of any studies they may have conducted on their GE crop. FDA reviews the submission, and normally issues a letter that states it has "no further questions."<sup>xxxii</sup> Notably, the letter also often includes a variation of the following, taken from FDA's consultation letter to Monsanto regarding MON 89034: "Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that corn grain and forage derived from the new variety are not materially different in composition, safety, or other relevant parameters from corn grain and forage currently on the market, and that they do not raise issues that would require premarket review or approval by FDA."<sup>xxxiii</sup> The letter thus explicitly disclaims FDA responsibility for the safety of the crop, noting that ensuring the crop's safety is the biotech firm's responsibility.

Because there has been no government-mandated, independent, peer-reviewed scientific testing of GE foods, the public has been serving as an unwitting laboratory for this experimental food technology. As the long-term health impacts of eating certain GE foods are gradually coming to light, the scientific community's and the public's understanding of the risks inherent in GE foods is in a state of flux. The same cannot be said of time-tested, conventional foods, the health impacts of which are by and large well established. Moreover, the uncertainty surrounding GE foods is a difference that is determinative of consumer purchases, as evidenced by the numerous public opinion polls discussed in Part IV.B *infra*.

In light of the foregoing, FDA has "failed to consider an important aspect of the [labeling] problem."<sup>xxxiii</sup> namely, the uniformly misleading character of GE foods without clear labeling. FDA's insistence that it lacks authority to mandate labeling of GE foods is therefore

arbitrary, capricious, and contrary to the agency’s mandate under FFDCA. Mandatory labeling of GE foods is necessary to prevent deception and economic fraud.

**B. Widespread Public Demand And Voluntary Labeling Certifications Demonstrate That Consumers Purchase Based On Production Processes**

The substantial consumer demand<sup>xxxiv</sup> for labeling underscores that there are numerous reasons that the failure to label GE foods is misleading to consumers. Public opinion polls have demonstrated that an overwhelming—and increasing—majority of Americans believe that GE foods should be labeled.<sup>xxxv</sup> Additionally, other studies have indicated that consumers, particularly Americans, are willing to pay substantial price premiums in order to avoid GE foods.<sup>xxxvi</sup> Given the wide reach of consumer concerns over GE foods, the proper response for FDA and the food companies “should not be to suppress process information, but rather to expose it to scrutiny and counter-argument.”<sup>xxxvii</sup>

Petitioners do not argue, nor have they ever argued, that consumer demand **alone** is sufficient basis upon which to label GE foods. Rather, the substantial consumer demand for labeling underscores that there are numerous reasons that the failure to label GE foods is misleading, such as their potential health impacts and unknown risks, as well as their myriad environmental impacts.

Additionally, the proliferation of voluntary labeling claims and certifications demonstrates that many consumers base their purchases on what they are able to find out about how a food was produced. For example, ecological claims such as “natural,” “sustainably grown,” “environmentally friendly,” and others are now common on food products, as food companies have realized the immense marketing advantage they yield. Independent certifications have similarly yielded huge marketing advantages for food and other companies. Member organizations of the International Social and Environmental Accreditation and Labeling Alliance certify products from a diverse range of production processes, including sustainable forestry (Forest Stewardship Council), sustainable fishing (Marine Stewardship Council), organic and sustainable agriculture (International Federation of Organic Agriculture Movements, International Organic Accreditation Service), and socially accountable labor (Fairtrade Labeling Organizations International, Social Accountability International).<sup>xxxviii</sup>

The prevalence and success of these voluntary claims and certifications for certain production processes demonstrate that facts about how food is produced are significant factors in consumer purchasing decisions. Accordingly, when food companies do not disclose production processes that consumers find significant, consumers are just as deceived as when companies do not disclose an unapparent organoleptic or performance trait, if not more so. FDA has so far “entirely failed to consider” this “important aspect of the problem.”<sup>xxxix</sup> Instead, by focusing only on organoleptic and performance traits—a limitation that appears nowhere in FFDCA, and that conflicts with the agency’s past interpretation of its statutory authority—FDA has “relied on factors Congress has not intended it to consider.”<sup>xl</sup> Accordingly, FDA’s failure to revisit and revise its labeling policy for GE foods would be arbitrary, capricious, and contrary to the mandates of FFDCA.

### C. **FDA Is Free To Revisit And Amend Its Current Interpretation Of “Material” Facts Under FFDCA**

As explained above, FDA has broad authority and the statutory duty to require that GE foods be labeled. This authority exceeds the agency’s previous extra-statutory, narrow guidance interpretation of “materiality.” However, even within its existing regulatory framework based on “materiality,” FDA can and should require labeling. The agency is fully empowered to change its interpretation of “material” facts under section 201(n) even though it has an interpretation in place,<sup>xli</sup> and *Alliance for Bio-Integrity v. Shalala*<sup>xlii</sup> does not constrain FDA in fulfilling its statutory duties.

FDA’s statutory authority to mandate labeling based on how a food is produced comes from its authority to mandate labeling for foods that are misbranded because they are misleading.<sup>xliii</sup> One way a label may be misleading is if it fails to reveal facts that are “material” either (1) in light of representations made on the label, or (2) with respect to the consequences that may result from using or consuming the food.<sup>xliv</sup> Congress has not given any guidance regarding the meaning or limits of the term “material.” Thus, FDA’s authority to mandate labeling of “material” facts turns entirely on which reasonable interpretation of “material” the agency chooses to adopt.

#### 1. **The Legislative History Of FFDCA Section 201(n) Demonstrates That It Was Intended To Require Labeling For Information That Consumers Find Significant**

Section 201(n) appeared for the first time four years into the debate over the legislation that would eventually become the FFDCA of 1938.<sup>xlv</sup> The language has been amended only once, to add the clause “or advertising” in two locations.<sup>xlvi</sup>

One of the factors triggering whether a representation or omission on a food label makes such food misbranded is if its labeling fails to reveal a “material” fact. The materiality requirement was written into the FFDCA of 1938 to have the same meaning as a corresponding paragraph in a bill addressing false advertising. The bill, S.1077, became known as the Wheeler-Lea Act and provided new powers to the Federal Trade Commission.<sup>xlvii</sup> FFDCA’s legislative history is silent as to what type of fact is “material,” stating only that the “**purpose is obvious.**”<sup>xlviii</sup> However, the drafters explicitly connected the language of section 201(n) with the Wheeler-Lea Act language. In interpreting that statute, the language has been traced back to the 1938 Restatement of Torts § 538, which defined a fact to be material “if its existence or nonexistence is a matter to which a reasonable man would attach importance in determining his choice of action in a transaction in question.”<sup>xlix</sup>

Thus, the legislative history of FFDCA illustrates that the statute’s intent was not to limit the agency’s inquiry to “organoleptic” differences or “performance characteristics;” rather, the term was meant to mandate, at a minimum, labeling that a reasonable person would find material. In contrast to this reasonableness test, FDA’s current standard finds no basis in the statutory text or the legislative history and conflicts with the “obvious” purpose of section 201(n). In so doing, FDA is relying on a factor that Congress never intended for it to consider.<sup>1</sup>

## 2. Past FDA Rulings And Pronouncements Demonstrate That A Broader Interpretation Of “Material” Is Permissible—Even Mandated—Under FFDCA

An interpretation of “material” that encompasses information about production processes that consumers find significant is a reasonable interpretation of section 201(n); FDA itself adopted this interpretation before. When issuing its rule requiring irradiated foods to be labeled, FDA stated in broad terms, “[w]hether information is material under [section 201(n)] . . . depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer. **The large number of consumer comments requesting retail labeling attest to the significance placed on such labeling by consumers.**”<sup>li</sup>

FDA’s mandatory source labeling for protein hydrolysates is another example in which the agency has found information unrelated to nutritional value, “organoleptic” properties, or functional characteristics sufficiently “material” for mandatory labeling. As FDA stated, “the food source of a protein hydrolysate is information **of material importance** for a person who desires to avoid certain foods for religious or cultural reasons.”<sup>lii</sup> FDA went on to require source labeling for protein hydrolysates out of concern for vegetarians and observant Jews and Muslims.<sup>liii</sup>

In a 1993 notice,<sup>liv</sup> FDA attempted to craft a revisionist history of these two regulatory actions in order to claim that the agency had always employed its then-newly-created definition of “material” facts. Regarding irradiated foods, FDA claims that it mandated labeling of irradiated foods because the process results in “organoleptic” changes to the food.<sup>lv</sup> However, a close reading of FDA’s irradiated foods notice reveals this to be incorrect, or at least incomplete. The focus of FDA’s reasoning in the irradiated foods notice was the fact that irradiation would “not change the food visually,” thereby leading to consumer deception. At no point in this notice did FDA even suggest that it was **because** the change was “organoleptic” that irradiation warranted labeling. Further debunking FDA’s insistence that it may not mandate labeling of a production process, the agency declared as part of its irradiation notice, “[I]t is **not relevant whether irradiation is considered a process in determining whether retail labeling is appropriate.**”<sup>lvi</sup> Finally, in 2007 FDA proposed a major weakening to its policy regarding the labeling of foods that have been irradiated.<sup>lvii</sup> FDA proposed that labeling should only be required on those irradiated foods in which the irradiation has lead to a “material change”—defined as a “change in the organoleptic, nutritional or functional properties”—in the food that is not obvious to the consumer at the point of purchase.<sup>lviii</sup> The existence of this proposed policy refutes the notion that FDA’s original irradiation policy only referred to “organoleptic” changes to food.

Regarding FDA’s decision to require source labeling of protein hydrolysates, FDA’s 1993 notice similarly cherry-picks from the many findings it made in the course of mandating such labeling. FDA’s 1993 notice thus creates the mistaken impression that silent “organoleptic” changes were not just sufficient, but necessary for mandatory source labeling of protein hydrolysates. Yet nothing in that rulemaking even suggested, much less stated this view. To the contrary, a full reading of FDA’s justification for mandating such labeling shows that the agency

placed devout religious consumers' right to know how their food was produced at least on equal footing with the physical characteristics of the food.

When the process of genetic engineering goes unlabeled, it presents consumers with an implied representation similar to irradiation. In the absence of labeling, a person who walks into the supermarket to purchase a tomato, for example, does not have a reasonable expectation that the tomato he/she may purchase contains novel proteins never before present in food and genetic material from a flounder.

The fact that FDA has already adopted this broad interpretation of "material" facts demonstrates that it is a reasonable interpretation of section 201(n). FDA's insistence that it lacks the authority to find a production process like genetic engineering "material" is incorrect and internally inconsistent with its own stance in other instances. Refusal to take the requested actions based on such an interpretation of "material" would be arbitrary, capricious, and contrary to law: it would run counter to the evidence before the agency, and FDA's reliance on the process/product distinction is a factor that Congress did not intend FDA to consider under FDCA section 201(n).<sup>lix</sup>

### 3. *Alliance For Bio-Integrity v. Shalala* Is Inapposite And Was Wrongly Decided

FDA has, on previous occasions, pointed to the district court decision in *Alliance for Bio-Integrity v. Shalala* as support for the agency's view that it lacks the authority to mandate labeling of genetically engineered foods as a class. However, this case did not irreversibly bind the agency to its current policy<sup>lx</sup> and, in any event, was wrongly decided. Reliance on that case to maintain the status quo is therefore misguided.

Central to the *Alliance* court's decision was its determination that FDA's interpretation of "material" facts in its 1992 Policy was entitled to *Chevron* deference,<sup>lxi</sup> but this determination was legal error. As the Supreme Court has clarified, "administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make **rules carrying the force of law**, and that the agency interpretation claiming deference was promulgated in the exercise of **that authority**."<sup>lxii</sup> In *Alliance for Bio-Integrity*, FDA made no claim that its 1992 Policy was an agency rule carrying the force of law; to the contrary, it vigorously argued the opposite. Moreover, even if FDA had promulgated its 1992 Statement of Policy as a rule, it would have been procedurally invalid because it did not fully comply with the APA's notice and comment requirements for rulemaking.<sup>lxiii</sup> Thus, FDA's interpretation of "material" facts in its 1992 Policy certainly did not qualify for *Chevron* deference and the district court in *Alliance* erred in giving it deference.<sup>lxiv</sup>

*Alliance for Bio-Integrity* was also wrongly decided because both the court and the government gave FDA's 1992 Policy inconsistent legal effect, arguing **simultaneously** (not in the alternative) that it was an interpretive rule and a policy statement, depending on which legal issue was being addressed. However, interpretive rules and policy statements are two mutually exclusive agency actions, each with different procedural prerequisites and legal consequences.<sup>lxv</sup> Had the court actually decided that the 1992 Policy was one or the other, it would have had to rule the agency action invalid no matter which way it decided: either the 1992 Policy was a rule

that was promulgated without observing mandatory APA notice and comment procedures; or it was a policy guidance, and FDA’s extra-statutory definition of “material” facts was not entitled to deference.

For all of these reasons, FDA can and should jettison the wrong-headed legacy of *Alliance for Bio-Integrity* and revise its policy to mandate the labeling of GE foods.

#### **4. FDA Has Supplemental Statutory Authority Under NEPA To Base Substantive Decisions Like Mandatory Labeling On Environmental Impacts**

At least one federal court decision has held that FDA has not just the authority, but also a statutory mandate to base substantive decisions such as labeling on environmental concerns. In *Environmental Defense Fund v. Mathews*,<sup>lxvi</sup> the plaintiffs challenged FDA’s regulations implementing NEPA, arguing that FDA improperly limited the scope of its obligations under the Act. FDA had amended its implementing regulations to state that NEPA did not provide the Agency with any additional authority to act apart from authority otherwise granted in authorizing statutes, such as FFDCFA. The court disagreed, stating that “[t]his limitation of the agency’s discretion to act in accordance with environmental considerations directly contravenes the mandate of NEPA . . . .”<sup>lxvii</sup> The court then elaborated:

The FDCA does not state that the listed considerations are the only ones which the Commissioner may take into account in reaching a decision. [. . .] It merely lists criteria which the Commissioner must consider in reaching his decision. In the absence of a clear statutory provision excluding consideration of environmental factors, and in light of NEPA’s broad mandate that all environmental considerations be taken into account, **we find that NEPA provides FDA with supplementary authority to base its substantive decisions on all environmental considerations including those not expressly identified in the FDCA and FDA’s other statutes.**<sup>lxviii</sup>

Judicial recognition of the environmental impacts of GE crops underscores that the use of genetic engineering in food production falls within the scope of these “environmental considerations” that FDA must take into account when making its substantive decisions, including the decision whether to mandate labeling. Most notably, in *Monsanto v. Geertson Seed Farms*, the Supreme Court recognized several environmental and socio-economic harms stemming from genetically engineered crops, such as transgenic contamination, as cognizable harms under NEPA.<sup>lxix</sup>

#### **D. FDA Should Exercise Its Authority To Revise Its Interpretation Of “Material” Facts**

##### **1. The Patentability Of GE Foods Shows They Are Novel, Not “Substantially Equivalent” To Traditionally Produced Foods**

FDA’s labeling policy for GE foods—which it claims comports with OECD’s “substantial equivalence” concepts for biotechnology—rests partly on its long-held

misconception that GE foods do not “differ from other foods in any meaningful or uniform way.”<sup>lxx</sup> However, GE foods produced using recombinant DNA technology must differ meaningfully from their conventional counterparts because they are patentable. To be patentable, a genetically engineered food must be “new” and “novel.”<sup>lxxi</sup> Thus, a product or process that is patentable cannot be both “novel” for patent purposes yet “substantially equivalent” to existing technology in other contexts.

The U.S. Patent Office has granted many patents for novel genes and biotechnological tools used to develop genetically engineered plants. These novel genes and tools indisputably make the corresponding GE plants novel organisms. For instance, Monsanto’s Roundup Ready soybean (the world’s most widely planted GE crop) contains a patented bacterial gene<sup>lxxii</sup> joined to a DNA sequence from the cauliflower mosaic virus that together form a patented “chimeric gene.”<sup>lxxiii</sup> Introduction of this chimeric gene makes the soybean able to survive direct application of Roundup herbicide. Both the presence of this chimeric gene and the ability to survive application of Roundup are characteristics that are novel to plants. As the U.S. Patent Office concluded when issuing the patent, “[D]espite the efforts of numerous research teams, prior to this invention no one had succeeded in (1) creating a chimeric gene comprising a plant virus promoter coupled to a heterologous structural sequence and (2) demonstrating the expression of such a gene in any type of plant cell.”<sup>lxxiv</sup>

GE insect-resistant plants contain a variety of genes derived from soil bacterium known as *Bacillus thuringiensis* (Bt). Plants containing these Bt genes produce an insecticide in all their tissues that kills certain insect pests.<sup>lxxv</sup> The presence of both the Bt genes and the corresponding insecticides in plant tissues are novel plant characteristics, a fact which has enabled the crop developers to secure patents on these crops.<sup>lxxvi</sup>

Both GE foods and the recombinant DNA techniques that produce them are novel enough to be patentable, and therefore are substantially different from traditionally produced foods. Continuing to treat GE foods as novel for patenting purposes but traditional for labeling purposes is arbitrary and capricious.

## **2. FDA’s Current Definition Of “Material” Actively Facilitates The Deception That Sections 403 & 201(n) Were Intended To Prevent**

FDA is the agency that administers our nation’s only all-encompassing food labeling statute: the Federal Food, Drug, and Cosmetic Act. The purpose of FFDCFA section 201(n) is to prevent consumer deception by clarifying that a food label is misleading (and the food therefore misbranded) if, *inter alia*, it omits significant, “material” information. However, for decades FDA has been enabling widespread consumer deception by allowing the sale and marketing of foods with labels that fail to disclose facts that are determinative of consumer purchases, and are therefore “material.” Because FDA allows these facts to go unlabeled, consumers are being deceived: they believe they are purchasing something different than what they actually are.<sup>lxxvii</sup>

The absence of mandatory labeling creates an implied representation that the food was produced without the use of novel production processes like genetic engineering. That consumers find genetic engineering to be a significant fact cannot seriously be contested:

countless public opinion polls demonstrate that the vast majority of the public is at least wary of, if not actively opposed to, purchasing foods derived through genetic engineering.<sup>lxxviii</sup> Moreover, consumers **do not expect** that their foods will be the product of genetic engineering. Consequently, when consumers nonetheless unwittingly purchase unlabeled, genetically engineered food believing it to be otherwise, they are victims of economic fraud.

### 3. **A Definition Of “Material” Facts Based On What Consumers Find Significant Would Enable FDA To Combat Widespread Deception That It Has So Far Ignored**

As discussed above, FDA’s current interpretation of “material” facts only mandates the disclosure of facts that the consumer would notice with their senses<sup>lxxix</sup>—a very narrow slice of deceptive food labeling. FDA is leaving a substantial source of its statutory authority unused while consumers are left in the dark about food production processes that they find crucial to making an informed purchase. In order to fulfill its statutory mandate to prevent deceptive food labeling, FDA must adopt a broader interpretation of “material” facts that encompasses the production processes that consumers find significant. Doing so will allow FDA to prevent a much larger share of the consumer deception that exists today. Failure to fulfill this statutory mandate is arbitrary, capricious, and contrary to law.

#### E. **Consumers Have A Judicially Recognized Fundamental Right-To-Know Product Information That They Will Find Significant**

U.S. courts have recognized a “right-to-know” rooted in the U.S. Constitution and in the common law. For example, in *American Meat Institute v. Ball*, a Michigan statute required sellers to disclose meat quality standards to their customers. Meatpackers challenged the statute, arguing that it was preempted by a less stringent federal labeling law.<sup>lxxx</sup> The court agreed in part, but stated that

[C]onsumers often knowingly buy items which are not the least expensive or the most nutritious. They base their purchasing decisions on many factors, but one of these should not be ignorance imposed by government and the product manufacturers. **Michigan’s consumers have a right, protected by the First Amendment, to receive this relevant product information** which the state seeks to disseminate to them.<sup>lxxxi</sup>

The court thus recognized consumers’ right-to-know, regardless of whether that information was relevant in the judgment of regulators or producers.

*Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.* similarly stands for a consumer’s right-to-know. At issue in that case was a Virginia statute that made a pharmacist guilty of unprofessional conduct if he published, advertised, or promoted any price for prescription drugs.<sup>lxxxii</sup> The U.S. Supreme Court struck down the statute, finding that just as advertisers had a First Amendment right to disseminate advertising information, consumers had a First Amendment **right to receive** the information.<sup>lxxxiii</sup> In invalidating the statute, the Court stated, “[i]t is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.”<sup>lxxxiv</sup>

The Court continued, “people will perceive their own best interests if only they are well enough informed, and [ ] the best means to that end is to open the channels of communication rather than to close them.”<sup>lxxxv</sup> The First Amendment thus protects consumers’ right to receive relevant product information, not just producers’ right to disseminate it.

State courts have also recognized a consumer’s common law right-to-know. For example, in *Paraco v. Dept. of Agriculture*, vendors challenged a California statute that required used motor oil that had been reprocessed to be labeled as “reclaimed.”<sup>lxxxvi</sup> In upholding the labeling requirement, the court stated that members of the public “have a **right to know what they are buying**. If this great buying public, consisting in this state of many millions of motorists and other users of lubricating oils, want to buy oils never before used, they have a right to do so and **appellants have no constitutional right to sell them something else against their will**.”<sup>lxxxvii</sup> In construing this common law right, the court focused on the importance of the information to consumers, not the relative performance of “reclaimed” oil compared to unused oil.

In *Ex parte Hayes*, the government prosecuted a fruit vendor for misbranding grapefruit with the word “Coachella,” falsely implying they had been grown in the Coachella Valley.<sup>lxxxviii</sup> The court rejected the defendant’s facial challenge to the statute, stating that “the matter of mislabeling is not dependent on whether the article so marked is of the same or equal quality with the article imitated. It is entirely a question of deception and **the buyer has the right to know what he is purchasing**.”<sup>lxxxix</sup> Thus, consumers’ right-to-know was not limited to information resulting in differences in quality; it encompassed the information that consumers found significant to their purchases.

Similarly, whether the FDA believes that GE foods are “of the same or equal quality” as their conventional counterparts is irrelevant to the question of whether it is misleading to label GE foods the same as conventional foods. The proper focus is whether consumers are deceived, and whether their common law right-to-know is being abridged. In the case of unlabeled GE foods, opinion polls overwhelmingly demonstrate that whether a food contains GE material is very significant for consumer purchases.<sup>xc</sup> Moreover, consumers do not expect foods to be genetically engineered absent specific labeling. Consumers therefore have a right-to-know whether foods are genetically engineered—a right that is compromised by FDA’s current policy of allowing the marketing and sale of unlabeled GE foods.

#### **F. Internationally, Widespread Mandatory Labeling For GE Foods Shows U.S. Policy To Be An Outdated And Mistaken Outlier**

While American consumers continue to be left in the dark about whether they are consuming GE foods, more and more countries are adopting regulations requiring that GE foods be labeled, including major trading partners of the U.S.<sup>xc1</sup> For example, in 2004 the European Union enacted regulations mandating labeling for all food products making direct use of genetically modified organisms (GMOs, equivalent to GE foods) at any point in their production.<sup>xcii</sup> Australia and New Zealand also jointly require labeling for GE foods with novel DNA/novel proteins present in the final food.<sup>xciii</sup> In Japan, labeling is required when GE soy, GE corn, or GE potato is present in the final food product in amounts greater than 5%.<sup>xciv</sup> Thailand,

Taiwan, and South Korea mandate labeling for GE foods when novel DNA is present in the food.<sup>xcv</sup> China requires labeling of certain listed GE foods including soybean-derived products, corn, rapeseed- and canola-derived products, and tomatoes.<sup>xcvi</sup> Since 1999, Russia has required labeling of GE foods for which novel DNA is present in the final food.<sup>xcvii</sup> Finally, Brazil requires that all GE foods display a symbol easily understood by people with limited reading skills: a yellow triangle with a “T” for transgenic.<sup>xcviii</sup>

At the Codex Committee on Food Labeling meeting in May 2010, the United States saw evidence of the dwindling international support for its stance against GE labeling. The United States refused to sign on to guidelines unless they contained a clause stating that GE foods are not different from other foods in any way.<sup>xcix</sup> Of the 50 countries present at the committee meeting, only Argentina, Costa Rica, and Mexico supported the U.S. position.<sup>c</sup> The longer the U.S. clings to its antiquated policy on GE food labeling, the more its standing as a leader in scientific integrity will be compromised. Accordingly, FDA must join the international community in its respect for consumers’ right to choose whether to consume GE foods.

## **V. Environmental Impact**

The specific actions requested by petitioners are categorically excluded under 21 C.F.R. § 25.30(h) and therefore do not require the preparation of an environmental assessment.

## **VI. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

## **VII. Conclusion**

Genetic engineering makes silent but fundamental changes to our food at the molecular and cellular level, the full human health and environmental consequences of which are still being discovered. Unlabeled GE foods are misleading to consumers, who in the absence of labeling overwhelmingly purchase based on the reasonable assumption that their food is produced conventionally. Mandatory labeling for GE foods is necessary in order to prevent consumer deception and economic fraud.

In accordance with FDA’s governing regulations and the APA, petitioners request that FDA provide an answer to this petition within a reasonable time.<sup>ci</sup>

Respectfully submitted,

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<sup>i</sup> 21 U.S.C. § 343(a)(1).

<sup>ii</sup> “Congress shall make no law ... abridging ... the right of the people ... to petition Government for a redress of grievances.” U.S. Const. amend. I. The right to “petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights.” *United Mine Workers of Am., Dist. 12 v. Ill. State Bar Ass’n*, 389 U.S. 217, 222 (1967). It shares the “preferred place” accorded in our system of government to the First Amendment freedoms, and has “sanctity and a sanction not permitting dubious intrusions.” *Thomas v. Collins*, 323 U.S. 516, 530 (1945). “[A]ny attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtful or remotely, but by clear and present danger.” *Id.* The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. *United States v. Cruikshank*, 92 U.S. 542, 552 (1875).

<sup>iii</sup> 5 U.S.C. § 553(e).

<sup>iv</sup> 21 C.F.R. §§ 10.20, 10.30.

<sup>v</sup> 21 U.S.C. § 301 *et seq.*

<sup>vi</sup> *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>vii</sup> *See id.*; 5 U.S.C. § 706(2)(A).

<sup>viii</sup> 57 Fed. Reg. 22984 (May 29, 1992).

<sup>ix</sup> 21 U.S.C. § 301, *et seq.*

<sup>x</sup> 5 U.S.C. § 706(2)(A).

<sup>xi</sup> Food & Drug Administration, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992) (hereinafter “1992 Policy”).

<sup>xii</sup> *Id.* at 22991.

<sup>xiii</sup> Food & Drug Administration, Preliminary Analysis of Comments: FDA Statement of Policy: Food From New Plant Varieties (undated).

<sup>xiv</sup> *See* discussion, section IV.B *infra*.

<sup>xv</sup> 57 Fed. Reg. at 22991.

<sup>xvi</sup> *E.g.* Memorandum from Linda Kahl, FDA Compliance Officer, to James Maryanski, FDA Biotechnology Coordinator (Jan. 8, 1992); Memorandum from Louis Pribyl, Comments on Biotechnology Draft Document, 2/27/92 (March 6, 1992); *see also* Michael K. Hansen, “Genetic Engineering Is Not An Extension of Conventional Plant Breeding: How Genetic Engineering Differs From Conventional Breeding, Hybridization, Wide Crosses and Horizontal Gene Transfer,” p. 7, Consumer Policy Institute/Consumers Union (1999).

<sup>xvii</sup> Hansen, *supra* note 16, at 1 (noting that there are limited exceptions for species hybridization {with a wild relative within the same genus}, wide crosses {only between fairly closely related plants} and horizontal gene transfer).

<sup>xviii</sup> *Id.* at 1, 7. The Cauliflower mosaic virus promoter (CaMV35S) is used because it leads to hyperexpression of the foreign gene to which it is linked. The CaMV35S promoter effectively puts the transgene(s) outside of virtually any regulatory control by the recipient plant. *Id.*

<sup>xix</sup> Food & Drug Administration, Memorandum on the use of microorganisms and plants as whole foods (notation dated Nov. 4, 1991), *reprinted in* Normal Miller, ENVIRONMENTAL POLITICS CASEBOOK: GENETICALLY MODIFIED FOODS, at 91 (CRC Press, 2002 ed.).

<sup>xx</sup> Hansen, *supra* note 16, at 1.

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<sup>xxi</sup> Food & Drug Administration, Comments on proposed approach to unknown and unexpected toxicants (undated); *see also* Memorandum from Dr. Samuel I. Shibko to Dr. James Maryanski, FDA Biotechnology Coordinator. Subject: "Revision of Toxicology Section of the Statement of Policy: Foods Derived from Genetically Modified Plants." (January 31, 1992); Memorandum from Dr. Mitchell Smith, Head, Biological and Organic Chemistry Section, to Dr. James Maryanski, Biotechnology Coordinator. Subject: "Comments on Draft Federal Register Notice on Food Biotechnology, Dec. 12, 1991 draft." (January 8, 1992).

<sup>xxii</sup> *See, e.g.*, Memorandum from FDA Divisions of Food Chemistry & Technology and Contaminants Chemistry, to James Maryanski, FDA Biotechnology Coordinator (Nov. 1, 1991).

<sup>xxiii</sup> Food & Drug Administration Draft Appendix: Specific Considerations in the Safety Assessment of Foods and Feeds Derived from Genetically Modified Plants (Dec. 12, 1991); Jan-Peter Nap *et al.*, "Biosafety of kanamycin-resistant transgenic plants: an overview" (undated).

<sup>xxiv</sup> 21 U.S.C. § 343(a) (emphasis added); *see also* 21 U.S.C. § 321(n).

<sup>xxv</sup> 21 U.S.C. § 321 (emphasis added).

<sup>xxvi</sup> Some scientists have concluded that it would be impossible for FDA to scientifically justify a generally recognized as safe (GRAS) presumption for GE foods in the first place because currently available testing methods generally do not allow scientists to isolate suspect chemicals present in GE crops in sufficient quantities for toxicity or allergenicity testing. For example, although GE crops frequently are engineered to contain pesticidal substances, the toxicity of resulting food products is difficult to predict or detect because the products do not lend themselves to traditional methods of risk assessment. *See* I.R. Rowland, "Genetically Modified Foods, Science, Consumers and the Media," 61 Proc. Nutrition Soc'y 25, 27 (2002) (noting that toxicity assessment typically involves exposing laboratory animals to high levels of isolated chemicals, and that "complex mixtures of complex chemicals," such as novel GE foods, cannot be administered to animal subjects in this conventional manner). Similarly, because bioengineers sometimes incorporate proteins from non-food sources whose allergenic potential is presently unknown, resulting GE food products pose at least a possibility of serious allergic reactions for some consumers. *See id.* at 28 (noting that "[a]ssessing the allergenic potential of novel foods presents major problems, since there are no reliable tests for predicting allergenicity").

<sup>xxvii</sup> *See* Aris A., Leblanc S., "Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada," (Feb. 18, 2011) *available at* <http://www.sciencedirect.com/science/article/pii/S0890623811000566> (last visited May 25, 2011). In approving Bt corn, FDA had previously relied on the industry's assurances that the Bt toxin would be broken down during digestion.

<sup>xxviii</sup> *International Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 636–37 (6th Cir. 2010).

<sup>xxix</sup> *Id.*

<sup>xxx</sup> *Id.* at 637.

<sup>xxxi</sup> William Freese, "Regulating Transgenic Crops: Is the Government Up to the Task?," *BIOTECHNOLOGY* (January / February 2007), *available at* <http://www.fdpi.org/pubs/update/toc/2007/issue1.html>.

<sup>xxxii</sup> FDA, Biotechnology Consultation Agency Response Letter BNF No. 000107 (consultation letter re: MON 89034) (Aug. 8, 2007).

<sup>xxxiii</sup> *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43.

<sup>xxxiv</sup> Petitioners do not argue, nor have they ever argued, that consumer demand alone is a sufficient basis upon which to label GE foods.

<sup>xxxv</sup> *See, e.g.*, Thomson Reuters PULSE™ Healthcare Survey, "National Survey of Healthcare Consumers: Genetically Engineered Food" (93% believe GE foods should be labeled) (October 2010), *available at* [https://mail.icta.org/owa/redir.aspx?C=9106a997096b4217baad078e5acfb3ad&URL=http%3a%2f%2fwww.factsforhealthcare.com%2fpresroom%2fNPR\\_report\\_GeneticEngineeredFood.pdf](https://mail.icta.org/owa/redir.aspx?C=9106a997096b4217baad078e5acfb3ad&URL=http%3a%2f%2fwww.factsforhealthcare.com%2fpresroom%2fNPR_report_GeneticEngineeredFood.pdf); Consumers Union, "Food-Labeling Poll: 2008," p. 13 (95% of consumers believe GE foods should be labeled) (November 11, 2008), *available at* <http://www.greenerchoices.org/pdf/foodpoll2008.pdf>; MSNBC.com, "Do you believe genetically modified foods should be labeled?" (over 96% of respondents answered "Yes"), *available at* [http://health.newsvine.com/\\_question/2011/02/25/6131050-do-you-believe-genetically-modified-foods-should-be-labeled](http://health.newsvine.com/_question/2011/02/25/6131050-do-you-believe-genetically-modified-foods-should-be-labeled) (last visited June 1, 2011); THE WASHINGTON POST, "Should genetically modified food be labeled?", (94% of respondents answered "Yes, I have a right to know what I am eating"), (September 17, 2010), *available at* <http://views.washingtonpost.com/post-user-polls/2010/09/should-genetically-modified-food-be-labeled.html> (last visited June 1, 2011).

<sup>xxxvi</sup> See Wen S. Chern et al., Consumer Acceptance and Willingness To Pay for Genetically Modified Vegetable Oil and Salmon: A Multiple-Country Assessment, 5 *AgBioForum* 105, 108 (2002) (reporting survey evidence of willingness to pay price premiums for non-GM vegetable oil ranging from 50-62% for American respondents); Catherine A. Mendenhall & Robert E. Evenson, Estimates of Willingness To Pay a Premium for Non-GM Foods: A Survey, in *Market Development for Genetically Modified Foods* 55, 58 (Vittorio Santaniello et al. eds., 2002) (reporting that 50% of survey respondents stated that they were very likely or somewhat likely to purchase non-GM foods at a premium of up to 20%); Matthew Rousu et al., Are United States Consumers Tolerant of Genetically Modified Foods?, 26 *Rev. Agric. Econ.* 19 (2004) (finding reduced consumer willingness to pay for food containing genetically modified material); Ababayehu Tegene et al., The Effects of Information on Consumer Demand for Biotech Foods: Evidence from Experimental Auctions, *USDA Technical Bull. No. 1903*, at 24 (Mar. 2003) (finding that American consumers discount their willingness to pay for GM-labeled foods by up to 14% under a variety of information settings); see also Charles Noussair et al., Do Consumers Really Refuse To Buy Genetically Modified Food?, 114 *Econ. J.* 102, 112, 117-18 (2004) (reporting that 35% of French consumers are unwilling to purchase GM foods and that 42% demand a price reduction in order to be willing to purchase GM foods); Jill J. McCluskey et al., Consumer Response to Genetically Modified Food Products in Japan 18 (Wash. State Univ., Research Paper TWP-2001-101, Sept. 21, 2001) (finding that consumers in Japan are willing to pay a premium of approximately 60% for non-GM noodles and tofu), available at <http://impact.wsu.edu/research/twp/01-101.pdf>.

<sup>xxxvii</sup> Douglas A. Kaysar, Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice, 118 *Harv. L. Rev.* 525, 592 (Dec. 2004). See also, Julia Forster, “GM Foods: Why Fight Labeling?”, *BUSINESS WEEK* (Nov. 11, 2002), available at [http://www.businessweek.com/magazine/content/02\\_45/b3807061.htm](http://www.businessweek.com/magazine/content/02_45/b3807061.htm).

<sup>xxxviii</sup> Int’l Soc. & Env’tl. Accreditation & Labeling Alliance, ISEAL Members, available at [http://www.isealliance.org/organisation/full\\_members](http://www.isealliance.org/organisation/full_members) (last visited May 19, 2011).

<sup>xxxix</sup> *State Farm Mut. Auto Ins. Co.*, 463 U.S. at 43.

<sup>xl</sup> *Id.*

<sup>xli</sup> An agency may change its interpretation of a statute so long as it provides a “reasoned analysis” explaining its altered stance. *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (“An agency must be given ample latitude to adapt their rules and policies to the demands of changing circumstances.”) (quoting *Permian Basin Area Rate Cases*, 390 U.S. 747, 784, 88 S.Ct. 1344, 1368–1369 (1968)). Moreover, unlike when an agency rescinds a rule entirely, a change in agency policy such as Petitioners’ request here does not need to be justified by reasons more substantial than the reasons for adopting the existing policy in the first instance. *F.C.C. v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1810–11 (2009) (“[O]ur opinion in *State Farm* neither held nor implied that every agency action representing a policy change must be justified by reasons more substantial than those required to adopt a policy in the first instance.”) In this petition, its citations and supporting record, as well as in the docket comments that will follow, FDA will find more than sufficient analysis to support the statutorily mandated change in policy.

<sup>xlii</sup> 116 F. Supp. 2d 166 (D.D.C. 2000).

<sup>xliii</sup> 21 U.S.C. § 321(n).

<sup>xliv</sup> *Id.*

<sup>xlv</sup> S.5 [Confidential Committee Print No. 2], 75th Cong., 1st Sess., § 201(n) (July 23, 1937), reprinted in *FDA, A Legislative History of the Food, Drug, & Cosmetic Act*, Vol. 5 at 772 (1979).

<sup>xlvi</sup> See Pub. L. No. 94-278 (1976).

<sup>xlvii</sup> S.5, H.R. Conf. Rep. No. 2139, 75th Cong., 3rd Sess. 3 (April 14, 1938), reprinted in *FDA, A Legislative History of the Food, Drug & Cosmetic Act*, Vol. 6 at 302 (1979); see also S.1077, H.R. Conf. Rep. No. 1774, 75th Cong. 3d Sess. § 15 (February 8, 1938).

<sup>xlviii</sup> H.R. Conf. Rep. No. 2139 at 3 (emphasis added).

<sup>xlix</sup> See Milton Handler, “The Control of False Advertising Under The Wheeler-Lea Act,” 6 *Law & Contemp. Probs.* 91, 97–98 (1939).

<sup>l</sup> *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43.

<sup>li</sup> Food & Drug Administration, “Irradiation in the Production, Processing, and Handling of Food,” 51 *Fed. Reg.* 13376, 13388 (April 18, 1986) (hereinafter “Irradiated Foods”). FDA also stated, “in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed.” *Id.* However, FDA’s broadly worded statement regarding when information is material makes clear that it was not limited in its applicability to processed foods.

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<sup>lii</sup> Food & Drug Administration, Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28592, 28600 (June 21, 1991).

<sup>liii</sup> Food & Drug Administration, Food Labeling; Declaration of Ingredients, 58 Fed. Reg. 2850, 2867 (January 6, 1993).

<sup>liv</sup> Food & Drug Administration, Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25837 (April 28, 1993) (hereinafter “1993 notice”).

<sup>lv</sup> *Id.* at 25838.

<sup>lvi</sup> 51 Fed. Reg. at 13390.

<sup>lvii</sup> Food & Drug Administration, Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16291 (April 4, 2007).

<sup>lviii</sup> *Id.*

<sup>lix</sup> *See State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43

<sup>lx</sup> Moreover, *Alliance for Bio-Integrity* has no binding precedential effect, and would not bind another district court hearing a challenge to FDA’s refusal to change its labeling policy.

<sup>lxi</sup> *Alliance for Bio-Integrity*, 116 F. Supp. 2d. at 178–79 (“Because Congress has not spoken directly to the issue, this Court must determine whether [FDA’s] interpretation of [FFDCA] is reasonable. *See Chevron*, 467 U.S. at 864, 104 S.Ct. 2778. ... The FDA’s exclusion of consumer interest from the factors which determine whether a change is ‘material’ constitutes a reasonable interpretation of the statute. ... The FDA has already determined that, in general, rDNA modification does not ‘materially’ alter foods ... this determination is entitled to deference.”).

<sup>lxii</sup> *U.S. v. Mead Corp.*, 533 U.S. 218, 226–27, 121 S. Ct. 2164 (2001).

<sup>lxiii</sup> *See Alliance for Bio-Integrity, Defs.’ 2nd Amend. Answer* ¶ 121; 5 U.S.C. §§ 553(b), (c).

<sup>lxiv</sup> Nor did FDA’s interpretation of “material” facts warrant deference according to the less deferential, non-rulemaking *Skidmore* factors. *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S. Ct. 161 (1944) (Under this analysis, “[t]he fair measure of deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to the degree of the agency’s care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency’s position ...”). FDA did not back up its “findings” or assumptions with any data or studies; its interpretation of “material” facts was a vacillation from its prior, much broader interpretation; FDA did not observe full public notice and comment procedures; and FDA was interpreting FFDCA in the context of an entirely new production process which it had virtually no experience regulating. Finally, in light of overwhelming public concern over untested GE foods and the legislative history demonstrating the “obvious” purpose of FFDCA section 201(n), FDA’s position limiting mandatory labeling disclosures to “organoleptic” differences—a limiting term that appears nowhere in FFDCA—was anything but persuasive.

<sup>lxv</sup> *Syncor Int’l v. Shalala*, 127 F.3d 90, 93 (D.C. Cir. 1997).

<sup>lxvi</sup> 410 F. Supp. 336 (D.D.C. 1976).

<sup>lxvii</sup> *Id.* at 338.

<sup>lxviii</sup> *Id.* (emphasis added).

<sup>lxix</sup> 130 S. Ct. 2743, 2754–55 (2010).

<sup>lxx</sup> 1992 Policy, 58 Fed. Reg. at 22991, 22992.

<sup>lxxi</sup> *See* 35 U.S.C. §§ 102, 103.

<sup>lxxii</sup> Patent No. 5,633,435, issued May 27, 1997; reissued as RE39,247 (both entitled: *Glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthases*), assigned to Monsanto, issued August 22, 2006.

This is one of Monsanto’s two chief patents on Roundup Ready crops. It covers a “chimeric gene” that comprises a promoter sequence from the DNA of a cauliflower mosaic virus coupled to an unspecified gene from another organism (i.e. heterologous). All genes naturally come with promoters (on-switches) which furnish a means for the organism/cell to turn the gene on when needed to produce a protein. Genetic engineers discovered that promoter sequences from viruses were much more effective on-switches than the natural promoters in the GE context of engineering a foreign gene into a plant.

<sup>lxxiii</sup> Patent No.: 5,352,605: *Chimeric Genes for Transforming Plant Cells Using Viral Promoters*, assigned to Monsanto, issued October 4, 1994.

<sup>lxxiv</sup> Patent No. 5,633,435, issued May 27, 1997; reissued as RE39,247 (both entitled: *Glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthases*), assigned to Monsanto, issued August 22, 2006.

<sup>lxxv</sup> Patent No. 6,943,282: *Insect Resistant Plants*, assigned to Mycogen Plant Science, Inc. (a division of Dow), issued Sept. 13, 2005.

<sup>lxxvi</sup> *Id.*

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<sup>lxxvii</sup> See MERRIAM WEBSTER'S DICTIONARY, "deceive," available at <http://www.merriam-webster.com/dictionary/deceive> (last visited May 13, 2011).

<sup>lxxviii</sup> See discussion, *supra* Part IV.B & note 34.

<sup>lxxix</sup> See, e.g., 1992 Policy, 57 Fed. Reg. at 22991.

<sup>lxxx</sup> 424 F. Supp. 758 (W.D. Mich. 1976)

<sup>lxxxii</sup> *Id.* at 769 (emphasis added).

<sup>lxxxiii</sup> 425 U.S. 748 (1976).

<sup>lxxxiv</sup> *Id.* at 756–57.

<sup>lxxxv</sup> *Id.* at 770.

<sup>lxxxvi</sup> *Id.*

<sup>lxxxvii</sup> 118 Cal.App.2d 348, 257 P.2d 981 (Cal. 1953).

<sup>lxxxviii</sup> *Id.* at 353–54.

<sup>lxxxix</sup> 134 Cal.App. 312, 25 P.2d 230 (Cal. 1933).

<sup>lxxxix</sup> *Id.* at 318 (*citing* In re Bear, 216 Cal. 536, 15 P.2d 489, 490 (Cal. 1932); U.S. v. 100 Cases of Tepee Apples, 179 F. 985 (W.D. Mo. 1908)).

<sup>xc</sup> See discussion, *supra* Part IV.B & note 34.

<sup>xcii</sup> See generally Center for Food Safety, "Genetically Engineered Crops and Foods: Worldwide Regulation and Prohibition," (February 2006) available at [truefoodnow.files.wordpress.com/2010/08/world\\_regs\\_chart\\_2-2006.pdf](http://truefoodnow.files.wordpress.com/2010/08/world_regs_chart_2-2006.pdf).

<sup>xciii</sup> EU Regulation 1829/2003 & 1830/2003 (April 2004).

<sup>xciii</sup> Standard 1.5.2 – Food produced using Gene Technology, contained in AUSTRALIA-NEW ZEALAND FOOD STANDARDS CODE.

<sup>xciv</sup> See Japanese Ministry of Health, Labor & Welfare, "Foods Produced by Recombinant DNA Techniques," available at <http://www.mhlw.go.jp/english/topics/foodsafety/dna/> (last visited June 3, 2011); USDA GAIN, "Update on Japan's Biotechnology Safety Approval and Labeling Policies," report #JA3002 (Feb. 28, 2003); Organic & Non-GMO Report, "Japan's Legislation on Labeling of Genetically Engineered Foods," available at <http://www.non-gmoreport.com/articles/millennium/japanlegislationlabelinggmfoods.php> (last visited June 3, 2011).

<sup>xcv</sup> See Ruud Valyasevi *et al.*, "Current Status of Biosafety of Genetically Modified Foods in Thailand," BIOTEC, at 5 (Sept. 2003), available at [http://home.biotec.or.th/newscenter/Uploads/WE\\_pic/radF9579.pdf](http://home.biotec.or.th/newscenter/Uploads/WE_pic/radF9579.pdf); USDA GAIN, "Biotechnology Safety Assessment Guidelines for Biotech Foods," report #TW1052 (Dec. 19, 2001); USDA GAIN, "Biotechnology: A Summary of Korean Regulations on Agro-Biotechnology Products," report #KS2034 (July 31, 2002).

<sup>xcvi</sup> USDA GAIN, "People's Republic of China, Food and Agricultural Import Regulations and Standards, Ag GMO Implementation Measures," report #CH2002 (January 14, 2002); Decree No. 10, Chinese Ministry of Agriculture (January 2002), available at [www.agri.gov.cn/](http://www.agri.gov.cn/) (Chinese).

<sup>xcvii</sup> See USDA GAIN, "Russian Federation: Biotechnology: Annual Agricultural Biotechnology Report," report #RS5054, at 9 (July 15, 2005).

<sup>xcviii</sup> Brazil Law No. 11.105: Genetically Modified Organisms (March 2005).

<sup>xcix</sup> Helena Bottemiller, "U.S. Urged to Back GM Labeling Agreement," GM WATCH (May 11, 2010), available at [http://www.gmwatch.org/index.php?option=com\\_content&view=article&id=12206](http://www.gmwatch.org/index.php?option=com_content&view=article&id=12206).

<sup>c</sup> Codex Alimentarius Commission, "Report of the 38th Session of the Codex Committee on Food Labeling," ¶¶134–161 (2010), available at <http://www.codexalimentarius.net/web/archives.jsp?year=10>; see also USDA FSIS, "U.S. Delegate's Report, 38th Session, Codex Committee on Food Labelling," (June 4, 2010) available at [http://www.fsis.usda.gov/Codex/Delegate\\_Report\\_38ccfl/index.asp](http://www.fsis.usda.gov/Codex/Delegate_Report_38ccfl/index.asp).

<sup>ci</sup> 21 C.F.R. § 10.30(e)(2) ("Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition."); 5 U.S.C. § 555(b) ("[W]ithin a reasonable time, each agency shall proceed to conclude a matter presented to it."); *id.* § 706(1) (The reviewing court shall ... compel agency action unlawfully withheld or unreasonably delayed."); *id.* § 555(e) ("Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding.").