



United States Food and Drug Administration
Office of the Commissioner
Margaret A. Hamburg, M.D., Commissioner
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

November 4, 2013

Re: *Cox v. Gruma Corp.*, No. 4:12-cv-6502-YGR (N.D. Cal. filed Dec. 21, 2012)

Dear Commissioner Hamburg:

Center for Food Safety (CFS) is a nonprofit public interest organization whose mission centers on protecting and furthering the public's right to know how their food is produced, through accurate labeling and other means. On July 16, 2013, in *Cox v. Gruma Corporation*, the United States District Court for the Northern District of California formally referred¹ to the United States Food and Drug Administration (FDA) the question of whether and under what circumstances food products containing ingredients produced using genetically engineered (GE or transgenic) seed may or may not be labeled "natural" or "all natural" or "100% natural."²

CFS writes on behalf of its over 350,000 nationwide members to urge FDA to decline defining the term "natural" for use on food labels in an *ad hoc*, fact-specific, and haphazard manner, per individual court request, lacking public process and general applicability. Rather, it should address this issue by defining "natural" through the rulemaking process provided for by the Administrative Procedure Act (APA), which requires that the agency provide notice of proposed rulemaking and an opportunity for the public to comment. In the alternative, if FDA does choose to act in the context of litigation, we urge FDA to define "natural" in a way that prohibits the labeling of any food as "natural" that was produced in whole or in part through the process of genetic engineering or that contains ingredients derived from genetically engineered organisms.³

¹ Order at 3-4, ECF No. 69, *Cox v. Gruma Corp.*, No. 4:12-cv-06502-YGR (N.D. Cal. July 11, 2013).

² Collectively referred to herein as "natural."

³ Foods that have been produced in whole or in part through the process of genetic engineering or foods that contain ingredients derived from genetically engineered organisms are collectively referred to herein as "GE foods."

I. HISTORY OF “NATURAL” LABELING.

This is not the first time FDA has been asked to consider whether a particular ingredient qualifies as “natural.” In 1991, FDA solicited comments on a potential rule adopting a definition for the term “natural,” noting that the use of “natural” on food labels “[is] of considerable interest to consumers and industry.”⁴ Two years later, however, FDA declined to define “natural,” concluding that while “the ambiguity surrounding the use of this term . . . could be abated” if the term were adequately defined, the agency would have to carefully consider many facets of the issue if it undertook a rulemaking to define “natural,” which it was unwilling to do because of “resource limitations and other agency priorities.”⁵

On January 6, 1993, FDA issued a guidance document to address “natural” labeling. The guidance stated that FDA would “maintain its current policy . . . not to restrict the use of the term ‘natural’ except for added color, synthetic substances, and flavors,” and that it would “maintain its policy regarding the use of ‘natural,’ as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food.”⁶ When questions over the use of “natural” arise, as they regularly do, FDA occasionally refers to these statements. However, the agency has yet to formally issue a definition of “natural,” and has not issued a final rule to address it.

In 2002, a nonprofit organization asked FDA to take action against an ice cream producer that labeled its products “all natural.” FDA’s response was that defining “natural” was “not among the FDA’s current enforcement priorities.” Then in 2006, the Sugar Association petitioned FDA to define “natural,” and FDA likewise declined to do so. Another petition sent in 2007 by Sara Lee Corporation, a leader in the U.S. market for baked goods, claimed that a formal definition of “natural” would provide consistency for consumers and manufacturers alike. While FDA has not formally responded to the petitions, a top-ranking FDA official was quoted as saying defining natural was not a priority because the agency was “not sure how high of an issue it is for consumers.”

In 2010, a number of U.S. District Courts issued six-month stays of pending litigation over the use of “natural” on beverages containing high-fructose corn syrup (HFCS), in the hopes that FDA would formally define “natural.” For example, on June 15, 2010, Judge Simandle of the United States District Court for the District of New Jersey referred to FDA for administrative determination, the question of whether HFCS qualifies as a “natural” ingredient.⁷ Once again, FDA declined to do so.⁸

⁴ See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60466 (proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 5, 101, and 105).

⁵ See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (to be codified at 21 C.F.R. pts. 5 and 101).

⁶ *Id.*

⁷ *Coyle v. Hornell Brewing Co.*, No. 08-02797, 2010 U.S. Dist. LEXIS 59467 (D.N.J. June 15, 2010).

II. FDA SHOULD REFRAIN FROM DEFINING “NATURAL” IN REACTION TO LITIGATION, UNLESS THROUGH NOTICE-AND-COMMENT RULEMAKING.

If FDA reverses its previous decision and determines that “natural” should now be defined, it should do so only after providing a renewed notice of proposed rulemaking with sufficient opportunity for the public to provide comments. This would be in line with the APA’s requirement that agencies give notice and an opportunity for comment before issuing a final rule.⁹ “In enacting the APA, Congress made a judgment that notions of fairness and informed administrative decision-making require that agency decisions be made only after affording interested persons notice and an opportunity to comment. . . . It is antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later.”¹⁰ Agency regulations do not have the force of law until they have gone through this process and are finalized “pursuant to the statutory procedural minimum” required by the APA.¹¹

There are two exceptions to the notice and comment requirement of the APA. The first is for “interpretive rules, general statements of policy, or rules of agency organization, procedure or practice.”¹² This exception “should not be deemed to include any action which goes beyond formality and substantially affects the rights of those over whom the agency exercises authority.”¹³ Because defining “natural” does affect “the rights of those over whom the agency exercises authority,”¹⁴ it does not fall into this exception. The second is the good cause exception, “when an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”¹⁵ This exception also does not apply.¹⁶

In its initial proposal to define natural in 1991, FDA recognized its duty under the APA and provided the public with notice and an opportunity to comment. FDA itself has acknowledged that defining “natural,” without engaging in notice-and-comment rulemaking, would be contrary to the principles of transparency and public participation to which the agency is committed. For example, in its response to a previous request by a court to define natural, similar to the one at issue here, FDA explained that it would be

⁸ See Order Lifting Stay, ECF No. 119, *Coyle v. Hornell Brewing Co.*, No. 08-02797 (D.N.J. Sept. 23, 2010).

⁹ 5 U.S.C. § 553.

¹⁰ *Paulsen v. Daniels*, 413 F.3d 999, 1004-1005 (9th Cir. 2005) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979)).

¹¹ *Chrysler Corp.*, 441 U.S. at 313.

¹² 5 U.S.C. § 553(b)(A).

¹³ *Pickus v. U.S. Bd. of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974).

¹⁴ *Id.*

¹⁵ 5 U.S.C. § 553(b)(B).

¹⁶ See Substances Generally Recognized as Safe, 62 Fed. Reg. 18938 (proposed Apr. 17, 1997) (to be codified at 21 C.F.R. pts. 170, 180, 186, 570).

inappropriate to respond to the court's question in this manner without participation of the public:

[In order to] resolve whether HFCS qualifies as a “natural” ingredient in defendants’ beverages, in the absence of a pre-existing regulatory definition, the agency would expect to act in a transparent manner by engaging in a public proceeding to establish the meaning of this term. *Given the issues involved, making such a determination without adequate public participation would raise questions about the fairness of FDA’s action.*¹⁷

Here FDA should adhere to the requirements of the APA, FDA’s longstanding position on transparency, and its own past practice when attempting to define “natural,” and allow the public an opportunity to comment on such an important matter of public health.

III. IN THE ALTERNATIVE, FDA SHOULD DEFINE “NATURAL” IN A WAY THAT PROHIBITS THE LABELING OF ANY GE FOODS AS “NATURAL.”

A. Products of Genetic Engineering are Not Natural.

If FDA determines that defining “natural” is appropriate in the context of the *Cox v. Gruma Corporation* litigation, it must specifically exclude GE foods as “natural.” Labeling GE foods with the word “natural” is exceptionally misleading to consumers. Most consumers, if asked, would *not* consider GE foods as natural, under the generally recognized meaning of the term. Black’s Law Dictionary defines “natural” as something that is “[i]n accord with the regular course of things in the universe and without accidental or purposeful interference” or “[b]rought about by nature as opposed to artificial means.”¹⁸ Foods that have been genetically engineered do not fit within either of these definitions.

Genetic engineering, in contrast to “natural” processes, normally involves the insertion of foreign (often bacterial) genetic material into a food plant or crop, followed by selection. Gene insertion occurs by *artificial* means—through a gene “gun,” a bacterial vector, or chemical or electrical treatment—without regard for natural species boundaries. Biotechnicians may 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.¹⁹

¹⁷ Order Lifting Stay, *supra* note 8.

¹⁸ *Black’s Law Dictionary* 1126 (9th ed. 2009).

¹⁹ 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* 1, 7, Consumer Policy Institute/Consumers Union (2000). The cauliflower mosaic virus

Scientists may even insert custom-designed genes that have no counterpart in nature.²⁰ 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.”²¹

As the name itself also affirms, there is nothing “natural” about *genetically engineered* organisms. Review of the Monsanto Company’s definition of genetically modified organisms (GMOs) confirms their decidedly *unnatural* nature. It defines GMOs as “[p]lants or animals that have had their genetic makeup altered to exhibit traits *that are not naturally theirs*. In general, genes are taken (copied) from one organism that shows a desired trait and transferred into the genetic code of another organism.”²² The World Health Organization defines genetically engineered organisms as “organisms in which the genetic material (DNA) has been altered in a way that *does not occur naturally*.”²³

On FDA’s website, its response to the frequently asked question, “what is the meaning of ‘natural’ on a label of food,”²⁴ is that “[f]rom a food science perspective, it is difficult to define a food product that is ‘natural’ because the food has probably been processed and is *no longer the product of the earth*. . . . However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.”²⁵

Not only are GE foods unnatural, they are the products of a radical new technology that raises greater food safety concerns than time-tested traditional breeding practices. According to FDA scientist Linda Kahl, “The processes of GE and traditional breeding are different, and. . . they lead to different risks.”²⁶

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.*

²⁰ *Id.* at 1.

²¹ U.S. Food & Drug Admin., Comments on proposed approach to unknown and unexpected toxicants (undated) (on file with author) (emphasis added); *see also* Memorandum from Dr. Samuel I. Shibko to Dr. James Maryanski, FDA Biotechnology Coordinator (January 31, 1992); Memorandum from Dr. Mitchell Smith, Head, Biological and Organic Chemistry Section, to Dr. James Maryanski, Biotechnology Coordinator (Jan. 8, 1992).

²² Monsanto, *Glossary*, <http://www.monsanto.com/newsviews/Pages/glossary.aspx#gmo> (last visited Oct. 29, 2013) (emphasis added).

²³ World Health Org. (WHO), *20 questions on genetically modified foods*, <http://www.who.int/foodsafety/publications/biotech/20questions/en/> (last visited Oct. 29, 2013) (emphasis added).

²⁴ U.S. Food & Drug Admin., *What is the meaning of 'natural' on the label of food?*, <http://www.fda.gov/aboutfda/transparency/basics/ucm214868.htm> (last visited Oct. 30, 2013).

²⁵ *Id.* (emphasis added).

²⁶ Comments from Dr. Linda Kahl, FDA Compliance Officer, to Dr. James Maryanski, FDA Biotechnology Coordinator, Regarding “Statement of Policy: Foods from Genetically Modified Plants” (Jan. 8, 1992).

Because GE foods lack a history of safe use, scientific testing is needed to assess them. The most widely discussed risk is food allergies.²⁷ Most GE foods are engineered to contain novel transgenic proteins that either have never been part of the human diet, or are new to the food in question. Allergies occur when one's immune system inappropriately attacks a food protein. Allergic reactions range in severity from mild respiratory distress to life-threatening anaphylactic shock. The number of allergy-related episodes in the U.S. doubled from 1997 to 2002, when GE crops were being introduced. Food allergies, which account for more than 30,000 emergency room visits each year, impact 11 million Americans, including 3 million children.²⁸

As one example, development of soybeans engineered to produce a Brazil nut protein was abandoned after testing revealed that the protein was allergenic; people with tree nut allergies who consumed foods containing derivatives of these soybeans would likely have suffered allergic reactions.²⁹ While these GE soybeans never came to market, GE corn may be causing food allergies today, unbeknownst to allergy sufferers. Most U.S. corn is genetically engineered to produce insecticidal proteins derived from the soil bacterium *Bacillus thuringiensis* (*Bt*).³⁰ Scientists advising the Environmental Protection Agency (EPA) have found that these *Bt* proteins “could act as antigenic and allergenic sources.”³¹ Hundreds of allergic reactions reported in 2000 and 2001 may have been caused by exposure to GE StarLink corn.³² In 2009, EPA funded research to develop better methods to assess the food allergy risks posed by GE crops, in particular the pesticidal corn varieties discussed above that the agency has been approving since the mid-1990s.³³

²⁷ For two of dozens of scientific reports on this issue, see, Food and Agric. Org. of the United Nations (FAO-WHO), *Evaluation of Allergenicity of Genetically Modified Foods: Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology* (Jan. 22-25, 2001), <ftp://ftp.fao.org/es/esn/food/allergygm.pdf> (last visited Oct. 30, 2013); Kleter, GA and Peijnenburg, Ad ACM, *Screening of transgenic proteins expressed in transgenic food crops for the presence of short amino acid sequences identical to potential, IgE-binding linear epitopes of allergens*, 2 BMC STRUCTURAL BIO. 8 (2002), available at <http://www.biomedcentral.com/1472-6807/2/8>.

²⁸ Press Release, U.S. Env'tl. Prot. Agency, *EPA Grant to University of Chicago for Research on Food Allergy Triggers* (July 23, 2009), available at <http://yosemite.epa.gov/opa/admpress.nsf/bd4379a92ceceac8525735900400c27/ed584ff1c2e1162a852575fc00536790!OpenDocument>.

²⁹ Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 11 NEW ENG. J. MED. 334, 688-692 (Mar. 14, 1996).

³⁰ In 2013, 76% of U.S. corn (74 million acres) contained insecticidal toxins. See U.S. Dept. of Ag., “Acreage” report 1, 25 (June 28, 2013), available at <http://usda01.library.cornell.edu/usda/current/Acre/Acre-06-28-2013.pdf>.

³¹ U.S. Env'tl. Prot. Agency Scientific Advisory Panel, *Bt Plant-Pesticides Risk and Benefits Assessments* 76, Report No. 2000-07 (FIFRA Scientific Advisory Panel Meeting, Oct. 18-20, 2000), available at <http://www.epa.gov/scipoly/sap/meetings/2000/october/octoberfinal.pdf>.

³² William Freese, *The StarLink Affair*, Friends of the Earth (2001); see also U.S. Env'tl. Prot. Agency Scientific Advisory Panel, *Assessment of Additional Scientific Information Concerning StarLink Corn*, Report No. 2001-09, available at <http://www.epa.gov/scipoly/sap/meetings/2001/july/julyfinal.pdf>.

³³ See Press Release, *supra* note 28.

GE organisms have likely had other adverse impacts. FDA scientists have warned that GE organisms could have “increased levels of known naturally occurring [plant] toxicants,” “new, not previously identified toxicants,” and “reduced levels of nutrients,” among other adverse alterations.³⁴ For instance, GE bacteria used to produce tryptophan, a sleeping aid, are the likely culprit in an outbreak of deadly eosinophilia myalgia syndrome, which killed dozens and injured thousands in the late 1980s and early 1990s.³⁵ Experimental GE yeast intended for use in food processing was unexpectedly found to contain high levels of the extremely toxic and mutagenic compound methylglyoxyl.³⁶ Unexpected changes found in GE plants include necrotic lesions in wheat and increased levels of toxic glycoalkaloids in potatoes.³⁷ Rats fed for two years (lifetime study) with GE corn had a higher incidence of tumors than rats fed conventional corn.³⁸ Scientists also caution that the use of antibiotic resistance marker genes in some genetically engineered crops may exacerbate the serious problem of antibiotic-resistant bacteria.³⁹ Because GE products are mixed indiscriminately with “natural” ones, however, GE food labeling and a system of post-marketing surveillance⁴⁰ would be required to definitively prove human health harms from GE foods.⁴¹

In view of these risks, FDA scientists in the early 1990s recommended that each new GE food be tested using genotoxicity assays and animal feeding trials.⁴² Others have advocated a similar testing regime,⁴³ while European food safety experts urge use of sophisticated profiling techniques capable of detecting novel toxins.⁴⁴ These recommendations of FDA working scientists and others have been entirely ignored by FDA administrators, who crafted the “voluntary consultation” process that prevails today.

³⁴ See, e.g., Memorandum from FDA Divisions of Food Chemistry & Technology and Contaminants Chemistry, to James Maryanski, FDA Biotechnology Coordinator (Nov. 1, 1991).

³⁵ EM Kilbourne et al., *Tryptophan Produced by Showa Denko and Epidemic Eosinophilia-Myalgia Syndrome*, 46 J. RHEUMATOL SUPPL. 81-88 (1996); David Schubert, *A Different Perspective on GM Foods*, 20 NATURE BIOTECHNOLOGY 969 (2002).

³⁶ Tomoko Inose & Kousaku Murata, *Enhanced accumulation of toxic compound in yeast cells having high glycolytic activity: A case study on the safety of genetically engineered yeast*, 30 INTL. J. FOOD SCI. TECH. 30, 141-146 (1995).

³⁷ See Harry A. Kuiper et al., *Assessment of the Food Safety Issues Related to Genetically Modified Foods*, 27 THE PLANT J. 503-528; FAO-WHO, *supra* note 27.

³⁸ Gilles-Eric Séralini et al., *Long Term Toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize*, 50 FOOD CHEM. TOXICOL. 4221-31 (2012).

³⁹ U.S. Food & Drug Admin., 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*, 1 TRANSGENIC RESEARCH 239, 239-249 (1992).

⁴⁰ Kuiper, *supra* note 37.

⁴¹ Consumers International, *Consumer Rights Victory as US Ends Opposition to GM Labeling Guidelines*, (July 5, 2011), available at <http://www.consumersinternational.org/news-and-media/news/2011/07/gm-labelling-victory-as-us-ends-opposition#.Uk90phZXaa4>.

⁴² Memorandum from Samuel I. Shibko, Director, FDA Division of Toxicological Review and Evaluation, to James Maryanski, FDA Biotechnology Coordinator (Jan. 31, 1992); Memorandum from FDA Divisions of Food Chemistry & Technology and Contaminants Chemistry, to James Maryanski, FDA Biotechnology Coordinator (Nov. 1, 1991).

⁴³ William Freese & David Schubert, *Safety Testing and Regulation of Genetically Engineered Foods*, 21 BIOTECH. AND GENETIC ENGINEERING REVIEWS 299-324 (Nov. 2004).

⁴⁴ Kuiper, *supra* note 37.

Companies that develop GE crops are not required to consult with FDA or to conduct any specific tests. If they choose to consult FDA, the agency does not respond by approving the crop as safe, but rather issues a “no questions” letter that makes the company (not FDA) responsible for the safety of the GE food.⁴⁵

Long-standing, time-tested procedures used to vet traditionally-bred, “natural” crops have been for the most part successful in safeguarding the food supply. The same cannot be said of GE foods, which pose greater food safety risks but are not adequately assessed by food safety authorities.

B. The Patentability of GE Foods Shows They Are Not Natural.

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.”⁴⁶ 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 GE 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 gene⁴⁷ joined to a DNA sequence from the cauliflower mosaic virus that together form a patented “chimeric gene.”⁴⁸ Introduction of this chimeric gene makes the soybean able to survive direct application of glyphosate, the active ingredient in Monsanto’s Roundup herbicide. Both the presence of this chimeric gene and the ability to survive application of Roundup are characteristics that are novel to plants. Monsanto’s patent application for “chimeric genes” states that “despite 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 heterologous⁴⁹

⁴⁵ William Freese, *Regulating Transgenic Crops: Is Government up to the Task?*, 1 FOOD AND DRUG LAW INST. 14-17 (Jan.-Feb. 2007), available at http://www.centerforfoodsafety.org/files/fdli-paper--jan-feb-2007_31582.pdf.

⁴⁶ See 35 U.S.C. §§ 102, 103.

⁴⁷ U.S. Patent No. 5,633,435 (issued May 27, 1997); *reissued as* U.S. RE39,247 (issued Aug. 22, 2006) (both entitled *Glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthases* and assigned to Monsanto).

⁴⁸ U.S. Patent No. 5,352,605 (issued October 4, 1994) (*Chimeric Genes for Transforming Plant Cells Using Viral Promoters* and assigned to Monsanto). The key feature of this patent is the cauliflower mosaic virus promoter. 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. However, genetic engineers discovered that promoter sequences from viruses were much more effective on-switches than the natural promoters in the transgenic context of engineering a foreign gene into a plant.

⁴⁹ In this context, “heterologous” means that the plant virus promoter is linked to a gene derived from a different species, *i.e.* not the cauliflower mosaic virus.

structural sequence and (2) demonstrating the expression of such a gene in any type of plant cell.”⁵⁰

GE insect-resistant plants contain a variety of genes derived from the *Bt* soil bacterium. Plants containing these *Bt* genes produce one or more insecticides in all of their tissues that kill certain insect pests.⁵¹ The presence of both the *Bt* genes and the corresponding insecticides in plant tissues are novel plant characteristics, a fact that has enabled the crop developers to secure patents on these crops.⁵²

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. Accordingly, continuing to treat GE foods as novel for patenting purposes but “natural” for labeling purposes would be arbitrary and capricious.

C. Allowing Products Labeled as “Natural” to Contain GE Foods is Misleading to Consumers.

Labeling GE foods as “natural” misleads consumers. A reasonable consumer would not expect foods labeled “natural” to contain novel “[p]lants or animals that have had their genetic makeup altered to exhibit traits *that are not naturally theirs.*”⁵³ Rather, the label “natural” connotes foods from plants and animals that have only their natural complement of traits, not entirely new ones never before exhibited by the species, such as the ability to produce bacterial insecticides or survive spraying with a powerful herbicide. Moreover, there is no way for consumers to detect whether or not a product contains GE foods from a visual inspection alone. Consumers are misled when foods with highly unnatural characteristics such as these are labeled as natural.

The proliferation of voluntary labeling claims demonstrates that many consumers base their purchases on what they are able to find out about how a food was produced. For example, 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. The prevalence and success of these voluntary claims for labeling demonstrate that facts about how food is produced and what is in, or is *not* in, the food are significant factors in consumer purchasing decisions. Accordingly, when food companies label GE foods as “natural,” consumers are deceived.

Moreover, the uncertainty surrounding GE foods is a difference that is determinative of consumer purchases. Studies have indicated that consumers, particularly Americans, are willing to pay substantial price premiums in order to avoid

⁵⁰ U.S. Patent No. 5,633,435, *supra* note 47.

⁵¹ U.S. Patent No. 6,943,282 (issued Sept. 13, 2005) (entitled *Insect Resistant Plants* and assigned to Mycogen Plant Science, Inc. (a division of Dow)).

⁵² *Id.*

⁵³ *See Monsanto, supra* note 22 (emphasis added).

GE foods.⁵⁴ Because most consumers would not expect foods labeled as “natural” to contain any GE content, consumers are deceived into paying premiums for “natural” foods that do not possess the qualities for which they are paying the premium. Given the wide reach of consumer concerns over GE foods, and the deceptive nature of foods labeled “natural” that have ingredients derived from GE organisms, the proper response for FDA should be to prohibit GE foods from being labeled as “natural.”

IV. CONCLUSION

FDA should reject the Court’s request to define “natural” for use on food labeling. 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. These changes fundamentally affect consumers, food manufacturers, and the public at large. Because of this and the growing consumer concern over GE foods, FDA should refrain from defining “natural” in an *ad hoc* and haphazard manner without engaging in APA rulemaking that provides to the public notice of the proposed rulemaking and an opportunity to comment on these important issues. In the alternative, if FDA considers it appropriate to define natural without issuing a rule, then it should specifically prohibit labeling GE foods as “natural.”

Respectfully submitted on this day of November 4, 2013,



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⁵⁴ 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*, (USA 2002); 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); Abeyayehu 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](http://impact.wsu.edu/research/twp/01-101.pdf) (last visited Oct. 30, 2013).