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FDA's Troubling Failures to Use Its Authority to Regulate Genetically Modified Foods

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INTRODUCTION

Many people—including consumers, politicians, and, increasingly, scientists—have been expressing growing concern about the environmental and health effects of certain genetically modified ("GM") crops and foods containing them.[1] Although many GM crops are engineered to resist herbicides and thus to permit more limited and targeted herbicide use, agricultural practices with GM crops are instead shifting towards significantly higher use of herbicides in part because of the increase in weeds' herbicide resistance.[2] The International Agency for Research on Cancer has recently classified the herbicides that farmers widely use with GM crops as "probable" or "possible" carcinogens,[3] while the National Academy of Sciences has convened a committee to assess the environmental and health effects of GM crops.[4] This is a critical issue for food production in the U.S., because over 90% of the soy and corn grown in this country are genetically modified.

The Food & Drug Administration ("FDA") is the federal agency responsible for regulating food safety in the United States. At present, it construes its authority to regulate GM foods as limited and primarily assesses their direct effects on the bodies of those who consume them. Even with respect to such direct health and safety effects, FDA has exercised its authority lightly, regarding GM foods as generally safe and thus subjecting them to minimal scrutiny.

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[1] Philip J. Landrigan & Charles Benbrook, *Perspective: GMOs, Herbicides, and Public Health*, 373 NEW ENG. J. MED. 693, 695 (2015).

[2] *E.g.*, Jane Qiu, *Genetically Modified Crops Pass Benefits to Weeds*, NATURE (Aug. 16, 2013), http://perma.cc/5G3T-UHFC.

[3] Dana Loomis et al., *Carcinogenicity of lindane, DDT, and 2,4-dichlorophenoxyacetic acid*, 16 LANCET ONCOLOGY 8, 891-92 (2015).

[4] *Genetically Engineered Crops: Past Experience and Future Prospects*, NAT'L ACADS. OF SCIS., ENGINEERING & MED., perma.cc/U44L-BW82 (last visited Jan. 17, 2015).

This constrained regulatory approach rests on multiple mistakes, or so we argue in this Article. First, FDA's limited premarket scrutiny of all GM foods is scientifically problematic. Second, FDA takes an unjustifiably narrow view of the scope of risks that it is statutorily authorized to consider in determining whether novel foods may be marketed to consumers. Finally, and in light of these first two deficiencies, FDA and the only federal district court to consider the question have developed an unjustifiably restrictive understanding regarding what kind of information about foods is "material" and thus required in food labels.

Of course, it is important to begin with a definition of "GM foods." As we use the term in this Article, "GM" refers to foods created through recombinant DNA technologies (rDNA), not through traditional husbandry techniques such as plant grafting (as used in hybrid tea roses) or careful seed selection (as with the purification of strains of heirloom tomatoes). GM and traditional husbandry have much in common in the effort to produce selected types of organisms, and nothing in this Article depends on GM crops being different in kind from crops developed through more traditional husbandry practices. To the contrary, both approaches can produce new crops that raise environmental or health concerns—although the introduction of such concerning traits into traditional crops, such as the ability of corn to produce its own pesticide, is likely to be more intentional in GM crops. Our argument here addresses FDA's failure to devote sufficient attention to the many factors that can affect the safety of GM foods. We do not mean to preclude whether similar arguments might be made for non-GM foods as well.

GM foods have many different purposes. Some increase the nutritional content of foods, such as the "golden rice" designed to address dietary deficiencies, a winner of the 2015 Patents for Humanity Award.[5] Others attempt to modify nutritional characteristics, such as the creation of potatoes with altered starch content that may absorb oil differently.[6] Still others create crops resistant to pests[7] or to weed killers such as RoundUp™[8] or to adverse growing conditions such as drought.[9] Still others have been arguably imaginative but ultimately unsuccessful efforts to improve products, such as the effort to create FLAVRSAVR™ tomatoes[10] that would ripen without turning soft.

GM crops in use today thus pursue many different benefits.[11] Some GM crops may counter critical nutritional deficiencies while others may permit cultivation under otherwise unfavorable growing conditions, a development that may become

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[5] GOLDEN RICE PROJECT, perma.cc/PZ89-A6NT (last visited Aug. 26, 2015).

[6] Genetically Engineered Modification of Potato to Form amylopectin-type Starch, EP 0563189 A1, perma.cc/EA2Q-UHUH (last visited Aug. 26, 2015); *Potatoes*, GMO COMPASS, perma.cc/ZE6B-WTJ9 (last visited Aug. 26, 2015)

[7] ECONS. RES. SERV., U.S. DEPT. OF AGRIC., AGRICULTURAL ECONOMIC REPORT NO. 786, GENETICALLY ENGINEERED CROPS FOR PEST MANAGEMENT IN U.S. AGRICULTURE (2000), http://www.ers.usda.gov/media/323484/aer786_1_.pdf.

[8] MONSANTO, *Alfalfa*, http://www.monsanto.com/products/Pages/alfalfa.aspx (last visited Aug. 26, 2015).

[9] Jason Lusk & Henry I. Miller, *We Need G.M.O Wheat*, N.Y. TIMES Feb. 2, 2014, at A23.

[10] G. Bruening & J.M. Lyon, *The Case of the FLAVR SAVR Tomato*, 54 AGRIC. CAL. AGRIC. 4 (July-Aug. 2000).

[11] Margaret Rosso Grossman, *Genetic Technology and Food Security*, 62 AM. J. COMP. L. 273, 280-2 (2014).

increasingly important as climate change alters weather patterns. Other GM crops may respond to supposed consumer tastes or aesthetic preferences or serve commercial needs of growers to produce food as cheaply as possible. These benefits arguably vary considerably in desirability, both in terms of safety and in terms of ethics, and any assessment of the benefits and risks of GM foods must take these differences into account. Thus, from the perspective of their benefits, GM foods are not all created alike, and a "one size fits all" approach to regulating GM foods is consequently inappropriate.

The possible risks of GM foods vary in important respects as well. Some GM foods may prove to be less or differently nutritious than consumers expect. Some may introduce unexpected allergic reactions in persons who consume them, while others may contradict the ethical or religious beliefs of consumers. Still others may have direct environmental effects as they interact with wild-type species, while some GM crops may encourage or require agricultural practices with different environmental or health risks to producers or consumers. Here, too, not all GM foods are created alike. Again, any assessment of GM regulation must take these differences in risks and benefits into account.

In the U.S. at least, the vast majority of some major crops are now genetically engineered. The U.S. Department of Agriculture estimates that about 90% of soy grown in the U.S. is genetically engineered; cotton and corn crops are also largely genetically engineered.[12] Other crops with significant genetic engineering representation include sugar beets,[13] rapeseed (canola), and potatoes.[14]

This Article concerns the particular regulatory responsibilities only of FDA. It sets to one side the possible regulatory authority of agencies such as the Environmental Protection Agency ("EPA") or the U.S. Department of Agriculture ("USDA"). This approach risks replicating the regulatory fracture introduced during the Reagan Administration and criticized by some scholars,[15] but there is a great deal to say about current FDA practices. Out of similar considerations of space and focus, this Article also sets to one side many other important issues that surround GM foods: intellectual property rights; rights to free speech or commercial speech; fair trade practice law and unfair competition law; warranty law; and the panoply of state and federal consumer product safety and consumer protection statutes, among others.

We should also note at the outset one further limit of the scope of this article. Our aim is to show that FDA has construed its authority too narrowly. As we discuss below, this includes FDA's understanding of its authority to prescribe the content of food labels. We do not propose a particular form that labels should take, including whether all GM foods should be labeled as such. Rather, our argument is that given the current

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[12] ECONS. RES. SERV., U.S. DEPT. OF AGRIC., RECENT TRENDS IN GE ADOPTION (2013), *available at* http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx.

[13] BETANEWS, *Top 10 Genetically Engineered Crops* (Dec. 12, 2012), perma.cc/4YBD-256T.

[14] Emilie Sennebogen & Gallagher Flinn, *10 Common Genetically Modified Foods*, HOWSTUFFWORKS.COM (Aug. 17, 2009), perma.cc/U9F9-2ZGS.

[15] *E.g.*, Douglas Kysar, *Preferences for Processes: The Process/Product Distinction and Consumer Choice*, 118 HARV. L. REV. 525, 590 (2004). Kysar points out that as a result of this "parceling out" of regulatory responsibilities, individual federal agencies may have less complete pictures of regulatory issues than well-informed consumers.

state of FDA oversight and the importance of transparency to consumers, examination of the labeling issue is within FDA's purview.

In what follows, we argue that FDA is misconstruing the limits of its regulatory authority over GM foods in three important ways. First, it has been too deferential in the scientific scrutiny required for pre-market approval of new GM crops. Second, it delineates risks in an unjustifiably constricted manner in construing the extent of its regulatory authority. Finally, and relatedly, it construes its authority to require labeling of GM foods too narrowly, thus potentially depriving consumers of the opportunity to make choices that may be important to them. We begin with FDA's scientific scrutiny of GM crops.

I. FDA'S SCIENTIFIC ASSESSMENT OF GM FOODS

FDA's statutory authority to regulate food safety extends back over a century. More recently, however, regulation of drugs and devices has consumed far more of FDA's attention and activity than regulation of food. Scholarly attention to FDA has been increasingly pharmaceutical-centric as well. To take one illustration, a major symposium devoted to FDA in the 21st century featured only one panel devoted to food (which included dietary supplements and tobacco),[16] and the volume published from the conference was limited to FDA's authority over drugs and devices.[17] Part of the explanation may be that FDA charges fees for the drug and device approval process and with federal budgetary constrictions, the portion of FDA's budget devoted to food has contracted.[18] The statutory standards provided for FDA food regulation are different, as well. In this section, we set out those standards and explain how they have not been utilized to their fullest extent in the regulation of the safety of GM foods.

A. FDA's Statutory Authority to Regulate Food Safety

The federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"),[19] as subsequently amended, supplanted the original Pure Food and Drug Act of 1906.[20] The FDCA has been amended many times over the years since it was enacted. Of particular relevance for our discussion here are the Food Additives Amendment of 1958,[21] the Nutritional

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[16] *See* PETRIE-FLOM CTR., *The Food and Drug Administration in the 21st Century: The 2013 Petrie-Flom Center Annual Conference*, perma.cc/PE5Y-MK6D. In the spirit of full disclosure, an earlier version of this article was presented at that conference.

[17] Correspondence from Holly Fernandez Lynch (on file with the authors).

[18] Peter Barton Hutt, Speech at the 2013 Petrie-Flom Center Annual Conference: The Food and Drug Administration in the 21st Century, Historical Themes and Developments over the Past 50 Years (May 3, 2013), *available at* https://vimeo.com/66653244.

[19] 21 U.S.C. §§ 321-399d (2006). The Act's food provisions are in Subchapter IV, 21 U.S.C. §§ 341-350l-1 (2006).

[20] Pure Food and Drug Act (1906). *United States Statutes at Large* (59th Cong., Sess. I, Chp. 3915, p. 768-772; cited as 34 U.S. Stats. 768), *available at* http://legisworks.org/sal/34/stats/STATUTE-34-Pg768.pdf.

[21] Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified as amended in 21 U.S.C. § 348 (2015)).

Labeling and Education Act (NELA) of 1990,[22] and the Food Safety Modernization Act (FSMA) of 2011.[23]

The FDCA gives FDA responsibility to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled."[24] Under this statute, "food" is "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[25] The original goals of the FDCA, still core today, were prevention of adulteration or misbranding of food.[26]

A food is adulterated if it contains poisonous or unsanitary ingredients, if valuable constituents have been removed or substituted, if it bears or contains an unsafe color additive, if it is a confection that contains alcohol or a non-nutritive substance, if it is oleomargarine that contains filthy or putrid matter, if it is an unsafe dietary supplement or a dietary supplement that contains unsafe ingredients, if it is a dietary supplement not manufactured through best practices, if it is an imported food that has previously been denied admission into the United States, or if it is transported under conditions that violate FDA's regulations.[27] FDA may recall any article of food if there is a "reasonable probability" that it is adulterated.[28]

B. Food Additives and the Generally Recognized as Safe (GRAS) Process.

Concerns about the safety of food additives such as dyes led Congress to enact the Food Additives Amendment Act (FAAA) in 1958. According to the FAAA, a food additive is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food . . . ."[29] Under the statute, pesticides used on raw agricultural products are specifically excluded as food additives, but herbicides are not.[30]

The FAAA requires that additives be determined to be safe before they can be marketed. Anyone interested in marketing an additive may petition FDA for pre-market approval. Petitioners must present all relevant safety data with regard to the product's intended use—both pro and con—to FDA.[31] An interdisciplinary team in FDA reviews this information, calling on supplementary expertise as necessary. If the

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[22] Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

[23] FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

[24] 21 U.S.C. § 393(b)(2) (2015). Accurate labeling requirements date from the initial Pure Food and Drug Act, enacted in 1906.

[25] 21 U.S.C. § 321(f) (2009).

[26] 21 U.S.C. § 331(a) (2013).

[27] 21 U.S.C. §§ 342(a)-(i) (2005).

[28] 21 U.S.C. § 350(a) (2011).

[29] 21 U.S.C. § 321(2)(s).

[30] *Id.*

[31] 21 C.F.R. § 171.1 (2016); *see also* Alan M. Rulis & Joseph A. Levitt, *FDA's Food Ingredient Approval Process Safety Assurance Based On Scientific Assessment*, REG. PHARMACOLOGY & TOXICOLOGY, at 2, perma.cc/2RR4-N6D8 (2008).

product is determined to be safe on a "fair evaluation" of the data, marketing approval is granted.[32] Factors enumerated in the statute for consideration in the safety determination include but are not limited to probable consumption, cumulative effects, and evidence considered relevant by experts; offsetting benefits are not on this list.[33]

Notice of FDA's proposed action with respect to a food additive is published in the Federal Register with an opportunity for public comment; approvals are published in the Federal Register as final rules with information about the technical basis for FDA's decision and responses to public comments.[34] Thus, pre-market clearance for a new additive is subject to the opportunity for public scrutiny associated with the notice and comment rulemaking process, together with the possibility of challenging FDA's action in court as failing to have a rational basis in the record.[35]

Many food additives—from oils to salts—have been used for millennia, however. In recognition of this reality, the FAAA created a method whereby these traditional additives could continue in use. These provisions reverse the burden of proving safety for any additive in common use and for any additive that experts generally recognize as safe (GRAS). Additives can qualify as GRAS if they were in common use before 1958 or if their safety is generally recognized in the expert community.[36] In creating this GRAS exception, Congress was responding to the contention that it would be unnecessarily burdensome to enter the full notice-and-comment rulemaking process for food additives that had been in use literally for thousands of years.[37] However, it is a considerable leap from the judgment that an additive that has been used across times and cultures—say, vinegar or yeast—is safe to the judgment that there is a consensus of expert opinion regarding the safety of a newly created type of additive, such as genetic modifications.

GRAS processes have evolved over the years away from the notice-and-comment approval, with far fewer additives *not* being considered GRAS.[38] At present, there are six subtypes of GRAS additives, determined by different procedures: common food ingredients in use before 1958 (such as salt, MSG, or baking powder); additives self-determined by manufacturers to be GRAS; expert-panel-determined GRAS substances; FDA-listed GRAS substances; FDA-affirmed GRAS substances; and substances covered by FDA GRAS notifications.[39] Very few established expert panels are in use. The FDA list process was discontinued in 1973, although additives on the

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[32] 21 U.S.C. § 348(c)(3) (2015).

[33] § 348(c)(5); 21 C.F.R §170.3(i) (2013). In this respect—i.e., in considering risks only—the food additive evaluation differs from the pharmaceutical risk/benefit analysis. Rulis & Leavitt, *supra* note 31, at 3.

[34] For a complete description of the process, see Thomas G. Neltner et al.,

Navigating the U.S. Food Additive Regulatory Program, 10 COMPREHENSIVE REVS. IN FOOD SCI. & FOOD SAFETY 6, 342-68 (2011), http://onlinelibrary.wiley.com/doi/10.1111/j.1541-4337.2011.00166.x/pdf.

[35] *E.g.*, Certified Color Manufacturers Association v. Mathews, 543 F.2d 284 (D.C. Cir. 1976) (upholding the FDA's decision under the Color Additives Act to delist Red Dye no. 2).

[36] 21 C.F.R. § 170.3. (2016).

[37] Rulis & Levitt, *supra* note 31, at 2 and accompanying text.

[38] FDA's Approach to the GRAS Provision: A History of Processes, FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/ucm094040.htm.

[39] Neltner et al., *supra* note 34, at 343-51.

list continue to be considered GRAS and may be de-listed if questions are raised about their safety.

As a result, manufacturer self-determinations and FDA determinations dominate the GRAS status processes, with both processes warranting improvement. Manufacturers submitting self-determinations of GRAS status should follow FDA guidance,[40] but this is not a legal requirement and manufacturers are not required to inform FDA of their GRAS decisions or the process by which they reached those decisions.[41] The FDA process for affirmation petitions has resulted in a number of additives being determined to be GRAS. However, the agency employed the notice-and-comment rulemaking process and took on average 72 months to reach a final GRAS determination.[42] Understandably, the length of the process was a source of frustration to GRAS petitioners.

In 1997, FDA issued a proposed rule for determining whether a substance is GRAS that employs a much shorter process, resulting in the issuance of a GRAS notice without the full notice-and-comment rulemaking process.[43] This proposed rule has never been finalized, but FDA has employed the process proposed in the rule since 1998.[44] The goal of the new process was to encourage manufacturers to submit their understandings of additives as GRAS to agency scrutiny, and data do indicate some increased frequency of GRAS determinations under the process.[45]

Under the GRAS notice program as it currently functions, anyone can notify FDA that a substance is GRAS and FDA will then reply to the notifier by letter.[46] FDA publicizes an inventory of GRAS notice requests on its website, including the status of the notice and FDA's letter in response.[47] As an example, DSM Food Specialties filed a GRAS notice for the asparaginase enzyme preparation from genetically modified *Aspergillus niger*, intended for use in wheat products. FDA had issued an earlier determination that wild-type asparaginase is GRAS[48] and determined based on evidence submitted by DSM that the GE asparaginase is substantially equivalent to the wild type and therefore also GRAS.[49]

Significant concerns have been raised about how the GRAS process currently functions. Submitting a GRAS notice request is not mandatory, and many producers

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[40] Redbook 2000, FOOD & DRUG ADMIN. (July 2000), http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/Redbook/default.htm.

[41] Neltner et al., *supra* note 34, at 348.

[42] U.S. FOOD & DRUG ADMIN., *FDA's Approach to the GRAS Provision: A History of Processes* (April 2006), perma.cc/Q7BS-GEZL [hereinafter *FDA's Approach*].

[43] Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (proposed Apr. 17, 1997) (to be codified at 21 C.F.R. pts. 170, 184, 186, 570).

[44] U.S. FOOD & DRUG ADMIN., *About the GRAS Notification Program* (Mar. 2009) perma.cc/X8U7-2GMX.

[45] Neltner et al., *supra* note 34, at 348-49.

[46] *Id.* at 354.

[47] *See* U.S. FOOD & DRUG ADMIN., *GRAS Notices*, perma.cc/UPB2-FCMS (last visited Jan. 17, 2016).

[48] U.S. FOOD & DRUG ADMIN., GRAS NOTICE NO. GRN 000214, AGENCY RESPONSE LETTER (March 12, 2007).

[49] U.S. FOOD & DRUG ADMIN., GRAS NOTICE NO. GRN 000428, AGENCY RESPONSE LETTER (Nov. 26, 2012).

rely on their own evidence to make these determinations. As a result, there are many GRAS decisions of which FDA and the public are entirely unaware.[50] Even when a manufacturer submits a notice request, FDA relies for its determination on information submitted by industry, with resulting risks of conflicts of interest.[51] Although the current process appears to have increased the frequency with which manufacturers consult FDA, it lacks transparency and an opportunity for public comment.[52] A recent study documents the frequency with which experts used by manufacturers for GRAS submissions appear to have significant conflicts of interest and concludes: "The lack of independent review in GRAS determinations raises concerns about the integrity of the process and whether it ensures the safety of the food supply, particularly in instances where the manufacturer does not notify FDA of the determination. FDA should address these concerns."[53] However, FDA devotes limited resources to the GRAS program[54]—one recent estimate is only 10 employees.[55] One recent report characterized the GRAS acronym as "Generally Recognized as SECRET" and the GRAS process as "the loophole that has swallowed the law."[56]

C. GM Foods and the GRAS Process

Any genetic change in a food crop can change its characteristics as a food, including changes brought about through traditional plant breeding; indeed, "improving" plants as foods was often the very point of plant breeding throughout the centuries that humans have been farmers. While we seldom think of traditional plant breeding as dealing in food additives—in large part because traditional plant breeding relies on genetic variations inherent in the species of interest, such as gene variations that make corn sweeter or sturdier—it is important to recognize that the more extreme products of traditional plant breeding could result in unexpected genetic expressions that could qualify as food additives. Neither FDA nor the general public, however, has expressed concerns about the health or environmental safety of foods derived from traditional plant breeding, and hence these kinds of new varieties have traditionally escaped all FDA attention.

GM foods, however, present an easier "additive" argument, because researchers are actively introducing rDNA into the crops' genetic makeup expressly to create new phenotypic traits and expressions. Moreover, such introductions often borrow genetic material from entirely different species, giving the food species a new phenotypic

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[50] PEW CHARITABLE TRUSTS, *Fixing the Oversight of Chemicals Added to Our Food: Findings and Recommendations of Pew's Assessment of the U.S. Food Additives Program* 11 (Nov. 2013), perma.cc/7P5P-XXUH; Neltner et al., *supra* note 34; David Acheson, *GRAS Continues to Grow in Industry's Yard*, THE ACHESON GROUP (Apr. 23, 2015), perma.cc/2ZGT-HWBG.

[51] PEW CHARITABLE TRUSTS, *supra* note 50, at 9.

[52] Neltner et al., *supra* note 34, at 367.

[53] Thomas G. Neltner et al., *Conflicts of Interest in Approvals of Additives to Food Determined to be Generally Recognized as Safe*, 173 JAMA INTERN. MED. 2032, 2033 (2013).

[54] PEW CHARITABLE TRUSTS, *What Did Pew Health Group Find in its Review of the US Food Additive Regulatory Program?* (July 27, 2012), perma.cc/V92C-2D7F (last visited at Feb. 16, 2016).

[55] Dan Schiff, *GRAS Self-Affirmation Fades as Sound Strategy Under FSMA*, THE TAN SHEET (Feb. 11, 2013), perma.cc/2M62-C9ZD (last visited Feb. 5, 2014).

[56] Tom Neltner & Maricel Maffini, *Generally Recognized as Secret: Chemicals Added to Food in the United States*, NAT'L RESOURCES DEF. COUNCIL (Apr. 2014), perma.cc/U2QM-6AYN (last visited at Feb. 16, 2016).

characteristic of exogenous origin, such as the ability to manufacture an insect-destroying protein in the plant's own tissues. As such, both the rDNA introductions to GM foods and more importantly the phenotypic traits that they produce often qualify as food additives in the regulatory sense both because they become new components of the food and because they affect the food's characteristics.[57]

FDA has recognized the logic of this reasoning.[58] However, FDA has developed a separate process for the approval of new GM agricultural products that largely ignores the potential health and environmental impacts of GM foods, effectively granting them a presumption of GRAS contrary to the requirements of the FDCA, so this Article contends.

After enactment of NELA in 1990, FDA received inquiries concerning the regulatory status of foods created through rDNA technologies. Specifically, these inquiries suggested that FDA should require labeling of foods to indicate that they contained GM ingredients. In response, FDA published its "Statement of Policy: Foods Derived from New Plant Varieties" (the "1992 policy").[59] The 1992 policy states that FDA "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, they present greater safety concern than foods developed by traditional plant breeding.[60] Based on this conclusion, and implicitly assuming that traditional plant breeding poses no risks to or from the food supply, FDA determined that the method of development of a new plant variety is not "material information within the meaning of 21 U.S.C. 321(n) and would not usually be required to be disclosed in labeling for the food."[61] This was a statement of policy concerning the need for labeling, not a GRAS determination under the notice-and-comment process in effect at the time for

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[57] The FDCA defines a "food additive" to be:

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

21 U.S.C. § 321(s) (2012).

[58] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992) [hereinafter 1992 Policy].

[59] *Id.*

[60] *Id.*

[61] *Id.*

GRAS affirmations in response to petitions. Nevertheless, it has had an important impact on the process for approving GM products. We shall return to food labeling in Section IV below.

FDA built the 1992 policy on the premise that it should regulate GM food under the existing framework of the FDCA, FDA's implementing regulations, and current practice, including the procedures for labeling, standards for approval of food additives, and GRAS determinations.[62] For example, the 1992 policy states that "consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted."[63] FDA uses as an example of a possible safety concern a peanut protein introduced into a tomato, where the allergenic effects of that protein are unknown.[64] Even if its basic taste and texture remained unchanged, "[s]uch information would be a material fact whose omission may make the label of the tomato misleading under section 403(a) of the act."[65] The 1992 policy also included guidance for industry about consulting with FDA before marketing of particular GM products.[66]

In 1996, FDA issued new guidance for GM foods consultation.[67] This consultation process is designed to ascertain whether there are material differences between the GM food and its wild-type counterpart. It parallels the current GRAS notification process in some respects, but without a complete listing of the information associated with consultations.[68] Presenting consultation as a prudent means to further consumer trust, FDA outlined a voluntary process for industry to use. The stated goal of the process is to allow FDA scientists to identify unresolved safety questions based on available scientific evidence.[69] As part of the new process, FDA established a multidisciplinary Biotechnology Evaluation Team (BET) that assesses information summaries provided by product developers.[70]

Using the 1996 consultation process, FDA has completed 147 reported consultations as of July 2015.[71] The most common crops listed in the consultations are corn (42), soybeans (19), and canola (18).[72] The most frequent purposes of the modifications are pest resistance (*e.g.*, to the corn borer), herbicide tolerance (*e.g*, to

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[62] *See generally* Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound are the Analytical Frameworks Used by FDA and Food Producers?* 54 FOOD & DRUG L.J. 667 (1999).

[63] 1992 Policy, *supra* note 56, at Section VI.

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Guidance on Consultation Procedures Foods Derived from New Plant Varieties*, FDA OFFICE OF FOOD ADDITIVE SAFETY, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096126.htm (1997) (last visited Feb. 4, 2014).

[68] Neltner et al., *supra* note 34, at 360.

[69] Biotechnology Consultations on Food from GE Plant Varieties, FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing (last visited Feb. 16, 2016).

[70] *Id.*

[71] *Id.*

[72] *Id.*

glyphosate), and fertility.[73] Other aims include delayed ripening (tomatoes, cantaloupe), enhanced content (canola, soybeans), increased protein content (corn), and decreased polyunsaturated fat (soybeans).[74]

This consultative process for GM foods has never received formal approval through rulemaking. In January 2001, FDA issued a notice of proposed rulemaking (NPRM) requiring premarket notification of bioengineered foods.[75] This NPRM appeared in the final days of the Clinton Administration, and FDA has never acted upon it.

Use of the 1996 consultative process did not continue without objection, however. The Alliance for Bio-Integrity, the International Center for Technology Assessment, and a number of individual scientists and religious leaders brought suit challenging FDA's 1992 determination that GM foods as a class do not require special treatment.[76] The plaintiffs most specifically challenged FDA's determination that GM foods do not require labeling; however, FDA's labeling decision rested in part on its judgments about the safety of GM foods. As we discuss below,[77] FDA may require labeling of "material" aspects of foods. The plaintiffs argued that FDA should have considered as "material" the "widespread consumer interest" in whether foods contain GM ingredients and "the special concerns of religious groups and persons with allergies."[78] The district court, however, found that the FDCA is unclear as to whether "materiality" refers to both safety and other consumer interests and thus deferred to the agency's interpretive judgment on the scope of materiality.[79]

Because their challenge was to FDA's exercise of its discretion, the *Alliance for Bio-Integrity* plaintiffs faced the daunting task of arguing that the agency's action was arbitrary and capricious.[80] They raised two specific arguments under the FDCA: that it was arbitrary and capricious for the agency not to require labeling of GM foods and that it was arbitrary and capricious for the agency to presume that GM foods are GRAS and hence not subject to regulation as food additives.[81] Importantly in this regard, the 1992 policy was not a document issued as a rule or indeed a determination that GM foods are GRAS; it simply assumed GRAS status for purposes of announcing a policy about labeling.[82] With regard to labeling, plaintiffs contended that genetic modifications to foods are material to consumers for religious reasons or because of concerns about allergies.[83] With respect to religious or moral concerns, the court deferred to the agency's discretion on the ground that Congress left open whether "materiality" is limited to safety issues.[84] In dicta, the district court also postulated that

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[73] *Id.*

[74] *Id.*

[75] Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,706 (proposed Jan. 18, 2001).

[76] Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000).

[77] *See infra* notes 136–234 and accompanying text.

[78] *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 178.

[79] *Id.* at 179.

[80] *Id.* at 170.

[81] *Id.*

[82] *Id.*

[83] *Id.* at 178.

[84] *Id.* In *Pom Wonderful LLC v. The Coca Cola Co.*, 134 S. Ct. 2228 (2014), the Court held that the FDCA's grant of labeling authority to the FDA does not preclude an unfair competition suit under the Lanham Act claiming that a label is misleading. In discussing how the FDCA and the Lanham Act

"consumer demand" by itself could not under the FDCA be sufficient basis for a determination of materiality.[85] Regarding allergies, the court deferred to the agency's scientific judgment that, as a group, GM foods are safe—but it also recognized that the case would be different if particular foods posed safety concerns.[86]

Central to the *Alliance for Bio-Integrity* plaintiffs' argument was their view that the widespread marketing of GM food creates significant potential risks to consumers. If genetic modifications raise safety questions, the modifications would be food additives that are not GRAS.[87] FDA's reasoning on this point was that rDNA engineering adds genetic material, but genetic material is necessary for life; safety questions arise only with respect to any resulting phenotypic expressions and must be analyzed on that basis.[88] So, for example, if there were evidence that plants genetically engineered to be pesticide resistant had phenotypic characteristics that raised safety concerns, they would not be GRAS.[89]

In focusing on the rDNA itself, however, rather than on the gene expression that is the true goal of genetic engineering, FDA perpetuated a presumption that GM foods are safe (GRAS). In so doing, FDA ignored one of *Congress*'s policy decisions within the FDCA: In order to protect consumers who largely cannot control the products available in the marketplace, FDA should presume that new food additives, like new drugs, are unsafe until safety is proven. Specifically, according to the FDCA, "A food additive *shall . . . be deemed to be unsafe*," unless testing, historic use, or another exception warrants the opposite determination.[90] Moreover, before a new food additive warrants a finding of GRAS, it must become "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, *as having been adequately shown through scientific procedures . . . . to be safe under the conditions of its intended use*."[91] The FDCA thus clearly puts the burden of proving safety on the proponents of food additives. FDA does not have the burden of proving risk—but neither does it have the authority to approve new food additives without proof of safety.

To analyze the potential safety questions created by GM foods, in the 1992 policy FDA considered scientific evidence concerning their unanticipated effects, known toxicants, nutrient changes (including bioavailability), new substances (such as a different protein or carbohydrate), allergenicity (for example, if transfer of a peanut gene brought with it peanut allergies), and antimicrobial resistance.[92] It concluded that no such concerns were evident for GM foods generally, but it also observed that in specific cases there could be need to scrutinize the safety of a food produced by rDNA

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complement one another, the Court observed that the Lanham Act protects against unfair competition (and thus affects consumers indirectly). The FDCA protects consumer health and safety. The statutes thus may both apply to food labeling, although they do so in different ways. *Id.* at 2238.

[85] *Alliance for Bio-Integrity*, 116 F. Supp. 2d 166 at 179.

[86] *Id.*

[87] *Id.*

[88] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

[89] *Alliance for Bio-Integrity*, 116 F. Supp. 2d 166 at 178.

[90] 21 U.S.C. § 348(a) (2012) (emphasis added).

[91] § 321(s) (emphasis added).

[92] 1992 Policy, *supra* note 56, at section VI.

techniques based on its objective characteristics.[93] Again, this conclusion reverses the FDCA's mandated burden of proof: Lack of proof of concern is *not* the same as proof of safety. Nevertheless, the court in *Alliance for Bio-Integrity* deferred to FDA's determination that GM foods do not "present any different or greater safety concern than foods developed by traditional plant breeding."[94] The court bolstered its conclusion by noting that the "rationale for deference is particularly strong when the [agency] is evaluating scientific data within its technical expertise."[95]

Like the GRAS process, this consultative process has been criticized as voluntary and as primarily reliant on the information that industry provides to FDA.[96] As with GRAS determinations,[97] therefore, such reliance on industry-generated evidence raises significant scientific concerns, including that FDA's review of GM foods is insufficiently transparent and potentially subject to significant conflicts of interest. These concerns about the consultative process do not rest on kinds of pseudoscience alleged to be relied on by many GM opponents; rather, they invoke generally recognized best scientific practices, including the needs for peer review, replication in control experiments, and, preferably, epidemiological studies to demonstrate relative risk in exposed human populations.

II. THE FOOD SAFETY MODERNIZATION ACT AND THE SCOPE OF RISKS FROM GM FOODS

On January 4, 2011, Congress enacted the Food Safety Modernization Act (FSMA) "[t]o amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply."[98] The Act was motivated by several highly publicized food safety incidents, such as the outbreak of *E. coli* in spinach that resulted in deaths and disabilities.[99]

A. FSMA Overview

The FSMA gives FDA additional authority to prevent risks to human health and the food supply and enhanced enforcement authority. It requires FDA to assess the vulnerability of the entire United States food system and to redress such vulnerabilities, with a particular focus on protecting the food supply from intentional adulteration ("food terrorism").[100] Nevertheless, while GMO foods were not Congress's concern in enacting the FSMA, the Act could become relevant to FDA's handling of those food products.

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[93] 116 F. Supp. 2d at 178 n. 8. The 1992 policy also included guidance to industry regarding such scrutiny. 1992 Policy, *supra* note 56, at section VII.

[94] *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

[95] *Id.* at 177.

[96] Michael Hansen, *Reasons for Labeling of Genetically Engineered Foods*, ORGANIC CONSUMERS ASS'N, http://www.organicconsumers.org/articles/article_ 2702 6.cfm (Mar. 19, 2012) (last visited Aug. 26, 2015).

[97] *See generally* Neltner et al., *supra* note 33.

[98] FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (Jan. 4, 2011).

[99] Food Safety Modernization Act, FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodSafety /FSMA/ucm247559.htm.

[100] § 106(a), 124 Stat. at 3905-06.

The FSMA sets out a detailed set of requirements for FDA. First, within a year of the FSMA's enactment, "the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall issue guidance documents related to protection against the intentional adulteration of food, including mitigation strategies or measures to guard against such adulteration . . . ."[101] Second, within the same year, "the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, shall prepare and transmit to the relevant committees of Congress, and make publicly available on the Internet Web sites of the Department of Health and Human Services and the Department of Agriculture, the National Agriculture and Food Defense Strategy."[102] This strategy must explain how these agencies will achieve four sets of goals: (1) enhancing the preparedness of the agriculture and food system; (2) improving the capabilities of the agriculture and food system to detect health and disease threats; (3) ensuring an efficient response to food emergencies; and (4) enhancing the ability of the food and agriculture system to recover after an emergency.[103] Although the immediate target, again, is food supply contamination, the second of these goals could ultimately improve the science regarding the impacts (if any) of GM foods on human health, particularly over the medium to long terms.

Third, within two years of the FSMA's enactment, "[t]he Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall . . . submit to Congress a comprehensive report that identifies programs and practices that are intended to promote the safety and supply chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities."[104] Such programs include new or improved programs to address food allergies and anaphylaxis,[105] new dietary ingredients,[106] and potential human health problems from raw oysters.[107] In addition, the FFSMA creates a new food illness surveillance system.[108] Again, while not directed at GM food concerns, these new requirements may well reveal specific health and safety issues arising from particular GM foods, such as allergenicity or impacts from plant-produced insecticidal proteins.

The FSMA also gave several federal agencies new enforcement authorities with respect to food. For example, the Act requires FDA to target its enforcement efforts against both domestic and foreign food facilities.[109] Laboratories for food analyses must now be accredited,[110] and "[t]he Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Commerce, and the Administrator of the Environmental Protection

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[101] § 106(b), 124 Stat. at 3906.

[102] § 108(a), 124 Stat. at 3910-11.

[103] § 108(b), 124 Stat. at 3911-12.

[104] § 110(a)(1), 124 Stat. at 3913.

[105] § 112, 124 Stat. at 3916–20.

[106] § 113, 124 Stat. at 3920–21.

[107] § 114, 124 Stat. at 3921–22.

[108] § 205, 124 Stat. at 3937–39.

[109] § 201, 124 Stat. at 3923–26.

[110] § 202, 124 Stat. at 3926–29.

Agency, shall maintain an agreement through which relevant laboratory network members" "agree on common laboratory methods in order to reduce the time required to detect and respond to foodborne illness outbreaks and facilitate the sharing of knowledge and information relating to animal health, agriculture, and human health" and shall "identify means by which laboratory network members could work cooperatively . . . ."[111] The FFSMA also seeks to improve the tracking and tracing of food and food recordkeeping.[112]

On January 16, 2013, FDA published its initial proposed rules for "Growing, Harvesting, Packing and Holding of Produce for Human Consumption"[113] and for "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" in the Federal Register.[114] These proposed regulations were the subject of extensive debate and the comment period for them was extended several times.[115] In the fall of 2014, FDA published revised proposed rules,[116] which it finalized in September 2015.[117]

While FDA's discussion of the new regulations (like the FSMA) nowhere mentions GM foods (either to explicitly include or explicitly exclude them from coverage), those regulations retain the FDCA's broad definition of "food,"[118] and the manufacture and processing of food that they regulate include "modifying or manipulating food, including food crops or ingredients," such as "treating to manipulate ripening . . . ."[119] There are thus good arguments that the new regulations apply to GM foods. Moreover, the regulations' hazard analysis and risk assessment requirements, including recordkeeping requirements, apply to "any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury."[120] Specifically, the facility "must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at [the] facility to determine whether there are any hazards requiring a preventive control," including hazards arising from "unapproved food . . . additives" and "food allergens."[121] Once a hazard is identified, the facility must adopt preventive controls sufficient to minimize or prevent misbranding and adulteration.[122] It should

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[111] § 203(a), 124 Stat. at 3929.

[112] § 204, 124 Stat. at 3930–37.

[113] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3,504 (proposed Jan. 16, 2013).

[114] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3,646 (proposed Jan. 16, 2013).

[115] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Periods, 78 Fed. Reg. 69604 (Nov. 20, 2013).

[116] FSMA Proposed Rule for Produce Safety, FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm.

[117] Current Good Manufacturing Process, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55,908 (Sept. 17, 2015).

[118] 21 C.F.R. § 1.227 (amended Sept. 17, 2015).

[119] 21 C.F.R. § 1.328 (amended Sept. 17, 2015).

[120] 21 C.F.R. § 117.3 (added Sept. 17, 2015).

[121] 21 C.F.R. § 117.130(a), (b) (added Sept. 17, 2015).

[122] 21 C.F.R. § 117.135(a) (added Sept. 17, 2015).

be expected that enterprising plaintiffs will use these new regulations against the producers of GM foods and food products that incorporate GM foods, seeking exclusion from the human food supply (because of adulteration) or labeling requirements (because of misbranding). The outcome of that litigation may well turn on not only on the scientific evidence of hazard that the plaintiffs can assemble but also whether and how stringently FDA chooses to argue that the FSMA regulations were never intended to apply to GM foods.

More generally, both industry consultants and GRAS critics have suggested that FDA may use FSMA to tighten the GRAS process.[123] If so, the FSMA may well incidentally affect GM foods. However, at present FDA has not addressed GRAS determinations; instead, it has directed regulatory attention primarily to address microbial food contamination.[124]

B. Pesticides, the FSMA, and the Scope of Risks

As described above, FDA's 1992 policy judged that GM foods as a category do not pose special risks by considering scientific evidence concerning unanticipated effects, known toxicants, nutrient changes (including bioavailability), new substances (such as a different protein or carbohydrate), allergenicity (for example, if transfer of a peanut gene brought with it peanut allergies), and antimicrobial resistance. Environmental impacts were not part of this assessment. The 1992 policy does note that the presence of unavoidable environmental contaminants such as lead would subject the food to the more stringent standards applied to adulterated food,[125] but it did not consider that farming methods might be systematically different with GM crops as a whole or even with major subcategories of GM crops.

Under the FDCA, the presence of pesticide residue is not considered an ingredient that adulterates a food.[126] The actual statutory language—"bears or contains"—arguably would cover both pesticides that have been applied to a plant and pesticides that the plant self-produces as a result its biochemical makeup, because the plant "contains" the latter. The statutory structure allocates pesticide regulation to the EPA,[127] but the EPA has been long criticized for inadequate attention to the environmental effects of chemicals such as pesticides, herbicides, or fungicides.[128] An alternative reading of the statutory language might be that pesticides "contained" by plants are different than pesticides "produced" by plants. This reading could be defended by the observation that the science of how GM organisms themselves

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[123]Maranda White, *FSMA Empowers FDA to Capture Food Safety's 'Great White Whale'—GRAS*, FOOD SAFETY NEWS (Apr. 10, 2015), http://www.foodsafetynews.com/2015/04/fsma-empowers-fda-to-capture-the-great-white-whale-of-food-safety-gras/#.VdpKndNViko; Dan Schiff, *GRAS Self-Affirmation Fades as Sound Strategy Under FSMA,* THE TAN SHEET (Feb. 11, 2013), http://www.fdli.org/docs/default-document-library/130211_05130211007.pdf?sfvrsn=0; Jeff Gelski, *SupplySide West: F.S.M.A. may give plaintiff lawyers more firepower,* FOOD BUS. NEWS (Nov. 15, 2013), http://www.foodbusinessnews.net/articles/news_home/Regulatory_News/2013/11/SupplySide_West_FSMA_may_give.aspx?ID=%7BAC43C93F-12DB-433F-969A-D55D2E324164%7D&cck=1.

[124]Margot J. Pollans, *Regulating Farming: Balancing Food Safety and Environmental Protection in a Cooperative Governance Regime*, 50 WAKE FOREST L. REV. 399, 399 (2015).

[125]1992 Report, Part V; 21 U.S.C. § 342(a) (2005).

[126]21 U.S.C. §§ 342(a)(1)(A)–(B) (2005).

[127]Pollans, *supra* note 124, at 404.

[128]*E.g.*, J.B. Ruhl, *Farms, Their Environmental Harm, and Environmental Law*, 27 ECOLOGY L.Q. 263, 309 (2000).

function or interact with humans as foods is within the purview of FDA rather than the EPA. Moreover, the FDCA does not set herbicides or fungicides aside in the manner of pesticides. On this view of the scope of risks, herbicide, fungicide, or pesticide production by GM plants would be within the scope of risks for FDA in judging the safety of an adulterated food or a food additive.

In addition, the enactment of FSMA in 2010 presented new opportunities for FDA. FSMA brings farms and farming practices under direct FDA oversight for the first time.[129] FSMA directs FDA regulatory attention to how products are produced as well as to the nature of the products themselves.[130] Changed farming practices such as the increased herbicide use associated with herbicide-resistant GM plants would seem to fall squarely within this augmented authority.

During the comment period preceding the September 2015 FSMA regulations, the public certainly made FDA aware of its concerns regarding the larger environmental and human health implications of pesticide use.[131] Some of these FDA considered outside the scope of its rulemaking,[132] but it also clearly included pesticide residues as potential food hazards[133] that can render a food adulterated.[134] Conversely, and perhaps more relevantly to GM foods, FDA focuses its regulation of pesticides on the actual control of pests and expressly allows some uses of pesticides in food processing.[135] More generally, however, the regulations do not address the larger environmental hazards associated with crop growing and pesticide use, given that they focus on the safety of the food itself.

III. FDA'S AUTHORITY TO REQUIRE LABELING OF GM FOODS

As discussed above,[136] the primary issue in *Alliance for Bio-Integrity* was whether genetic modification is a "material fact" that requires labeling. This section describes FDA's authority over labeling and its understanding of what makes a fact "material." We then argue that FDA has construed its statutory authority too narrowly with respect to the required labeling of GM foods.

A. FDA's Statutory Authority over Labeling: "Material" Facts

The FDCA prohibits "misbranding" of food. By FDCA definition, foods are "misbranded" if labels either contain affirmatively misleading representations or fail "to reveal facts material in the light of such representations or material with respect to

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[129]Pollans, *supra* note 124, at 412-13.

[130]Pollans, *supra* note. 124, at 414.

[131]*See, e.g.*, 80 Fed. Reg. 55,917 (relaying comments about the effects of pesticides on honeybees).

[132]*Id.*

[133]*Id.* at 55,951, 56,027.

[134]*Id.* at 56,016.

[135]*Id.* at 56,001 ("We also modified the regulatory text to clarify that the restrictions on use of pesticides is when the pesticides are used 'to control pests.' We made this modification because we are aware that some food processing processes (such as fumigating almonds) involve treating food with substances that are classified as 'pesticides.' Without this modification, the provision could mistakenly appear to prevent establishments from conducting such processes.").

[136]*See supra* notes 76-97 and accompanying text.

consequences which may result from the use of the articles to which the 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."[137] The misbranding provisions effectively require labeling for all packaged foods,[138] for all foods containing artificial flavoring, artificial coloring, or chemical preservatives,[139] for dietary supplements,[140] and for vitamins and minerals.[141] Section 403 of the FDCA provides specific standards for what constitutes misbranding of foods.[142]

FDA has promulgated extensive regulations regarding food labeling, codified at Title 21 of the Code of Federal Regulations, Part 101. These regulations concentrate on packaged foods and, more specifically, on the rules governing nutrition labeling, nutrient content claims, and health claims. However, with the exception of a statutory requirement to label foods that have been irradiated, FDA does not construe processes of production as "material."

Labeling requirements vary depending on the type of food. For packaged foods, labels must include name and place of business of the manufacturer, packer, or distributor; an accurate statement of quantity (subject to reasonable variations); [143] and the common name of the food or of each ingredient in the food.[144] Ordinarily spices, flavorings, and colorings do not require separate listing,[145] but food labels must indicate whether the food "bears or contains any artificial flavoring, artificial coloring, or chemical preservative."[146] This provision does not apply to eggs, butter, or cheese, or to pesticides applied to raw agricultural products before harvesting.[147] Pesticides applied after harvesting must be disclosed, but the disclosure may be on the shipping container and is not required at all if disclosure would not be expected in the usage of trade.[148] In addition, all foods offered for sale for human consumption must have a nutrition label[149] that includes information deemed relevant to consumer health, such as calories, fat calories, sodium, cholesterol, carbohydrates, sugar, fiber, and protein per serving size.[150] Labels are also generally required for foods containing significant allergens.[151]

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[137] 21 U.S.C. § 321(n) (2015).

[138] § 343(e).

[139] § 343(k).

[140] § 343(s).

[141] § 350(b).

[142] § 343.

[143] § 343(e).

[144] § 343(i).

[145] §343(i).

[146] § 343(k).

[147] *Id.*

[148] § 321(l).

[149] §§ 343(q), (r); § 343-1.

[150] § 321(q)(1).

[151] § 343(w), (x).

Separate labeling requirements apply to foods promoted for "special dietary use."[152] These include vitamins or minerals or foods for special diets. Special labeling requirements also apply to dietary supplements,[153] such as the names and quantities of ingredients, identification as a dietary supplement, and accurate representation of quality standards. In addition, a dietary supplement will be deemed misbranded if it "is marketed in the United States, unless the label of such dietary supplement includes a domestic address or domestic phone number through which the responsible person . . . may receive a report of a serious adverse event with such dietary supplement."[154] However, "[a] dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings."[155]

Even food that does not fit one of the categories requiring a label—primarily produce and other agricultural commodities[156]—can still be considered misbranded if any label that it does have "is false or misleading in any particular,"[157] if the food "is offered for sale under the name of another food,"[158] if the food is imitation and the label does not specify "imitation,"[159] or "[i]f any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[160]

For raw agricultural products and raw fish, disclosures are subject to guidelines issued by FDA. The voluntary guidelines concern nutrition information.[161] They are met if the seller makes information available about 90% of the products it sells.[162] An example would be brochures available to consumers that contain nutrition information about produce. FDA tests 2000 stores and considers there to be compliance if 60% of these stores have the information available.[163] FDA may adopt regulations if it

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[152] § 351(c)(3).

[153] The FDCA provides an extensive definition of "dietary supplement." § 321(ff).

[154] § 343(y).

[155] § 343(s). In addition, the FDCA contains a list of exemptions from the dietary supplement labeling requirement. § 343-2.

[156] For example, the FDCA specifies that:

> The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment. *Id.* § 345.

[157] § 343(a)(1).

[158] § 343(b).

[159] § 343(c).

[160] § 343(f).

[161] 45 C.F.R. § 101.45 (2015).

[162] 21 C.F.R. § 101.43 (2015).

[163] § 101.43(b)–(c).

concludes that its guidelines are not being followed.[164] It has not as yet seen the need to adopt regulations regarding raw agricultural products or raw fish.

Use of radiation with food is subject to special statutory labeling requirements. Irradiation is a method of treating food to reduce risks of contamination. Under the FDCA, food that has been subject to radiation is considered adulterated[165] unless it meets the regulatory standards for food additives.[166] Foods that have been irradiated must bear a logo and verbal warning to that effect.[167] Congress established this statutory requirement because of (unfounded) concerns about whether radiation would remain in food, thus putting consumers at risk of exposure,[168] and hence this labeling requirement was politically a concession to scientifically confused consumer fears. Nevertheless, the label can still serve a useful purpose, because consumers can have realistic concerns that radiation will be ineffective in achieving food safety and that it may alter food characteristics.[169]

Irradiation is the only instance in which a disclosure of a processing technique has been required under section 201(n).[170] Notably, the requirement was "not based on safety concerns about irradiation," but on educating consumers about possible changes in flavor or shelf life of irradiated food because these changes could be "significant and material in light of the consumer's perception of such foods as unprocessed."[171] Possibly recognizing its earlier confusion, in the Food and Drug Administration Modernization Act of 1997,[172] Congress provided that disclosures about radiation do not need to be larger than disclosures about ingredients.[173]

The FDCA gives FDA explicit authority to define and set labeling standards for particular foods, subject to a few exceptions. Specifically, "Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of

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[164] § 321(q)(4).

[165] § 342(a).

[166] § 321(s).

[167] § 179.26(c).

[168] Letter from the Dep't of Health, Educ., and Welfare to Hon. Oren Harris, Chairman, House Comm. on Interstate and Foreign Commerce (July 12, 1975), in Legislative History of the Federal Food, Drug and Cosmetic Act as amended, vol. 14, p. 188–191, http://www.heinonline.org.ezproxy.lib.utah.edu/HOL/Page?men_tab=srchresults&handle=hein.leghis/foodrug0014&id=202&size=2&collection=leghis&terms=Irradiation|irradiation&termtype=phrase&set_as_cursor=3#200

[169] Gardiner Harris, *FDA Allows Irradiation of Some Produce*, N.Y. TIMES (Aug. 21, 2008), http://www.nytimes.com/2008/08/22/health/policy/22spinach.html?ex=1377144000&en=4d87f8791e3baa62&ei=5124&partner=permalink&exprod=permalink&_r=0.

[170] Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 FOOD & DRUG L.J. 301, 306 (2000) (citing 51 Fed. Reg. 13,376 (1986)).

[171] *Id.*

[172] Food and Drug Admin. Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296.

[173] 21 U.S.C. § 343-3 (2015).

container."[174] FDA has used this authority to establish identity and quality standards for a wide variety of foods, from milk and cheese to catsup to frozen pies.[175]

Importantly, FDA's authority to establish identity and quality standards contemplates that FDA will promulgate labeling requirements for optional ingredients.[176] Moreover, a food will be considered misbranded if:

> "it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations . . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food."[177]

Thus, FDA's authority to define food identities and to establish food quality standards effectively gives the agency broad authority to promulgate labeling requirements for specific foods beyond those that the FDCA itself requires.

B. Labeling Foods as GM

As we described above, FDA's conclusion about GM foods is that they do not raise special safety concerns as a group as compared to foods created with traditional husbandry practices. Thus, the mere fact that a food has been genetically engineered is not considered "material" for purposes of food labeling.[178] Nevertheless, if particular GM foods present identified risks—e.g., of allergies—or differ in taste or nutritional value in a manner consumers might not expect, those risks and changes would be considered "material" and be required to be disclosed in a label.[179]

The FDCA's statutory requirements could be construed in a number of ways to require disclosure of information about GM foods. These arguments include that the identity of the food is sufficiently different that its common name is no longer accurate, that the new genetic material is an ingredient that must be listed, that the quality of the food is affected, that the modifications are additives (like irradiation), or that the modifications introduce potential allergens. Absent specific information about the safety or quality of a GM food, however, FDA has taken the position that information about genetic modification is not "material" for consumers and so labels need not include the information that the food has been genetically modified.

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[174] § 341. However, "No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons." *Id.*

[175] 21 C.F.R. Parts 130-169 (2015).

[176] *Id.* ("In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label.").

[177] 21 U.S.C. § 343(g) (2013).

[178] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,984-85 (May 29, 1992) [hereinafter 1992 Policy] ("The method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.").

[179] *Id.*

A central difficulty for consumers in challenging this determination has been to explain why genetic modification achieved through recombinant DNA technologies is different in kind from genetic modifications achieved through sophisticated cultivation or breeding techniques. As we have argued above, however, concerns about FDA's assessment of GM foods do not depend on the idea that these foods are different in kind. Rather, they rest on questions about the adequacy of the scientific assessment of many of these foods and the scope of risks considered by FDA in these assessments. The core of our argument is that in the absence of transparency about scientific scrutiny and in light of FDA's constricted understanding of health and environmental risks, information that foods contain GM ingredients is "material" for consumers.

Transparency has been recognized as critical to fair information practices at least since the declaration in 1973 by the Department of Health, Education and Welfare that there should be no secret personal data collection systems.[180] In U.S. law, transparency has increasingly been used as a consumer protection strategy in lieu of regulatory mandates or prohibitions—albeit with mixed success.[181] Examples range from corporate financial disclosures to disclosures and monitoring of hazardous substances in the workplace to sex offender registries, complete with addresses. These disclosure requirements reflect the importance of the protected consumer interests and the inability of consumers to readily acquire the information they need on their own. The processes of food production and the content of foods are another example where transparency is important to consumers.

To be sure, with some foods and for some types of information, it may be reasonable to expect consumers to ferret out information on their own: consumers who watch Popeye cartoons might know that spinach is rich in vitamin C, for example. However, consumers do not have ready access to much information about food that might matter to them. For example, examining a bunch of spinach and having general knowledge about spinach does not yield information about where the spinach was grown, whether there were possibilities of exposure to *E. coli* from nearby activities, what chemical sprays were employed in growing the spinach, or whether the spinach has been genetically engineered to withstand drought or to be Roundup Ready™. In the absence of more robust scrutiny of the science, therefore, there is an argument for at least giving consumers the information that foods have been directly genetically modified or contain genetically modified ingredients (e.g., breakfast cereals or tortilla chips containing GM corn).

FDA's approach limits "materiality" to risks, taste, quality, or nutritional differences. The court in *Alliance for Bio-Integrity* dismissed consumer demands as not "material" enough a reason to require labeling and further suggested that FDA does not have authority to consider such concerns as material.[182] In so reasoning, the court characterized consumer ethical and religious views as mere "demands," at least with respect to the FDCA's understanding of materiality.[183] Thus, unless the processes

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[180] Report of the Secretary's Advisory Committee on Automated Personal Data Systems, *Records, Computers, and the Rights of Citizens* (July, 1973), http://www.hsdl.org/?view&did=479784 (last visited Jan. 20, 2015). For a critical evaluation of the success of these and other transparency requirements, see ARCHON FUNG, MARY GRAHAM & DAVID WEIL, FULL DISCLOSURE: THE POLITICS, PERILS, AND PROMISE OF TARGETED TRANSPARENCY (2007).

[181] FUNG ET AL., *supra* note 180.

[182] *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

[183] *Id.*

used to manufacture foods manifest themselves in differences in the actual characteristics of resulting products, information about them is not material, according to FDA and the federal district court.

Of course, consumer demand can drive some food producers to label their products "GM free," just as consumer demand has led to a boom for organic food growers. However, this market-driven "reverse labeling" does not fully address the broader concerns. First, the reverse labeling is not comprehensive, nor are GM-free foods available in all markets. Second, and more importantly, the presence of foreign genetic material in foods may be an objectively determinable characteristic that offends the deeply-held religious or ethical views of some consumers, even if they cannot readily perceive that characteristic. For example, animal genes in plants may raise concerns for vegetarians or for those who keep kosher.[184] Similarly, production of animals through cloning may be ethically objectionable to some consumers, yet that fact is not reflected in product labels.[185] Third, there is reason to believe that consumers in the U.S. do not fully appreciate how pervasive GM foods are in their food supply, suggesting that consumers who consciously seek to avoid GM foods on religious, ethical, or other grounds cannot do so. As such, consumers are being stripped of freedom of choice with respect to one of their most basic needs and pleasures.

FDA's rejection of production processes as a reason for labeling requirements, in comparison to product characteristics, has drawn powerful criticism from Douglas Kysar, among others. Kysar contends that consumers often attach great importance to the means by which their products were made: "made in America," union labor, worker safety, and environmental protection are among the many process considerations important to consumers.[186] Kysar describes three types of reasons consumers reasonably demand process information: They want to encourage (or discourage) particular production processes through purchasing activity; they may believe aspects of the process affect the value of goods; and they may have ethical or religious concerns about certain consumption decisions.[187] In each case, Kysar contends, the consumer concern can be seen not merely as a preference but as in some sense an exercise of civic responsibility.

Judgments by agencies such as FDA that consumers will fail to understand the current state of the science are paternalistic in that they both presume consumer irrationality and make value judgments that consumers might prefer to make for themselves, such as the extent to which a consumer wants to be risk-averse.[188] Along these lines, another criticism of the product/process distinction is that the two cannot really be separated in the case of GM food: What consumers fear are the unknown long-term risks of GM foods.[189] While consumer concerns may be misplaced for

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[184]Rachel Bergland Bailey, Comment: *A Tale of Two Systems: A Comparison Between U.S. and E.U. Labeling Policies of Genetically Modified Food*, 15 SAN JOAQUIN AGRIC. L. REV. 193, 210–11 (2006).

[185]John F. Murphy, *Mandatory Labeling of Food Made from Cloned Animals: Grappling with Moral Objections to the Production of Safe Products*, 63 FOOD & DRUG L.J. 131 (2008) (criticizing the moral objections).

[186]Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 526 (2004).

[187]*Id.* at 531–32.

[188]*Id.* at 590.

[189]Laurie Zeichner, *Product vs. Process: Two Labeling Regimes for Genetically Engineered Foods and How They Relate to Consumer Preference*, 27 ENVIRONS: ENVTL. L. & POL'Y J. 467, 487 (2004).

certain categories of GM foods, they are gaining increased salience as concerns about the health effects of farming practices for GM crops become manifest.[190] More generally, we can again consider the consumer protection policies that Congress made manifest in the FDCA's burdens of proof: In the absence of long-term evidence of safety, consumers should be entitled to know what they are eating, just as consumers are entitled to lists of ingredients for packaged foods.

The failure to regard methods of production as material to consumers is not unique to GM foods. FDA's decision to allow "flavorings" to be grouped despite the possibility of derivation from animal products has been criticized by vegetarians.[191] So has the failure to designate meat or dairy products as factory farmed.[192] A difficulty for vegetarians and vegans is that there is no consistently understood method employed in the United States to designate foods as vegetarian or vegan.[193] In contrast, for kosher foods, there are longstanding private certifying organizations such as the Orthodox Union of New York City that bring some consistency to labels,[194] while the Islamic Food and Nutrition Council of America certifies food as halal.[195] In these cases, there are at least some ways for consumers to ascertain features of products that are important to them.

The FDCA neither defines "material" nor specifies that material information is limited to objectively manifest safety or quality features of food. The language of the statute is that food is misbranded if the label 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 articles to which the 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."[196] This language does not limit consequences to the health, nutrition, or palate of the consumer. Species contamination, ethical distress, or religious censure are all potential consequences of the customary use of GM foods and thus arguably come within the ambit of FDCA misbranding. Risks may also be "consequences that may occur," even if their exact contours and probabilities are unknown. Thus, the statutory language arguably does not preclude FDA from taking into account the consumer concerns we have discussed.

Absent an explicit FDCA labeling requirement, neither food additives nor production processes need be disclosed to consumers. In this respect, the FDCA treats foods very differently from drugs and medical devices. Disclosure of drug or medical device indications and side effects is a core consumer right enforced by FDA.[197] One explanation for the difference between the treatment of pharmaceuticals and foods with respect to disclosures is the consumer's presumed familiarity of foods, especially agricultural products that have not been processed. However, this assumption does not

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[190] *See supra* note 1 and accompanying text.

[191] Carrie Griffin Basas, *"V" is for Vegetarian: FDA-Mandated Vegetarian Food Labeling*, 2011 UTAH L. REV. 1275 (2011).

[192] Hemy v. Purdue Farms, Inc., No. 11-888, 2011 WL 6002463 (D.N.J. Nov. 20, 2011).

[193] Basas, *supra* note 191, at 1276.

[194] *Get Certified*, ORTHODOX UNION, http://oukosher.org/ (last visited Jan. 20, 2016).

[195] INFANCA, http://www.ifanca.org/ (last visited Jan. 20, 2016).

[196] 21 U.S.C. § 321(n) (2013).

[197] § 321(m); § 352.

hold for processed foods or food additives—if indeed it even holds for today's industrial and global agriculture.[198]

C. *The Right to Food and FDA*

A further argument for changes in FDA's understanding of its regulatory authority with respect to GM foods can be found in contemporary understandings of human rights. Protecting the right to food requires a more expansive understanding of the type of information that could be material to consumers; beyond simple physical sustenance, matters of social conscience also matter. Such human rights norms counsel FDA to engage in more, not less, food labeling.

In the aftermath of World War II, the United States played a leading role in crafting the Universal Declaration of Human Rights (UDHR).[199] This initial articulation came to provide the international community with a framework for creating a world order codified in subsequent binding treaties that would respect human dignity by securing to everyone, everywhere, fundamental freedoms and basic human rights.[200] Among its numerous rights guarantees, the UDHR recognizes that "everyone has the right to a standard of living for himself and his family, including *adequate food* . . . and to the continuous improvement of living conditions."[201] Since the inception of the international human rights regime, the United States helped to craft, the right to food has been central.[202]

The International Covenant on Economic, Social and Cultural Rights (ICESCR) codifies the right to food first articulated in Article 25 of the UDHR.[203] Two interrelated norms together compose the food right: (1) access to adequate food; and (2) freedom from hunger.[204] The right to adequate food is a "relative" standard, while

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[198] *See generally* FDA's Approach, *supra* note 42.

[199] ELIZABETH BORGWARDT, A NEW DEAL FOR THE NEW WORLD: AMERICA'S VISION FOR HUMAN RIGHTS, 263–64 (2005).

[200] *See, e.g.*, JACK DONNELLY, UNIVERSAL HUMAN RIGHTS IN THEORY & PRACTICE, 23 (2d. 2003).

[201] Universal Declaration of Human Rights art. 25(1), G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 12, 1948) [hereinafter UDHR]; *see also* Declaration on the Rights of the Child, Principle 4, G.A. Res. 1386 (XIV), U.N. Doc. A/RES/1386 (XIV) (Nov. 20, 1959) ("The child shall have the right to adequate nutrition . . . .").

[202] Smith Narula, *The Right to Food: Holding Global Actors Accountable Under International Law*, 44 COLUM. J. TRANSNAT'L L. 691, 705 (2006).

[203] *Id.* at 705-06.

[204] Article 11 of the ICESR provides, in pertinent part:

(1) The State Parties to the present Covenant recognize the right of everyone to an adequate standard of living for himself and his family, including adequate food . . . and to the continuous improvement of living conditions. The State Parties will take appropriate steps to ensure the realization of this right recognizing to this effect the essential importance of international cooperation based on free consent.

(2) The State Parties to the present Covenant, recognizing the fundamental right of everyone to be free from hunger, shall take, individually and through international co-operation, the measures, including specific programs, which are needed:

(a) To improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge by disseminating knowledge of the principles of nutrition and by developing or reforming agrarian systems in such a way as to achieve the most efficient development and utilization of natural resources;

(b) Taking into account the problems of both food-importing and food-exporting countries, to ensure an equitable distribution of world food supplies in relation to need.

the right to freedom from hunger is understood to be absolute.[205] Accordingly, a state cannot derogate from its immediate obligation to ensure that at minimum individuals are free from hunger. Access to adequate food can be achieved over time.

The right to be free from hunger also finds expression in the International Covenant on Civil and Political Rights (ICCPR). Article 6 of the ICCPR implies a right to food as essential to the fundamental right to life.[206] Freedom from hunger enjoys singular status as the only right qualified as "fundamental" in both the ICESCR and the ICCPR.[207] The United States became a party to the ICCPR when it ratified the instrument in 1992,[208] and it has regularly submitted reports to the Human Rights Committee on the nation's compliance with the ICCPR.[209] While the United States is not a party to the ICESCR because the Senate has not yet ratified this instrument, as a signatory to the ICESCR the government "is obliged to refrain from acts which would defeat the object and purpose" of the treaty.[210] Indeed, the United States government has routinely recognized the importance of the right to food in congressional debates concerning foreign aid policies and development priorities.[211] Accordingly, a human rights approach should not be alien to FDA regulatory considerations but should rather inform them.

The Committee on Economic, Social and Cultural Rights (ESCR Committee or Committee), the institution that interprets and monitors compliance with the ICESCR, has determined that the "core content" of the right to adequate food entails guaranteeing: "the availability of food in a quality and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances and acceptable within a given culture; [t]he accessibility of such food in ways that are sustainable and that do

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International Covenant on Economic, Social and Cultural Rights art. 11, Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR], *see also* PHILIP ALSTON, INTERNATIONAL LAW AND THE HUMAN RIGHT TO FOOD, IN THE RIGHT TO FOOD 32 (Alston & Tomasevski eds., 1984).

[205]THE RIGHT TO FOOD GUIDE THROUGH APPLICABLE INTERNATIONAL LAW, xviii (Tomasevski, ed. 1987).

[206]*See, e.g.*, U.N. CHR, General Comment 6, ¶ 5, 16th Sess. (1982), U.N. Doc. HRI/GEN/1/Rev.1 at 6 (Committee pronouncement on need to reduce infant mortality through adoption of measures to eliminate malnutrition) ; *see also* Food and Agriculture Organization of the United Nations, Intergovernmental Working Group for the Elaboration of a Set of Voluntary Guidelines to Support the Progressive Realization of the Right to Adequate Food in the Context of National Food Security, Implications of the Voluntary Guidelines for Parties and Non-Parties to the International Convention on Economic, Social and Cultural Rights, IGWG RTFG 3/INF/1 (Feb. 2004), *available at* ftp://ftp.fao.org/docrep/fao/meeting/007/j1632e.pdf.

[207]*See* Narula, *supra* note 190, at 707.

[208]For status of ICCPR ratifications, see INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS, http://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-4&chapter=4&lang=en (last visited Jan. 22, 2016).

[209]For status of ICESCR ratifications, see INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en (last visited Jan. 22, 2016).

[210]Vienna Convention on the Law of Treaties art. 18, *opened for signature* May 23, 1969, 1155 U.N.T.S. 331.

[211]*See, e.g.*, Global Partnerships Act of 2012, H.R. 6644, 112th Cong. § 1201 (2012) (referring to food as basic human right).

not interfere with the enjoyment of other human rights."[212] According to the Committee, food should provide sustenance and food should be safe.[213] Sustenance is sufficient where the "diet as a whole contains a mix of nutrients for physical and mental growth, development and maintenance, and physical activity . . . human physiological needs at all stages throughout the life cycle."[214] Ensuring food safety is also essential and requires a "range of protective measures by both public and private means to prevent contamination of foodstuffs through adulteration and/or through bad environmental hygiene or inappropriate handling at different stages throughout the food chain; care must also be taken to identify and avoid or destroy naturally occurring toxins."[215]

The Committee has acknowledged that the precise meaning of "adequacy" will to a substantial extent be determined by prevailing social, economic, cultural, climatic conditions,[216] but the core of the right ensures that dietary needs are met and that food remains free of adverse substances or adulteration.[217] The FDCA's regulations prohibiting adulteration and misbranding are consistent with the Committee's interpretation that the core of an adequate food right involves freedom from adulteration.

For the Committee, not only does the food right require a range of protective measures to ensure food safety and prevent adulteration and contamination, but the right also implies the need to account for "perceived non nutrient-based values attached to food and food consumption and informed consumer concerns regarding the nature of accessible food supplies."[218] Put another way, there is a social dimension beyond basic sustenance that should be taken into account when crafting food policy. Part of having a food supply "sufficient to satisfy" nutritional needs is that food be acceptable.

Only States are parties to the Covenant and only States are ultimately accountable for compliance with it.[219] However, the Committee has stated that "all members of society, individuals, families, local communities, NGOs, civil society organizations as well as the private business sector have responsibilities in the realization of the right to adequate food."[220] Accordingly, interdependent obligations of different actors relevant to the right to food have been outlined as follows. The State should provide an environment that facilitates implementation of these responsibilities.[221] The private business sector should "pursue its activities within the framework of a code of conduct conducive to the respect of the right to adequate food, agreed jointly with the

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[212] ECOSOC, U.N. Comm. on Econ, Soc., & Cultural Rights, General Comment No. 12, The Right to Adequate Food, ¶ 8, U.N. Doc. E/C.12/1999/5 (May 12, 1999) [hereinafter General Comment 12]. International and domestic laws protect the free exercise of religion and freedom of conscience.

[213] *Id.*

[214] *Id.* ¶ 9.

[215] *Id.* ¶ 10.

[216] *Id.*

[217] *Id.*

[218] *Id.* ¶ 11.

[219] *Id.* ¶ 21.

[220] *Id.* ¶ 20.

[221] *Id.*

Government and civil society."[222] However, consistent with the responsibility to protect people's resource base for food, States parties should "take appropriate steps to ensure that the activities of the private business sector and civil society are in conformity with the right to food."[223]

States are responsible for implementing the right to food through the formulation and implementation of national strategies that comply with "the principles of accountability, transparency, people's participation, decentralization, legislative capacity and the independence of the judiciary."[224] For instance, a system of rulemaking in which regulatory authorities receive public input and share information would be central features of a properly function system.[225] The present emerging patchwork of state-by-state and retailer-by-retailer initiatives to meet express consumer demands for access to information about GM foods to enable informed consumer choices, while positive, does not constitute a national strategy. FDA's process for determining GRAS and the process for determining safety with respect to GM foods do not allow for the robust notice and comment available to the public in other administrative agency rulemaking contexts. There are serious questions as to whether present processes are truly consistent with principles of accountability, transparency, and participation.

According to the Committee, a State's strategy to protect the right to food should not only address critical issues and measures in regard to all aspects of the food system, "including the production, processing, distribution, marketing and consumption of safe food," but should also include "parallel measures in the fields of health, education, employment and social security."[226] Moreover, the Committee advises that "care should be taken to ensure the most sustainable management and use of natural and other resources for food at the national, regional, local and household levels."[227] There is open debate with respect to whether GM foods pose risks to interests identified by the Committee as meriting special care, such as the sustainable management and use of natural resources.[228] While outside the scope of the present paper, some environmental advocates argue that genetically engineered products pose a risk to natural resources and biodiversity. The possibility of such risks to the natural environment would merit care when making assessments concerning the acceptability of GM food products were the State responsibilities under the right to food taken into account.

A rights-based approach could have much to offer regulatory authorities in assessments concerning food labeling and food safety. Asbjoern Eide, in his analysis of responsibilities with respect to realizing the right to adequate food, developed a framework for assessing State obligations.[229] Obligations include the duty to respect,

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[222] *Id.*

[223] *Id.* ¶ 27.

[224] *Id.* ¶ 21.

[225] *Id.* ¶ 23.

[226] *Id.* ¶ 25.

[227] *Id.*

[228] *See generally* BIOSAFETY FIRST – HOLISTIC APPROACHES TO RISK AND UNCERTAINTY IN GENETIC ENGINEERING AND GENETICALLY MODIFIED ORGANISMS (Terje Traavik & Lim Li Ching eds., 2007).

[229] *See*, Narula, *supra* n. 190, at 707 (citing U.N. ECOSOC, Sub-Comm. On Prevention of Discrimination & Protection of Minorities, The New International Economic Order and the Promotion of

the duty to protect, and the duty to fulfill.[230] States respect the right by refraining from undertaking policies that would prevent food access.[231] States protect the right by actively implementing policies to ensure that enterprises or individuals do not deprive others of access to adequate food.[232] Finally, States fulfill the right by engaging in activities intended to strengthen people's access.[233]

FDA occupies a particularly advantageous position from which to ensure that the U.S. progressively realizes the human right to food. Increasing concern in the U.S. over the potential adverse effects of certain GM food products could counsel for regulatory intervention by FDA to ensure that scientific concerns are addressed and consumers are informed through transparency, including more open processes of scrutiny and labeling. FDA is well situated to promote the right to food because it is the agency that has been granted broad authority to ensure food is safe through setting standards for quality and for the identification of food products. FDA is empowered to impose any labeling requirements it deems necessary. A rights-based approach to food points to the necessity of providing consumers with information through promulgating regulations to label GE foods. Access to information is an implicit element of the right to adequate food as evidenced by the acceptability imperative it contains. Acceptability must be understood to encompass under FDA regulatory responsibility not only concerns about food safety and quality but also arguably religious, ethical and environmental concerns. A rights approach would make these concerns material. Without information, a consumer cannot make an educated determination with respect to whether or not a particular food product is acceptable. Safety notwithstanding, acceptability necessarily enters the inquiry in order to satisfy the right to adequate food. The right to food finds expression in the right to know.[234] While it may not be realistic to expect FDA to rely on a right to food as such to justify GM regulation, a rights approach could provide a more robust frame of reference for understanding domestic consumer protection in a global marketplace.

IV. CONCLUSION

This Article has argued that FDA is construing its authority over GM foods too narrowly, in three respects. First, scientific scrutiny of these foods is not fully transparent and appears rife with conflicts of interest, effectively reversing the FDCA's requirement that manufacturers prove that food additives are safe. Second, FDA largely omits risks created in production processes from food safety analyses, despite authority to do so granted under FSMA and despite increasing consumer and scientific concern that at least some GM foods pose such risks. Finally, FDA's limited construction of what makes information "material" for food labeling purposes

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Human Rights: Report on the Right to Adequate Food as a Human Right, U.N. Doc. E/CN.4/Sub.2/1987/23 (July 7, 1987) (by Asbjorn Eide)).

[230] *Id.* at 707–08.

[231] *Id.*

[232] *Id.*

[233] *Id.* at 708.

[234] Peter H. Sand, *Labeling Genetically Modified Food: The Right to Know*, 15 REV. EUR. COMP. & INT'L ENVTL. L. 185, 185 (2006) (arguing that the controversy over GE foods appears to be shifting from risk communications toward a debate over democratic governance: "right-to-know" versus "need-to-know").

compounds the lack of transparency in the regulatory process and interferes with consumers' abilities to avoid allergens, respect religious requirements, and implement personal ethical and risk avoidance choices.

Arguments from the law governing the human right to food also support broader understanding of FDA's authority to regulate food safety and labeling. In light of growing scientific concerns about at least some GM foods, reconsideration of FDA's constricted interpretation of its authority to regulate food is imperative. Indeed, irony abounds in the current FDA approach: despite FDA's broad authority to "regulate through revelation" and label products, the consultative process that enables manufacturers to evade disclosing the genetic identity of food products remains opaque and potentially rife with conflicts of interest, while transparency to consumers is absent.