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Do You Know What's On Your Plate?: The Importance of Regulating the Processes of Food Production

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1 This is the name of a documentary, WHAT'S ON YOUR PLATE (Bullfrog Films 2009), and has also been used by the USDA in connection with its "My Plate" dietary guidance, *Choose My Plate*, USDA, http://www.choosemyplate.gov/ (last visited Oct. 17, 2013).

INTRODUCTION

Eating is an intimate act, and the decision about what foods to eat is complex.[2] Besides flavor, many consumers also consider factors such as food safety, nutrition, cost, and convenience. But most Americans know very little about how their food is produced.[3] This fact is not surprising, considering the realities of the modern food system. As the United States Food and Drug Administration Commissioner, Margaret Hamburg, recently testified before Congress, the United States has "evolved from a country that once consumed simple, primarily domestically-produced goods to one that consumes complex products manufactured in every corner of the globe."[4] Today, the average food item is said to travel an average of

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2 *Cf. President's Fiscal Year 2013 Budget Request for the FDA: Hearing Before the Subcomm. on Agric., Rural Dev., Food & Drug Admin., & Related Agencies*, 112th Cong. (Feb. 29, 2012) (statement of Margaret A. Hamburg, Comm'r of Food and Drugs), *available at* http://www.fda.gov/NewsEvents/Testimony/ucm293842.htm.

3 *See* Helena Bottemiller, *Consumer Advocate Seeks Poultry Inspection Gig*, FOOD SAFETY NEWS (Apr. 12, 2012), http://www.foodsafetynews.com/2012/04/consumer-advocate-seeks-poultry-inspection-gig/ (attributing this observation to Secretary of Agriculture, Tom Vilsack). "Produced," as used in this article, encompasses feeding of animals and fertilizing of crops; applying chemicals as pesticides, preservatives, or to improve taste, texture or appearance of the food; and handling, preparing, cutting or trimming, packaging, storage, and so on. In other words, "produced" encompasses many steps taken both on and off the farm to make the food product that is eventually purchased by consumers.

4 Hamburg, *supra* note 2; *see also* PAUL ROBERTS, THE END OF FOOD 141 (2008) (noting that the United States' "food-trade balance actually went negative in 2004," in that

1,500 miles from farm to plate.[5] Consumers rarely have the opportunity to see where, how, or by whom their food is produced.[6] Long-distance transportation often requires processing steps to preserve freshness and packaging to minimize damage en route,[7] yet consumers rarely inquire, or are informed about, substances used to preserve or package their foods. Much food today is sold wrapped or packaged in ways that impede consumers' ability to assess the freshness or quality of the product using their senses of sight, smell, or touch.[8] Additional processing steps transform whole or raw commodities into more or less finished food products requiring little or no preparation by consumers.[9] These processes, too, are a mystery to consumers. Seldom can consumers obtain satisfactory explanations from retailers, who themselves are mere resellers of packaged products they buy from large-scale producers. Much work, such as butchering, that was once done in individual stores is now done much further up the production and distribution line.[10]

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the United States imported more food, in dollar value, than it exported, and that by 2016, the United States "will be the world's largest importer of meat").

5 BARBARA KINGSOLVER ET AL., ANIMAL, VEGETABLE, MIRACLE 5 (2007).

6 *See generally* Katharine A. Van Tassel, *Regulating in Uncertainty: Animating the Public Health Product Safety Net to Capture Consumer Products that Use Innovative Technologies*, 2013 U. CHI. LEGAL F. (forthcoming 2013) (manuscript at 28–29), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2240034 (discussing "information asymmetry" that developed as consequence of food processing revolution of the 1930s through 1950s); *id.* (manuscript at 25–26) (discussing labeling requirements and consumers' lack of common knowledge about risks of new ingredients).

7 *See* ORAN B. HESTERMAN, FAIR FOOD 18 (2011) (discussing energy use in packaging and transporting of food).

8 Such "organoleptic" assessment of food has long been used by inspectors and consumers alike:

> Inspectors from the USDA's Food Safety and Inspection Service ("FSIS") generally conduct post-mortem inspections while stationed at fixed points along the slaughter processing line. Using organoleptic methods, that is, relying on sight, touch and smell, the inspectors examine the head, viscera, and exterior of each carcass for signs of adulteration, such as tumors, inflammation, parasites, and other diseases . . . . The method of inspection just described had remained unchanged for decades.

Am. Fed'n of Gov't Emps. v. Glickman, 215 F.3d 7, 8–9 (D.C. Cir. 2000); Stauber v. Shalala, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995) (discussing organoleptic differences in milk); *see also* 9 C.F.R. §§ 310–11, 381.76–94 (2013). Similar procedures apply to inspections under the Poultry Production Inspection Act. *Id.* §§ 391.81–89.

9 *See generally* BEN HEWITT, MAKING SUPPER SAFE 129–31 (2011); MARION NESTLE, WHAT TO EAT 305–07 (2006); MICHAEL POLLAN, THE OMNIVORE'S DILEMMA 90–99 (2006); ROBERTS, *supra* note 4, at 73 (discussing the "lost art" of cooking).

10 ROBERTS, *supra* note 4, at 73 (discussing "case-ready" meat).

In part, consumers' ignorance is traceable to a regulatory approach that largely ignores process-of-production concerns. The two federal agencies responsible for food regulation, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA), focus primarily on food safety, fair dealing, and nutrition.[11] Thus, existing regulations generally address the identity (name and description) and composition (ingredients and nutrients) of foods. Consumer concerns extend further, however, to encompass matters such as ethics, environmental impact, long-term health effects, and the relative value of food products.[12] Moreover, these broader concerns are linked in important ways to food safety.[13]

There are so many steps from farm to plate that accountability of the many actors in the chain is weak.[14] This situation is just what Congress had in mind when it passed the Federal Food, Drug, and Cosmetic Act of 1938[15] (FDCA), which still provides the basic framework for regulation of food. Interpreting the FDCA shortly after its passage, the Supreme Court observed that

> [t]he Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control . . . and stiffened the penalties for disobedience.

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11 The FDA oversees domestic and imported food of virtually all types except meat and poultry. NEIL D. FORTIN, FOOD REGULATION 25 (2009). The USDA oversees meat, poultry, products containing meat or poultry, and processed egg products. *Id.*

12 *See, e.g.*, Rosie Mestel, *Lots of Chatter, Anger over Stanford Organic Food Study*, L.A. TIMES, Sept. 12, 2012 (quoting Marion Nestle, Michael Pollan, and others to the effect that nutrition is not the only reason why people buy organic foods). Some of the concerns listed above—in addition to others like animal welfare—while highly relevant to consumers, are beyond the authority of the FDA and the USDA to regulate.

13 *See, e.g.*, ROBERTS, *supra* note 4, at 178–80 (discussing the link between food-borne illness and industrial food system); Debra M. Strauss, *The Role of Courts, Agencies, and Congress in GMOs: A Multilateral Approach to Ensuring the Safety of the Food Supply*, 48 IDAHO L. REV. 267, 276 (2012) (suggesting the link between organic production and food safety); Nicholas D. Kristof, Op-Ed., *Cleaning the Henhouse*, N.Y. TIMES, Sept. 1, 2010 (discussing the link between salmonella outbreak related to eggs and "factory-farming" practices); *see also* Van Tassel, *supra* note 6 (manuscript at 20–21) (discussing the "information void" that exists as a result of the fact that "development of novel technologies . . . far outpace[s] the development of the science necessary to test for the health risks associated with these technologies" and concluding that "FDA's reliance on establishing hazard," during the substantial period of scientific uncertainty about a new technology, "short circuits its ability to act" to protect consumers).

14 *See* Hamburg, *supra* note 2 (discussing the increasing complexity of supply chain by which food products reach consumers).

15 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012); *see also* Federal Meat Inspection Act, 21 U.S.C. §§ 601–695 (2012).

> The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.[16]

Thus, "[b]alancing relative hardships, Congress has preferred [not] . . . to throw the hazard on the innocent public who are wholly helpless."[17]

When consumers learn of worrisome production methods, their reactions show not only a desire to understand how their food is produced but also outrage at having been kept in the dark.[18] In several controversies, consumer reaction has eventually prompted the food industry to change its ways.[19] But so far, consumer ire has met with little success in encouraging more robust regulation by the FDA and USDA.

The FDCA's basic approach is simple: it prohibits the "adulteration or misbranding of any food"[20] and the "introduction or delivery for introduction into interstate commerce"[21] or the "receipt in interstate commerce of any food . . . that is adulterated or misbranded."[22] The definition and interpretation of the concepts of "adulteration" and "misbranding," therefore, are the key to the regulatory framework establishing the FDA's authority regarding the food system. With refinements to be discussed in detail below, a food is "adulterated . . . [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health."[23] Adulteration under the statute extends to so-called "economic adulteration" of food, which occurs "[i]f any valuable constituent has been in whole or in part omitted or

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16 United States v. Dotterweich, 320 U.S. 277, 280 (1943).

17 *Id.* at 285.

18 *See* Strauss, *supra* note 13, at 270; *see also* Van Tassel, *supra* note 6 (manuscript at 37) (suggesting that "much of the controversy over . . . possible health effects [of GMO foods] would have abated" if the use of GM technology in production of food "had been identified as such").

19 *See* Strauss, *supra* note 13, at 311; Dan Flynn, *Alar Apples Case Precedence for BPI v. ABC*, FOOD SAFETY NEWS (Sept. 14, 2012), http://www.foodsafetynews.com/2012/09/alar-case-is-precedent-for-bpi-v-abc/ (describing the "collapsed demand for apples" following a television report about the use of a dangerous chemical); *see also* Alessandra Ram, *Teach Us, Trader Joe: Demanding Socially Responsible Food*, ATLANTIC (Aug. 7, 2012), http://www.theatlantic.com/health/archive/2012/08/teach-us-trader-joe-demanding-socially-responsible-food/260786/.

20 21 U.S.C. § 331(b) (2012).

21 *Id.* § 331(a).

22 *Id.* § 331(c).

23 *Id.* § 342(a)(1).

abstracted therefrom"[24] or "if any substance has been substituted wholly or in part therefor."[25] A food is "misbranded," in general, if "its labeling is false or misleading in any particular."[26]

Although this article focuses primarily on the FDCA and its administration by the FDA, the landscape of food regulation also encompasses other statutes and agencies. Additional statutes include the Federal Meat Inspection Act (FMIA),[27] the Poultry and Poultry Products Inspection Act (PPIA),[28] and the Egg Products Inspection Act (EPIA),[29] all of which are administered by the USDA.[30] These statutes, like the FDCA, prohibit the sale in interstate commerce of products that are "adulterated" or "misbranded."[31] Their definitions of adulteration and misbranding closely track those of the FDCA.[32] Hence, discussions in this article of the adulteration and misbranding provisions of the FDCA should be taken to include the comparable provisions of the FMIA, PPIA, and EPIA unless otherwise noted.

The FDA has interpreted both "adulteration" and "misbranding" to relate to the identity, content, and composition of food but not generally to the processes by which it has been produced.[33] The FDA's focus has been the safety and nutritive value, rather than the

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24 *Id.* § 342(b)(1).

25 *Id.* § 342(b)(2).

26 *Id.* § 343(a)(1).

27 Federal Meat Inspection Act, 21 U.S.C. §§ 601–695 (2012).

28 Poultry and Poultry Products Inspection Act, 21 U.S.C. §§ 451–472 (2012).

29 Egg Products Inspection Act, 21 U.S.C. §§ 1031–1056 (2012).

30 *See* 21 U.S.C. §§ 453(*i*), 601(a), 1033(x) (all defining "Secretary" as the Secretary of Agriculture).

31 *See, e.g.*, 21 U.S.C. § 458(a)(2)–(3) (poultry); *id.* § 610(c)–(d) (meat); *id.* § 1037(a)–(b) (eggs).

32 *See, e.g.*, 21 U.S.C. § 453(g) (adulteration); *id.* § 453(h) (misbranding) (poultry); *id.* § 601(m) (adulteration); *id.* § 601(n) (misbranding) (meat); *id.* §1033(a) (adulteration) (eggs). The misbranding provision for eggs is somewhat different. *See id.* § 1033(*l*) ("The term 'misbranded' shall apply to egg products which are not labeled and packaged in accordance with the requirements prescribed by regulations of the Secretary under section 1036 of this title.").

33 *See* TIM JOSLING ET AL., FOOD REGULATION AND TRADE 187 (2004); Jim Chen, *Food and Superfood: Organic Labeling and the Triumph of Gay Science over Dismal and Natural Science in Agricultural Policy*, 48 IDAHO L. REV. 213, 215 (2012). With respect to meat, poultry, and eggs the picture is somewhat more complicated as there are additional statutory provisions relating to slaughter, pre-market inspection, and pre-market approval of labels. These provisions obviously address some process-related concerns, but even they ignore many processes that occur prior to arrival at the slaughterhouse or processing plant. *See, e.g.*, 21 U.S.C. § 603 (examination and inspection of animals immediately prior to slaughter).

quality or attributes, more broadly speaking, of food.[34] The FDA interprets safety and health narrowly to include acute effects of contamination and long-term effects of nutritional deficiencies but not, apparently, to include long-term effects of exposure to food containing genetically engineered technologies, antibiotics, hormones, and other chemicals used in food production, processing, or packaging.[35] As a result, the FDA has not seen fit to regulate matters such as the use of genetic engineering technology,[36] synthetic hormones,[37] or sub-therapeutic antibiotics[38] in food production, or the use of BPA in food packaging.[39] The USDA has declined to address the sale of "pink slime" as beef, other than by approving voluntary labeling as to the inclusion of LFTB in beef products.[40] Both agencies approve of modified atmosphere packaging (MAP) of foods under their jurisdiction.[41]

Because the FDA and the USDA view foods produced using new methods as not differing "materially"[42] from their more traditionally-produced counterparts and therefore as "safe,"[43] the agencies consider regulation unnecessary and even unauthorized.[44] A clear indication of this hands-off approach is the agencies' decision not to require pre-market approval of foods and ingredients produced using new or controversial processes despite their recent development and the relative paucity of scientific testing.[45] The European Union, by contrast, bases food regulation on a precautionary principle such that

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34 *See* JOSLING ET AL., *supra* note 33, at 162, 171, 187.

35 *Cf.* Chen, *supra* note 33, at 215.

36 *See infra* Part II.A.1.

37 *See infra* Part II.A.2.a.

38 The United States District Court for the Southern District of New York recently ordered the FDA to start proceedings to withdraw approval for the use of common antibiotics in animal feed unless makers of the drugs can produce evidence that their use is safe. NRDC, Inc. v. FDA, 884 F. Supp. 2d 127 (S.D.N.Y. 2012).

39 *See infra* Part II.A.3.a.

40 *See infra* Part II.A.2.b.

41 *See infra* Part II.A.3.b.

42 *See infra* Part II.A.1.

43 *Id.*

44 *Id. See generally* Van Tassel, *supra* note 6 (manuscript at 17) (discussing the FDA's "regulatory stance of bioequivalence"); *cf.* Chen, *supra* note 33, at 216–17.

45 Van Tassel, *supra* note 6 (manuscript at 14).

a different process of production renders food "no longer equivalent to an existing food or food ingredient."[46]

Consumers, meanwhile, exhibit an increasing general tendency "toward identifying foods by process as well as content attributes."[47] Accordingly, "the regulation of process attributes to achieve quality goals" presents the "most contentious" emerging issue.[48] New technologies and industrial methods of production raise "fundamental questions about the balance between public- and private-sector decisions on labeling and providing consumers with information . . . . In addition, . . . these issues [raise] the problem of distinguishing between risk and quality goals."[49] On many issues relating to the process of production, consumers are utterly unable to assess suitability for purchase by examining the product itself.[50] Moreover, process-related attributes that could reduce consumer acceptance are unlikely to be disclosed voluntarily by producers.[51]

This article argues that the current regulatory approach—focusing on the supposed equivalence of new foods to traditional ones—is unduly narrow, particularly given the characteristics of the modern food system. To achieve the broad objectives of the FDCA in the context of the industrialized, highly processed, and global food supply of the twenty-first century requires adopting a broader understanding of consumer protection needs with respect to food. The FDCA itself is written in very broad terms and provides much of the authority needed today. The FDA's enforcement capacity, however, already is severely strained.[52] Moreover, the scientific basis for some process-oriented regulations[53] may be in dispute. Thus, the FDA and the USDA—like other food regulatory agencies around the world—must determine which kinds of process attributes merit regulation and what regulatory mechanisms are most appropriate.[54] To the extent that such

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46 JOSLING ET AL., *supra* note 33, at 165 (quoting Regulation 258/97, 'Concerning Novel Foods and Novel Food Ingredients, 1997 O.J. (L 43) art. 8(a) (EC)); *see also* Strauss, *supra* note 13, at 268.

47 JOSLING ET AL., *supra* note 33, at 151; *see also* Ram, *supra* note 19.

48 JOSLING ET AL., *supra* note 33, at 151.

49 *Id.* at 152.

50 *See id.* at 175. For example, consumers cannot tell by looking at a tomato, an egg, or a package of bacon whether the tomato was produced using GMO technology, the hen was fed antibiotics to hasten growth, or the sow was confined in a gestation crate.

51 *See id.* at 129.

52 *See* Hamburg, *supra* note 2.

53 JOSLING ET AL., *supra* note 33, at 191.

54 *Id.* at 181.

regulation responds to consumers' demands to know how their food is produced, a broad social discussion may be required.[55] This article seeks to help shape that discussion.

The article proceeds in three parts. Part I describes recent food production controversies involving the use of genetic engineering technology, the use of synthetic hormones in dairy cattle, the sale of Lean Finely-Textured Beef (LFTB), and the use of chemical substances like Bisphenol A (BPA) and carbon monoxide in the packaging of food. In particular, Part I describes consumers' reactions to use of these production methods and details their demand for more information and greater regulation. Part II then details the mismatch between consumers' demands and the regulatory approach taken by FDA and USDA. Agency actions in response to the same controversies discussed in Part I are examined in detail here. Part II concludes with a brief discussion of the consequences that flow from agency inaction.

Part III then argues that the FDA and the USDA have ample authority under existing statutes to address food production concerns. Part III explores one key reason the agencies have declined to address many of the concerns highlighted in Parts I and II. The FDA and the USDA exempt many new processes from regulation as adulterants on the ground that foods produced with them are not materially different from traditionally-produced counterparts. Consumers and retailers, by contrast, often differentiate the "same" foods on the basis of the process of production.[56] Likewise, the agencies improperly equate "facts material" in labeling with a notion of "substantial equivalence" or "no material difference" between traditional food products and those produced with new technologies. Many food labels are replete with unregulated claims about the process of production, particularly that the product is "all natural." In the agencies' view, regulatory authority to address both adulteration and misbranding is lacking if a new production method yields an end product that is equivalent (in composition and nutritional value) to its more traditionally-produced precursor. The article concludes, contrary to the agencies' interpretation, that the statutes allow regulation of the process-related attributes of food.

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55 *Id.* at 2.

56 Two bunches of carrots, for example, are differentiated as "organic" or not; two packages of chicken are differentiated as antibiotic-free or not.

I
CONSUMER DEMAND FOR INFORMATION ABOUT HOW FOOD IS PRODUCED

Recently, print, broadcast, and online media have been replete with stories about consumer demand for more information about various aspects of food production. This article details four such controversies: labeling of foods produced with Genetic Engineering (GE) technology, the use of hormones in animal agriculture, the sale of a ground beef product now known as "pink slime," and the use of BPA and other chemical substances in food packaging. As described below, consumer sentiment on these issues runs high. Actual or desired results include both tougher regulation and industry capitulation. Consumers appear willing to resort to self-help tactics such as ballot initiatives and boycotts to achieve the desired changes in their food supply when federal agencies fail to do so. Such tactics, however, yield temporary, inconsistent, and ineffective results even when they result state legislation or industry capitulation.[57]

A. Use of Genetic Engineering[58] Processes

The use of GE technology in food production is perhaps the issue that has received the most extensive coverage and widest discussion.[59] Although many opposed to the use of GE technology would like to "stop or slow its arrival into the food supply,"[60] that battle has largely been lost. GE technology is used in many staple plant-based human foods and in the feed of animals raised for human consumption.[61] The

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57 *See generally* Gordon G. Bones, *State and Federal Organic Food Certification Laws: Coming of Age?*, 68 N.D. L. REV. 405, 407–09 (1992) (discussing the inconsistency in state regulation of organic industry and the need for nationwide standards).

58 This article uses the term "genetic engineering" (GE) in place of terms like "genetic modification," "GMO," or "transgenic," except where quoting sources that use other terminology.

59 *See generally* Guy R. Knudsen, *Where's the Beef: How Science Informs GMO Regulation and Litigation*, 48 IDAHO L. REV. 225, 225–26 (2012).

60 Julia Moskin, *Modified Crops Tap a Wellspring of Protest*, N.Y. TIMES (Feb. 7, 2012), http://www.nytimes.com/2012/02/08/dining/a-suit-airs-debate-on-organic-vs-modified-crops.html (discussing the comments of A.C. Gallo, copresident of Whole Foods, Inc.).

61 GE technology advocates point to several potential benefits: improved yield; improved resistance to diseases, insects, and herbicides; and ability to thrive under adverse conditions such as drought. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22985 (May 29, 1992); *see also* Moskin, *supra* note 60; Annual Letter from Bill & Melinda Gates Found. (Jan. 2012), *available at* http://www.gatesfoundation.org/who-we-are/resources-and-media/annual-letters-list/annual-letter-2012.

USDA estimated in 2012 that over ninety percent of U.S.-raised soybeans, about eighty percent of cotton, and over seventy percent of corn were grown from genetically engineered seed.[62] Genetically engineered canola and sugar beets have been adopted in smaller percentages.[63] According to the Grocery Manufacturers Association, most processed foods contain at least one (and sometimes many) genetically engineered ingredients.[64] Genetically engineered salmon—the first non-plant based GE food for human consumption—is on the horizon.[65] Furthermore, pollen from genetically engineered plants has a tendency to drift onto fields planted with non-GE varieties, increasing the presence of GE technology even beyond its intentional introduction into the food supply.[66]

In a 1992 Policy Statement, the FDA announced its decision not to regulate the use of GE technology in food production or the labeling of GE-produced foods.[67] Courts have deferred to the agency's decision not to regulate.[68] Despite the prevalence of GE technology,

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Arguably, these traits would make it possible to feed the world's growing population and to do so at a lower cost. *See, e.g.*, Graham Brookes et al., *The Production and Price Impact of Biotech Corn, Canola, and Soybean Crops*, 13 J. AGROBIOTECHNOLOGY MGMT. & ECON. 25, 36 (2010) (describing expected decreases in yield and increases in price if existing biotech traits were no longer used). Some argue that GE technology also minimizes agriculture's environmental impact by reducing the need for pesticides and other chemicals, thereby lessening water pollution and other environmental harms. *See Do Current GE Crops Provide Any Benefits?*, Question 16 in *Frequently Asked Questions*, CENTER FOR SCI. PUB. INT., www.cspinet.org /biotech/faq.html (last updated Apr. 2012).

62 *See Adoption of Genetically Engineered Crops in the U.S.*, USDA, http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us /recent-trends-in-ge-adoption.aspx#.UYu_2rWyD9k (last updated July 9, 2013).

63 *Id.*

64 Moskin, *supra* note 60.

65 The Food and Drug Administration in 2012 issued a draft Environmental Assessment and preliminary Finding of No Significant Impact pertaining to AquaBounty Technologies' application for AquAdvantage Salmon. The public comment period on these documents, originally slated to end on February 25, 2013, closed on April 26, 2013. The FDA notes that the draft Environmental Assessment and preliminary Finding of No Significant Impact are one step in the FDA's evaluation of the AquAdvantage Salmon and do not indicate an approval of the application. *See FDA Extends Comment Period on AquAdvantage Salmon Documents*, USDA (Feb. 13, 2013), http://www.fda.gov /AnimalVeterinary/NewsEvents/CVMUpdates/ucm339270.htm.

66 *See* Peter Thomison, *Managing "Pollen Drift" to Minimize Contamination of Non-GMO Corn, AGF-153*, OHIO ST. UNIV., http://ohioline.osu.edu/agf-fact/0153.html (last visited Oct. 17, 2013).

67 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22985 (May 29, 1992).

68 *See, e.g.*, Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000).

the fact that the FDA considers it safe[69] and the fact that no known health risks are conclusively linked with eating GE foods,[70] consumer resistance to the use of this technology has run high ever since its introduction.[71] Recognizing that GE technology is already firmly entrenched and GE foods are unlikely to be eradicated from the market, many opponents have turned their attention to efforts to require labeling of GE foods.[72] Pollsters consistently report that about ninety percent of customers believe that foods produced using GE technology should be labeled to reflect that fact.[73] Some reports suggest that the "voices of discontent are growing louder."[74]

GE labeling fights have been carried out on several battlefields. Led by the Center for Food Safety (CFS), numerous organizations and businesses petitioned the FDA to rescind its 1992 Statement of Policy regarding GE foods and to issue new regulations "requiring

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69 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984; Andrew Pollack, *U.S. Approves Genetically Modified Alfalfa*, N.Y. TIMES, Jan. 27, 2011; Jack Kaskey, *Genetically Modified Crops to Get Faster Approval, USDA Says*, BUSINESSWEEK, Feb. 22, 2012.

70 Moskin, *supra* note 60. *But see* Letter from Don Huber, Emeritus Professor, Purdue Univ., to Thomas Vilsack, Sec'y of Agric. (Jan. 17, 2011), *available at* fhrfarms1.com/blog/hot-topic-letter-to-US-secretary-of-agriculture/; Gilles-Eric Séralini et al., *Long Term Toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified* Maize, 50 FOOD & CHEMICAL TOXICITY 4221; Steven Salzberg, *Does Genetically Modified Corn Cause Cancer? A Flawed Study Fails to* Convince, FORBES (Sept. 24, 2012), www.forbes.com/sites/stevensalzberg/2012/09/24/does-genetically-modified-corn-cause-cancer-a-flawed-study/.

71 Moskin, *supra* note 60.

72 *Id.* (discussing Whole Foods); Marc Lifsher, *Big Agriculture Pumps $10 million into Anti-GMO-Labeling Campaign*, L.A. TIMES (Aug. 13, 2012), http://articles.latimes.com/2012/aug/13/business/la-fi-mo-big-ag-pumps-10-million-into-antigmo-labelling-campaign-20120813.

73 Moskin, *supra* note 60 (citing Reuters/National Public Radio poll conducted by telephone in October 2010 in which ninety-three percent of respondents favored labeling); Ethan A. Huff, *MSNBC Poll: Nearly Everyone Supports Mandatory GMO Labeling*, NATURALNEWS (Mar. 3, 2011), //www.naturalnews.com/z031569_GMO_GMOS_food.html (noting that nearly ninety percent of respondents to an MSNBC poll favored labeling, ninety-three percent of respondents in an ABC poll favored mandatory labeling, and eighty-seven percent of respondents in a CBS/New York Times poll supported GMO labeling). *But see* Anna Almendrala, *Prop 37 Defeated: California Voters Reject Mandatory GMO-Labeling*, HUFFINGTON POST (L.A.) (Nov. 7, 2012), http://www.huffingtonpost.com/2012/11/07/prop-37-defeated-californ_n_2088402.html.

74 Deniza Gertsberg, *GMO Labeling Fights Multiply Across U.S.*, GMO JOURNAL: FOOD SAFETY POLITICS (Feb. 22, 2012), http://gmo-journal.com/2012/02/22/gmo-labeling-fights-multiply-across-u-s/.

labeling for all foods produced using genetic engineering."[75] Fifty-five Members of Congress wrote the FDA Commissioner in support of the petition.[76] An online campaign called "Just Label It" invited individuals to endorse this petition; more than six hundred thousand Americans commented in the first three months.[77]

On the state front, an initiative requiring the labeling of genetically engineered foods appeared on the November 2012 California ballot.[78] To qualify, the petition garnered over five hundred thousand valid signatures.[79] In all, nearly twenty states have considered labeling mandates.[80] In part, these actions indicate frustration with the lack of success GE opponents have encountered in securing federal regulation.[81]

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75 Petition Seeking Mandatory Labeling for Genetically Engineered Foods, Ctr. for Food Safety v. Taylor (USDA Oct. 11, 2011), *available at* http://www.centerforfoodsafety.org/files/ge-labeling-petition-10-11-2011-final.pdf.

76 Letter from Barbara Boxer, U.S. Senator, et al., to Hon. Margaret Hamburg, FDA Comm'r (Aug. 13, 2012), *available at* http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Issue_Briefs/feinstein-letter.pdf.

77 Moskin, *supra* note 60.

78 News Release, Debra Bowen, Cal. Sec'y of State, Eighth Measure Qualifies for November California Ballot (June 11, 2012), *available at* http://www.sos.ca.gov/admin/press-releases/2012/pdf/db12-068.pdf.

79 According to California Secretary of State, Debra Bowen,

> [i]n order to qualify, the food labeling initiative needed 504,760 valid petition signatures, which is equal to five percent of the total votes cast for governor in the November 2010 gubernatorial election. A measure can qualify via random sampling of petition signatures if the sampling projects a number of valid signatures greater than 110 percent of the required number. The food labeling initiative needed at least 555,236 projected valid signatures to qualify by random sampling, and it exceeded that threshold today.

Id. Though once predicted to pass, this measure was defeated after a hard-fought campaign. Almendrala, *supra* note 73. Reasons to explain the defeat of Proposition 37 include a "heavy-handed industry campaign" and the spending of $46 million by opponents. Marion Nestle, *Proposition 37 Take-Home Lesson: The Power of Money in Politics*, FOOD POLITICS (Nov. 9, 2012), www.foodpolitics.com/2012/11/election-take-home-lesson-the-power-of-money-in-politics/.

80 *Conn. Bill Looks to Add Labels to Engineered Food*, WALL ST. J. (Feb. 22, 2012), http://online.wsj.com/article/AP9410e654372640ea91fb0e55f4f8fecc.html. The Connecticut legislation failed to pass, as did a similar measure in Vermont. *Genetically Modified Food Labels Legislation Fails in Connecticut*, HUFF POST: GREEN (May 10, 2012), http://www.huffingtonpost.com/2012/05/10/genetically-modified-food-labels_n_1506897.html.

81 *See* Strauss, *supra* note 13, at 272–76 (discussing agency inaction); *id.* at 276–96 (discussing availability and limits of judicial review). *Cf.* Helena Bottemiller, *Advocates Launch New Campaign to Combat Antibiotics in Ag*, FOOD SAFETY NEWS (June 21,

B. Production of Meat, Poultry, and Dairy Products

If consumers are to evaluate accurately the safety and value of the animal-based foods they purchase, they must consider all stages of production, including both on-farm processes and those that take place after the animal leaves the farm. Concerns abound relating to the housing and feed of animals and the processing and packaging of meat. This section considers two examples, one involving FDA regulation of milk and the other USDA regulation of beef products.

1. Synthetic Hormones

An early controversy in animal agriculture involved the use of a synthetic hormone known as recombinant bovine somatotropin (rbST).[82] This hormone combines with naturally occurring bovine somatotropin (bST) to increase milk production in cows by up to ten percent.[83] Although bST occurs naturally in cows, the recombinant version is "one of the first major commercial biotechnology products . . . used in the U.S. food and agricultural sector."[84] The FDA approved the use of rbST as a new animal drug in 1993,[85] concluding that the hormone was safe for cows and that milk produced from such cows was safe for human consumption.[86] Because no test currently exists to "differentiate analytically between naturally occurring bST and [rbST] in milk," FDA concluded that the two types of milk were indistinguishable.[87] Thus, in FDA's view, any labeling referring to the

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2012), http://www.foodsafetynews.com/2012/06/advocates-launch-new-campaign-to-combat-antibiotics-in-ag/#.Ui_bRWTTVgK.

82 *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 69 (2d Cir. 1996); Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 632 (6th Cir. 2010).

83 *Boggs*, 622 F.3d at 632.

84 *Amestoy*, 92 F.3d at 75 (Leval, J., dissenting) (citation omitted).

85 Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279-04 (Feb. 10, 1994) (discussing the FDA's approval of rbST in an earlier regulation); *see generally* Animal Drugs, Feeds, and Related Products, 21 C.F.R. § 510 (2013); Sterile Sometribove Zinc Suspension, 21 C.F.R. § 522 (2013).

86 *Boggs*, 622 F.3d at 632; *See* Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279-04. FDA's findings would apply, by extension, to food products made from milk, such as yogurt and ice cream.

87 Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279-04. *See also* RICHARD RAYMOND ET AL., RECOMBINANT BOVINE SOMATOTROPIN (RBST): A SAFETY ASSESSMENT 3 (Mar. 22, 2010), *available at* http://www.naiaonline.org/uploads/WhitePapers/RecombinantSomatotropinASafetyAssessment2010.pdf ("There is no FDA-approved test that can differentiate between milk

presence, absence, or use of rbST was likely to be "misleading" and prohibited as misbranding under the FDCA.[88]

Though the scientific evidence appears inconclusive, many believe that the use of rbST harms dairy cows,[89] leading to the increased use of antibiotics that wind up in the food supply;[90] causes a number of health problems in humans, including cancer;[91] and impairs the quality of the milk.[92] Surveys showed that consumers favor labeling to reflect that milk has been produced with the use of rbST;[93] consumer demand for rbST-free dairy products has increased over time.[94]

2. Processed Beef Products

As noted above, the USDA rather than the FDA is assigned regulatory responsibility for most meat. Several recent controversies relate to practices in the production of meat products for retail sale. The most notorious involved the widespread use, including in school lunch programs and by fast-food chains, of "lean finely textured beef" (LFTB) produced from "fatty trimmings . . . once relegated to pet food and cooking oil."[95] Because such trimmings are "particularly susceptible to contamination" with the deadly pathogen *E. coli*, LFTB is injected with ammonia to kill the pathogen.[96] The use of trimmings

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from rbST-supplemented and non-supplemented cows."). Research for the report was sponsored by Elanco, an animal agriculture company. *See id.*

88 *See Boggs*, 622 F.3d at 632, 636.

89 *See About rbGH*, CENTER FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/1044/rbgh/about-rbgh (last visited Oct. 17, 2013) (discussing increased incidence of lameness, mastitis, reproductive disorders, and birth defects).

90 *Id.* (discussing allergic reactions and increased resistance to antibiotics).

91 *See Recombinant Bovine Growth Hormone*, AM. CANCER SOC'Y, http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/recombinant-bovine-growth-hormone (last revised Feb. 18, 2011) (discussing mixed evidence regarding breast and colorectal cancers).

92 *Boggs*, 622 F.3d at 636–37 (discussing the tendency of milk to sour more quickly).

93 *Id.*

94 *Id.* at 633; *see also Commonly Asked Questions About rbST*, CLOVER FARMS, http://www.cloverfarms.com/rbst.html (last visited Oct. 17, 2013) ("Currently there is not a test for [rbST]. There is no difference in the molecular structure of [rbST] and [bST]"). Clover Farms notes, however, that "[d]ue to growing consumer concerns, as part of our Quality Assurance Program, we have now asked our Clover Farms family farmers to pledge not to use the artificial growth hormone [rbST]." *Id.*

95 Michael Moss, *Safety of Beef Processing Method Is Questioned*, N.Y. TIMES (Dec. 30, 2009), http://www.nytimes.com/2009/12/31/us/31meat.html.

96 *Id.* (discussing the USDA's endorsement of ammonia treatment as safe).

that otherwise have "no functional value" as human food increases profits for producers and may lower prices for consumers.[97] Institutional customers bought the product "because its price [was] substantially lower than ordinary meat trimmings, saving about $1 million a year."[98] Beef Products, Inc. (BPI) says its product, described by others as a "mashlike substance frozen into blocks or chips," is "used in a majority of the hamburger sold nationwide."[99] Few outside industry or regulatory circles had ever heard of it.[100]

Hamburger meat produced in this fashion was widely sold to the general public without labeling as to the use of ammonia.[101] Because labels for meat must be approved prior to sale,[102] the industry "request[ed] that the ammonia be classified as a 'processing agent' and not an ingredient that would be listed on labels."[103] The USDA agreed; as a result, ground beef containing LFTB was allowed to be labeled as "100% ground beef"[104] precisely because ammonia was not considered an ingredient, while trimmings were considered "beef." Thus, consumers had no opportunity to learn that the ground beef they buy and consume contains ammonia. But LFTB eventually gave rise to both safety and economic adulteration issues. When ammonia was used in sufficient quantity to kill nearly all pathogens, "school lunch officials and other customers complained about the taste and smell of the beef."[105] BPI responded by reducing the level of ammonia used, rendering the product potentially unsafe.[106] The potential safety issues make labeling as to the use of ammonia all the more important.

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97 *Id.* (quoting David M. Theno, M.D., a food safety consultant). Producers originally developed the ammonia process as a way of addressing safety concerns in ground beef produced from trimmings. *Id.*

98 *Id.* (referring to the USDA school lunch program).

99 *Id.*; *see also* James Andrews, *BPI and 'Pink Slime': A Timeline*, FOOD SAFETY NEWS (Apr. 9, 2012), http://www.foodsafetynews.com/2012/04/bpi-and-pink-slime-a-timeline.

100 Moss, *supra* note 95.

101 *See generally* Andrews, *supra* note 99 (describing the product as "ubiquitous").

102 *See* LABELING & CONSUMER PROT. STAFF, USDA, A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS 7 (2007), *available at* http://www.fsis.usda.gov/PDF/Labeling_Requirements_Guide.pdf.

103 Moss, *supra* note 95.

104 Andrews, *supra* note 99 (citing *Pink Slime and You* (ABC News broadcast Mar. 7, 2012)).

105 Moss, supra note 95.

106 *Id.*; Andrews, *supra* note 99.

Consumer disgust grew rapidly as reports of the product, now popularly known as "pink slime," proliferated. [107] A 2012 survey showed that "88 percent of U.S. adults are aware of 'pink slime,' 76 percent are . . . 'at least somewhat concerned' and 30 percent are . . . 'extremely concerned.'"[108] In response to consumer demand, members of Congress introduced legislation requiring labeling of beef products containing LFTB[109] and wrote to Secretary of Agriculture Tom Vilsack urging the USDA to disallow use of LFTB in the school lunch program.[110] Several supermarkets announced that they would stop selling LFTB,[111] and some school districts announced that they would no longer use it.[112] Only then did USDA "agree[] to approve label requests by ground beef producers who wish to label their products that contain LFTB."[113] Meanwhile, BPI suspended production at three of its four plants due to loss of business.[114] Another producer filed for bankruptcy protection as a result of declining sales.[115]

Beyond the LFTB controversy, an additional processing concern relates to the mechanical tenderizing of meat by puncturing it with needles or blades.[116] Mechanical tenderization is an issue because the process allows pathogens like *E. coli* to travel from the surface of the intact cut of meat to the interior, where they are less likely to be killed by cooking. Consumers have been taught that intact cuts of beef are

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107 *See* Helena Bottemiller, *BPI Sues ABC News, Former USDA Officials for 'Pink Slime' Defamation*, FOOD SAFETY NEWS (Sept. 13, 2012), http://www.foodsafetynews.com/2012/09/bpi-sues-abc-news-former-usda-officials-for-pink-slime-defamation.

108 Andrews, *supra* note 99.

109 *Id.* (describing a bill that was introduced March 30, 2012, by Representative Pingree).

110 *Id.* (citing letter of March 14, 2012).

111 *Id.* (citing actions of March 20–23, 2012, by several large supermarket chains).

112 *Id.* (citing announcement of New York City Public Schools Chancellor on March 22, 2012).

113 *Id.* (citing USDA action of April 2, 2012). Unlike most other foods, meat products regulated by USDA are subject to a pre-approval requirement for all labels. *See* 21 U.S.C. § 607 (2012).

114 Andrews, *supra* note 99 (citing BPI's action of March 25, 2012). BPI recently sued ABC news for defamation of its product. Bottemiller, *supra* note 107.

115 Andrews, *supra* note 99 (citing action of AFA Foods on April 3, 2012).

116 *See* Mary Rothschild, *E. Coli Tests Spur Recall of Tenderized Beef in Maine*, FOOD SAFETY NEWS (Apr. 12, 2012), http://www.foodsafetynews.com/2012/04/e-coli-tests-spur-recall-of-tenderized-beef-in-maine.

safer than ground beef when cooked rare.[117] There is no labeling requirement to indicate that mechanical tenderization has taken place and to put consumers on notice that the meat should be cooked thoroughly. Paradoxically, the lack of labeling about this processing step keeps consumers ignorant of a potentially serious food safety issue and minimizes the chance that they will demand more complete information about meat production processes.

C. Use of Chemicals in Food Packaging

1. Bisphenol A (BPA)

Consumer anger prompted industry action in a controversy involving the use of an endocrine-disrupting chemical[118] known as Bisphenol A (BPA) in food containers including baby bottles and cups.[119] According to the Natural Resources Defense Council (NRDC),

> BPA is used to make polycarbonate plastics, which are commonly used in consumer products including baby bottles, sippy cups, and reusable water bottles. BPA can leach from these containers into the liquid inside. Another major use of BPA is in the resin lining of canned food and beverages, including beer and soda cans, and canned liquid infant formula. . . . BPA has been detected in infant formula, canned food, and canned beverages.[120]

Food producers use BPA in food packaging because the substance prevents interaction between metal cans and the foods inside them;

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117 *See* Sandra McCurdy, *Ground Beef: Safe Handling and Cooking*, FOOD SAFETY NEWS (Aug. 31, 2009), http://www.foodsafetynews.com/2009/08/ground-beef-the-importance-of-safe-handling-practices-and-accurate-final-product-temperature/ ("Although other meats have caused foodborne illness, there are several attributes of ground beef which suggest that more careful handling–particularly use of a thermometer to cook to 160°F– is required. . . . The process of grinding distributes any pathogens present throughout the meat. In contrast, whole muscle cuts of meat that have not been tenderized or injected with an enhancement fluid, are considered 'pathogen free' in the interior portion of the meat.").

118 *See* Michele Simon, *BPA Is FDA's Latest Gift to Food Industry*, FOOD SAFETY NEWS (Apr. 5, 2012), http://www.foodsafetynews.com/2012/04/bpa-is-fdas-latest-gift-to-food-industry.

119 *See* Gretchen Goetz, *BPA Banned from Baby Bottles, Sippy Cups*, FOOD SAFETY NEWS (July 18, 2012), http://www.foodsafetynews.com/2012/07/bpa-banned-from-baby-bottles-sippy-cups.

120 Sarah Janssen, *Our Patience Has Run Out, NRDC Sues FDA for Failure to Regulate BPA*, SWITCHBOARD: NRDC STAFF BLOG (June 29, 2010), http://switchboard.nrdc.org/blogs/sjanssen/our_patience_has_run_out_nrdc.html.

such interactions may affect flavor.[121] Containers made with BPA are also clear, lightweight, and shatter-resistant.[122] BPA-free containers are available but either cost more or are less effective.[123]

Scientific studies have linked the use of BPA with increased rates of "everything from cancer to heart disease to fertility problems, and . . . even obesity";[124] BPA has also been linked to early puberty in humans.[125] Despite these concerns, the FDA continued to approve use of BPA in food containers, including those intended for baby food.[126] Consumers responded by declining to purchase baby products containing BPA.[127] This consumer reaction caused the industry, in a petition filed by the American Chemistry Council, to urge the FDA to ban use of BPA in baby products.[128] The FDA agreed, "not because BPA is unsafe when used in these products, but because the substance simply isn't 'used' in [baby bottles or cups] anymore."[129] BPA is still approved for use in other food packaging.[130] Under these conditions, industry is likely to find it advantageous to continue using BPA in packaging foods not intended for infants.

2. Modified Atmosphere Packaging (MAP)

The food industry uses Modified Atmosphere Packaging (MAP)[131] to help extend the shelf life of packaged foods including fresh meat,[132]

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121 Nina Notman, *BPA: Friend or Foe?*, ROYAL SOC'Y OF CHEMISTRY (Nov. 20, 2012), www.rsc.org /chemistryworld/2012/11/bpa-bisphenol.

122 *Id.*

123 Jenn Savedge, *Campbell's Soup to Phase out BPA*, MOTHER NATURE NETWORK (Mar. 7, 2012), http://www.mnn.com/food/healthy-eating/blogs/campbells-soup-to-phase-out-bpa.

124 Simon, *supra* note 118.

125 *See* Adam Hinterthuer, *Just How Harmful Are Bisphenol A Plastics?*, SCI. AM. (Aug. 26, 2008), http://www.scientificamerican.com/article.cfm?id=just-how-harmful-are-bisphenol-a-plastics ("[D]ozens of scientists around the globe have linked BPA to myriad health effects in rodents: mammary and prostate cancer, genital defects in males, early onset of puberty in females, obesity and even behavior problems such as attention-deficit hyperactivity disorder").

126 Simon, *supra* note 118.

127 Goetz, *supra* note 119.

128 *Id.*

129 *Id.*

130 *Cf. id.*

131 MAP is one form of a broader category of reduced oxygen packaging methods. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., FDA FOOD CODE 2009: ANNEX 6–FOOD PROCESSING CRITERIA (2009), *available at* http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm188201.htm.

fresh fruits and vegetables,[133] and dairy products like cheese.[134] Depending on the specific food in question, air in the package is replaced with either a single gas or a mix of gases.[135] One of the gases used in MAP, particularly in the packaging of fresh meat, is carbon monoxide.[136]

MAP can "extend shelf life by slowing respiration, maintain appearance by slowing color development, maintain texture by slowing softening, maintain quality by slowing the growth of some microorganisms, and preserve flavor by slowing use of sugars during respiration."[137] MAP can keep beef looking red for weeks.[138] MAP will not, however, "improve quality . . . , contribute to product safety, improve flavor, or make the product more nutritious."[139] Nor does MAP significantly inhibit the growth of "many bacteria associated with foodborne illness, such as *Clostridium* spp., *Campylobacter* spp., and *Listeria* monocytogenes."[140]

MAP has "become more widely used [in the packaging of meat] as supermarkets eliminate their butchers and buy precut, 'case-ready' meat from processing plants."[141] According to one study, retailers lost at least $1 billion a year as safe and fresh meat turned brown from exposure to oxygen.[142] Although meat that appears brown may be "fairly fresh and perfectly safe, consumers simply judged meat's freshness by its color[,]"[143] preferring cuts with a redder appearance.

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132 *See* P.I. Zakrys-Waliwander et al., *The Effects of High Oxygen Modified Atmosphere Packaging on Protein Oxidation of Bovine* M. Longissimus Dorsi *Muscle During Chilled Storage*, 131 FOOD CHEMISTRY 527 (2012).

133 *See* Krishi Vigyan Kendra et al., *Modified Atmosphere Packaging of Fresh Produce: Current Status and Future Needs*, 43 FOOD SCI. & TECH. 381–92 (2010).

134 *See* Preeti Singh et al., *The Use of Carbon Dioxide in the Processing and Packaging of Milk and Dairy Products: A Review*, 65 INT'L J. DAIRY TECH. 161–77 (2012).

135 *Frequently Asked Questions*, EUR. FOOD INFO. COUNCIL, http://www.eufic.org/page/en/page/FAQ/faqid/what-is-modified-atmosphere-packaging-map/ (last visited Oct. 17, 2013).

136 *Id.*

137 Devon Zagory, *What Modified Atmosphere Packaging Can and Can't Do for You*, WASH. ST. UNIV. (Mar. 14, 2000), http://postharvest.tfrec.wsu.edu/pages/PC2000X.

138 Marian Burros, *Which Cut is Older? (It's a Trick Question)*, N.Y. TIMES (Feb. 21, 2006), http://www.nytimes.com/2006/02/21/national/21meat.html.

139 Zagory, *supra* note 137.

140 EUR. FOOD INFO. COUNCIL, *supra* note 135.

141 Burros, *supra* note 138. MAP is also widely used to preserve the freshness of fruits and vegetables on their long journey from field to table. Kendra et al., *supra* note 133.

142 *See* Burros, *supra* note 138 (citing study that was conducted at Oklahoma State University for the Cattlemen's Beef Board in 2003).

143 *Id.*

While USDA considers the use of carbon monoxide itself to be safe, the artificial preservation of a red color may preclude consumers from evaluating the freshness of the product or its safety for consumption.[144] So far, the USDA has not responded to requests for labeling.[145] Some supermarkets report that they do not carry MAP-treated meat, but Cargill reported that it sold 100 million packages of it in 2005.[146]

In sum, controversies including the use of GE technology, the injection of dairy cows with artificial hormones, the inclusion of trimmings treated with ammonia in ground beef, and the packaging of foods in contact with harmful substances or in ways designed to enhance apparent freshness illustrate a few of the many situations in which consumers are unable to evaluate the foods they purchase and consume. When consumers become aware of the ways in which food is produced, processed, and packaged they demand information and change. Ironically, consumers have so little awareness of many such practices that they often fail to assert their concerns.

II
THE MISMATCH BETWEEN CONSUMER DEMAND AND CURRENT REGULATORY APPROACH

As recounted above, consumers' reactions upon learning of various process-related attributes of their food have been to demand information about their food and changes to the system that produces it. Consumers, for example, overwhelmingly favor labeling as to use of GE technology,[147] much as they strongly favored labeling of milk as to the use of synthetic hormones to increase milk production.[148]

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144 *Id.* (describing length of time the MAP-treated beef remained red, even under improper storage conditions).

145 *See Fact Sheet: Modified Atmosphere Packaging Using Carbon Monoxide*, NAT'L CATTLEMEN'S BEEF ASS'N, http://www.beefusa.org/uDocs/factsheet.doc (last visited Oct. 17, 2013) ("[USDA's] Food Safety and Inspection Service (FSIS) reviewed scientific data on modified atmosphere packaging using carbon monoxide. FSIS does not require labeling for modified atmosphere gases, including carbon monoxide. As such, similar to uses of other MAP gases (e.g., nitrogen), there are no labeling issues in regard to meat cuts and ground meat packaged using this MAP system.").

146 Burros, *supra* note 138.

147 *See supra* text accompanying notes 72–74.

148 Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 75 (2d Cir. 1996) (Leval, J., dissenting).

The *Supermarket Guru* recently discussed food shoppers' quest for a wide range of information, predicting that

> [m]ore shoppers are interested in knowing not only where their foods are coming from, but also want to know about the people making their foods . . . . Shoppers are spending the time and reading more food packages as they shop the aisles in the supermarkets. They are looking for real information . . . . Food transparency is here to stay.
>
> . . . .
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> As we have seen over the past twelve months, people are choosing their foods more holistically based on all the "food factors"; taste, ingredients, source, nutritional composition as well as asking who is making their foods along with understanding the impact on our environment and animal welfare.
>
> We predict that 2013 will be a transitional year as on package claims proliferate and may confuse; look for supermarkets to take up the role of gatekeeper and actually demand proof . . . of these claims before they will permit them to be sold on their shelves.[149]

The FDCA was enacted in large part in order to "provide . . . sufficient information on the labels of food products so that reasoned and informed shopping decisions could be made"[150] and to "promote honesty and fair dealing in the interest of consumers."[151] As the Supreme Court recited in an early decision, the FDCA is intended "to make it possible that the consumer should know that an article purchased was what it purported to be. . . . "[152] The objective of protecting consumers from "economic adulteration"[153] of their food is

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149 Phil Lempert, *The Lempert Report: Top Ten Food Trends 2013 (Trends #6-10)*, SUPERMARKET GURU (Dec. 12, 2012), http://www.supermarketguru.com/articles/top-ten-food-trends-2013-(trends-6-10).html.

150 Am. Frozen Food Inst. v. Mathews, 413 F. Supp. 548, 551 (D.D.C. 1976).

151 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. 593, 594 (1951). The phrase appears in the statutory provision conferring authority on the Secretary to promulgate standards of identity, quality, and fill for any food. 21 U.S.C. § 341 (2012). It appears, however, that Congress viewed "honesty and fair dealing" as an overall objective of the Act. *See* H.R. REP. NO. 75-2139, at 1–2 (1938) ("While the [1906] law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions. The [1938] measure contains substantially all the features of the old law that have proved valuable in promoting honesty and fair dealing.").

152 United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 409 (1914) (discussing the legislative intent behind the 1906 Pure Foods and Drugs Act).

153 "Economic adulteration" results from the substitution of cheaper ingredients for those expected, even if the substituted ingredients are not deleterious. United States v. 306

of equal importance in the Act as the objective of "ensur[ing] the purity of the Nation's food supply."[154] The Supreme Court noted further, in a case involving over-the-counter drugs, that it is especially important "to protect consumers who under present circumstances are largely unable to protect themselves . . . ."[155] Federal regulators, however, have been slow to respond to consumer demand and have taken a narrow view of their authority. This Part details FDA and USDA responses to the controversies described above and then describes some consequences of regulatory inaction.

A. Regulatory (In)Action

The FDA's response to consumer demand for regulation of various food production processes often hinges on the assertion that FDA lacks authority to regulate such matters. The Agency appears to read the statute unduly narrowly and fails to implement authority that FDA itself sometimes admits it has.

1. The Use of GE Technology in Food Production

With respect to the use of GE technology, FDA's 1992 Statement of Policy admits that "FDA has ample authority under [existing] food safety provisions to regulate and ensure the safety of foods derived from new plant varieties, including plants developed by new techniques. This includes authority to require, where necessary, a premarket safety review by FDA prior to marketing of the food."[156]

Cases Containing Sandford Tomato Catsup with Preservative, 55 F. Supp. 725, 726 (E.D.N.Y. 1944).

154 Young v. Cmty. Nutrition Inst., 476 U.S. 974, 976 (1986). *See also* H.R. REP. NO. 75-2139, at 2 (discussing twin objectives "to safeguard the public health and prevent deception").

155 Kordel v. United States, 335 U.S. 345, 349 (1948). The FDCA applies equally to food, drugs, medical devices, and cosmetics; "adulteration" and "misbranding" are not defined separately for each. *See* United States v. Sullivan, 332 U.S. 689, 694 (1948). The "circumstances" to which the *Kordel* Court refers are the "circumstances of modern industrialism," *62 Cases*, 340 U.S. at 596, in which "the number, variety, and varying combinations of . . . ingredients tend to confuse . . . consumers . . . [whose lack of] knowledge essential to discriminating purchase" leave them vulnerable to "exploitation by the sale of foods . . . of whose inferior or unsuitable quality they are not informed." Fed. Sec. Adm'r v. Quaker Oats, 318 U.S. 218, 226 (1943). Professor Van Tassel provides a useful discussion of the particular types of consumer vulnerability the 1938 Act was intended to address. Van Tassel, *supra* note 6 (manuscript at 33).

156 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22988 (May 29, 1992). This authority relates to the potential adulteration of foods. The Advisory Committee on Biotechnology and 21st Century Agriculture—known as AC21—

FDA has not, however, "found it necessary to conduct, prior to marketing, routine safety reviews of whole foods derived from" GE plant varieties.[157] FDA also has authority to subject "food additives" to a more stringent safety review.[158] FDA notes that "in the case of foods derived from new plant varieties, it is the transferred genetic material and the intended expression product or products that could be subject to food additive regulation, if such material or expression products are not GRAS [or generally recognized as safe]."[159] These provisions would seem to authorize much more review and regulation of GE technologies in food production than the FDA has exercised to date.

But the FDA reads an exception into the statute exempting from regulation foods that are "not significantly different" from traditional foods.[160] If not different in identity or composition from their

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was created in 2003. Dan Flynn, *AC21 Report Won't Drop Until After Election*, FOOD SAFETY NEWS (Aug. 31, 2012), http://www.foodsafetynews.com/2012/08/ac21-report-wont-drop-until-after-election/. The Committee was "charged with examining the long-term impacts of biotechnology on the U.S. food and agriculture system . . . and providing guidance to USDA." *Advisory Committee on Biotechnology & 21st Century Agriculture* (AC21), USDA, https://www.usda.gov/wps/portal/usda/usdahome?navid=BIOTECH_AC21&navtype=RT&parentnav=BIOTECH (last modified Feb. 27, 2013). The Committee's report, issued in November 2012, stated that

> the AC21 will present a package of recommendations for USDA-led activities intended to:
>
> • educate farmers and others in the food and feed production chain about coexistence and the importance of coexistence and their roles, particularly with reference to stewardship, contracting, and attention to gene flow, in making it work;
>
> • provide farmers with tools and incentives to promote coexistence through its farm programs and coordination with other entities;
>
> • conduct research in a range of areas that are integral to understanding the current state of coexistence and gene flow management, as well as the development of improved tools and practices to manage coexistence in the future;
>
> • provide increased assurance about the quality and diversity of U.S. seed and germplasm resources; and
>
> • provide a framework for the establishment of a system of compensation for actual economic losses for farmers intending to grow identity-preserved products, if the Secretary determines that there are adequate loss data to justify such a step.

USDA ADVISORY COMM. ON BIOTECHNOLOGY & 21ST CENTURY AGRIC. (AC21), ENHANCING COEXISTENCE: A REPORT OF THE AC21 TO THE SECRETARY OF AGRICULTURE (Nov. 19, 2012), *available at* http://www.usda.gov/documents/ac21_report-enhancing-coexistence.pdf.

157 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22988.

158 *Id.* at 22989.

159 *Id.* at 22990.

160 *See* Strauss, *supra* note 13, at 272; Van Tassel, *supra* note 6 (manuscript at 16).

traditional counterparts, the logic runs, foods derived from GE technology must be "generally recognized as safe." Treating a new process as GRAS essentially gives that process a free ride on the historical safety of a traditional food produced *without* use of the new process. To illustrate, the FDA generally "does not anticipate that transferred genetic material would itself be subject to food additive regulation. Nucleic acids are present in the cells of every living organism, including every plant and animal used for food by humans . . . , and do not raise a safety concern as a component of food."[161] Only in the event that "the intended expression product in a food could be a protein, carbohydrate, fat or oil, or other substance that differs significantly in structure, function, or composition from substances found currently in food" would FDA require premarket review.[162] This approach indulges many assumptions about the safety of new processes, rather than requiring scientific evidence of safety prior to marketability. Whether this view is based on reliable science may be open to question, but it is not well founded in the statutes regulating our food supply.

This view seems to fly in the face of the text, history, and existing interpretations of the FDCA. The concept of "significant difference," or its opposite, "substantial equivalence,"[163] nowhere appears in the food provisions of the FDCA.[164] The term "substantial equivalence" does appear in several sections of the FDCA relating to drugs and medical devices.[165] Although the Act applies equally to food, drugs, and devices in terms of its broad purposes and its general prohibitions,[166] different regulatory regimes apply to drugs and medical devices than to food.[167] It seems unlikely that Congress intended a specific standard it used with respect to one category of products to be applied to another category where the term was

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161 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22990.

162 *Id.*

163 Professor Van Tassel uses the term "bioequivalence." *See* Van Tassel, *supra* note 6 (manuscript at 17).

164 *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301-399 (2012).

165 *Id.*

166 *Id.*

167 *See* 21 U.S.C. § 355 (establishing extensive pre-market testing and approval process for drugs and medical devices).

conspicuously absent.[168] It appears that FDA may have simply imported the concept of "substantial equivalence" into food regulation from the drug arena and then conflated this concept with the actual standard for misbranding of food: "facts material" to consumers.[169]

Much of the concern that motivated passage of the 1938 Act was the advent of new food technologies and the prospect that consumers would be defrauded or their health endangered by new processes whose effect consumers could not assess for themselves at the point of purchase.[170] The FDA's use of the "substantial equivalence" approach deprives consumers of an important protection that the FDCA provides: the assurance that foods produced using additives or processes that Congress (via the FDCA) deems "unsafe"[171] cannot be sold in interstate commerce absent scientific proof of safety.

In addition, the FDA has authority to require labeling regarding GE production or ingredients under the misbranding provision. As the FDA itself noted in 1992, the statute requires food producers to "reveal all facts that are material in light of representations made or suggested by labeling or with respect to consequences that may result from [the] use" of the product.[172] But, "[t]o date, FDA has not considered the methods used in the development of a new plant variety . . . to be material information within the meaning of [section 321(n)]."[173] Instead, the "FDA believes that the new techniques are extensions at the molecular level of traditional methods and will be used to achieve the same goals as pursued with traditional plant breeding."[174] Thus, information that a food was produced using GE technology "would not usually be required to be disclosed in labeling for the food."[175]

The FDA's use of the "substantial equivalence" approach departs significantly from the statutory prohibition on misbranding by

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168 *See* WILLIAM N. ESKRIDGE, JR., ET AL., LEGISLATION AND STATUTORY INTERPRETATION 263–64 (2d ed. 2006) (discussing cases applying similar presumption).

169 *Cf.* Van Tassel, *supra* note 6 (manuscript at 17) (discussing concepts of "bioequivalence" and materiality).

170 *See generally* Wesley E. Forte, *The Food and Drug Administration and the Economic Adulteration of Foods*, 41 IND. L.J. 346, 346–402 (1966) (recounting the history of the FDA's regulation of economic adulteration).

171 21 U.S.C. § 348 (2012).

172 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22991 (May 29, 1992) (citing sections 343(a) and 321(n) of the United States Code).

173 *Id.*

174 *Id.*

175 *Id.*

allowing producers to omit material facts from food labels. Materiality of facts ought to be judged by reference to consumers' expectations. The consumer-centered nature of the misbranding provision is clear from statements of the FDA itself and of courts applying the provision in specific cases.[176] Substantial equivalence, by contrast, is a determination that focuses on producers' claims, market conditions, or other matters outside consumers' knowledge. Whether a GE-produced food is or is not the "substantial equivalent" of its traditionally-produced counterpart is not a determination that consumers can make for themselves, particularly when they are not informed of the use of the new technology. What consumers want and deserve is the opportunity to choose for themselves what kinds of food to purchase and eat. Though most consumers cannot judge the safety of food technologies or additives, they can decide for themselves what their values dictate with respect to the intimate choice of what to eat.

The FDA's 1992 Policy Statement on Foods Derived from New Plant Varieties articulates and depends on the substantial equivalence concept. As noted above, the FDA considers the pre-market approval process for food additives unnecessary in the case of foods produced using GE technology. This policy was challenged on both procedural and substantive grounds in *Alliance for Bio-Integirty v. Shalala.*[177]

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176 *See* Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed. Reg. 78002-01, 78003–04 (Dec. 20, 2002); *see also* United States v. 88 Cases, More or Less, Containing Bireley's Orange Beverage, 187 F.2d 967 (3d Cir. 1951) (discussing "ordinary" versus "ignorant" consumers in context of economic adulteration charge).

177 Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000). The district court noted that from the time of adoption of the Statement of Policy in 1992 until 2000, "[a]t least thirty-six foods, genetically altered through rDNA technology, have been marketed." *Id.* at 170. Challenges to the Statement of Policy included, among others, that "the Statement was not properly subjected to notice-and-comment procedures; . . . [that] the FDA's presumption that rDNA-developed foods are GRAS and therefore do not require food additive petitions under 21 U.S.C. § 321(s) is arbitrary and capricious; [and that] the FDA's decision not to require labeling for rDNA-developed foods is arbitrary and capricious." *Id.* The Alliance for Bio-Integrity describes itself as follows:

> The *Alliance for Bio-Integrity* is a nonprofit, nonpolitical organization dedicated to the advancement of human and environmental health through sustainable and safe technologies. To this end, it aims (a) to inform the public about technologies and practices that negatively impact on health and the environment and (b) to inspire broad-based, responsible action that helps correct the problems and uphold the integrity of the natural order.

One substantive challenge related to the presumption that foods produced using GE technology are GRAS; the other involved the FDA's decision not to require labeling of genetically engineered foods. The latter decision in turn rests on the FDA's presumption that GE foods are GRAS, and therefore that the use of GE processes in production is not a "material" fact.

With respect to the GRAS presumption, the district court noted that its review was circumscribed by the *Chevron* doctrine requiring deference to agencies on matters committed to their discretion and expertise.[178] The court admitted that the food additive provisions include a broad definition of "food additive" and are intended "to require the processor who wants to add a new and unproven additive to accept the responsibility of first proving it safe for ingestion by human consumption."[179] But because the FDA considers foods produced via GE technology not to differ materially from traditionally-produced foods, in the agency's view there are no "additives" to trigger review. The court's deference may have been misplaced, as *Chevron* requires deference only to the extent that the statute is silent or ambiguous. Under the statute, a finding of "safety" requires both technical evidence of safety and acceptance of such evidence in the scientific community.[180] Scientific assessment of GE technology arguably fails to meet this standard even today. In any event, the FDA has not required producers to demonstrate the requisite level of safety. That approach is inconsistent with statutory text.

The Bio-Integrity plaintiffs presented evidence of "significant disagreement . . . among scientific experts as to whether or not nucleic acid proteins are generally recognized to be safe."[181] The court found, however, that this evidence was not in the record before the FDA. Accordingly, the court found the FDA's GRAS presumption neither arbitrary nor capricious.[182] But the statute

Purpose and Goals, ALLIANCE FOR BIO-INTEGRITY, http://www.biointegrity.org/#anchor2468503 (last visited Oct. 17, 2013).

178 *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 176–77 (quoting Int'l Fabricare Inst. v. EPA, 972 F.2d 384, 389 (D.C. Cir. 1992)) ("The rationale for deference is particularly strong when the [agency] is evaluating scientific data within its technical expertise").

179 *Id.* at 177 (quoting S. REP. NO. 85-2422, at 2 (1958)).

180 21 U.S.C. § 321(s) (2012).

181 *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177.

182 *Id.* (suggesting that relevant evidence was not in the record considered by the FDA and could not now be considered by the court).

unambiguously demands that the *producer* establish the safety of a new process. The FDA's failure to demand evidence of safety of GE technology in food production contravenes the statute and is not entitled to deference.

As for labeling, the statutory escape route relates to the lack of any "facts material" in light of representations made on the label. The FDA relied on the GRAS presumption again in deciding that foods produced with GE technology need not be labeled as to that fact.[183] The court noted that the statute itself does "not squarely address[] whether materiality pertains only to safety concerns or whether it also includes consumer interest."[184] Because the statute is ambiguous on this point, *Chevron* requires that the agency's decision be upheld provided that it is reasonable.[185] The *Bio-Integrity* court found the "FDA's exclusion of consumer interest from the factors which determine whether a change is material" to be a "reasonable interpretation of the statute."[186] In short, the court accepted the FDA's view that it is "without authority to mandate labeling."[187] In fact, however, the GRAS concept is entirely absent from section 343, which regulates labeling in great detail.[188] Many substances that are unquestionably safe are required to be listed on labels. The standard for what makes a label misleading is not whether the substance in question is safe but rather whether information about that substance is "material" to consumers.[189] Consequently, the FDA's failure to require labeling as to the use of GE technology, on the ground of its supposed safety—even if eventually established as true— contravenes the statute's focus on material facts and thus is not a reasonable interpretation entitled to deference.

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183 *Id.* at 178.

184 *Id.*

185 *Id.* (citing Chevron U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837 (1984)).

186 *Id.* at 179 (internal quotation marks omitted).

187 *Id.*

188 *See* 21 U.S.C. § 343 (2012).

189 *See id.* § 343(a). A 2012 study linked the ingestion of GE corn (or the herbicides the modification allows the corn plant to tolerate) to tumors, organ damage, and premature death in rats. *See* Séralini et al., *supra* note 70. Though the science remains in dispute, *see* Salzberg, *supra* note 70, these findings add to the urgency of the matter in the minds of consumers.

2. Production of Meat, Poultry, and Dairy Products

a. Synthetic Hormones

As noted, the FDA in 1993 approved the use of injectable rbST, having concluded that the hormone "is safe and effective for dairy cows, that milk from rbST-treated cows is safe for human consumption, and that production and use of the product do not have a significant impact on the environment."[190] The FDA's Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin states unequivocally that "the agency found that there was no significant difference between milk from treated and untreated cows *and, therefore, concluded that* under the Federal Food, Drug, and Cosmetic Act . . . *the agency did not have the authority* in this situation *to require special labeling for milk from rbST-treated cows.*[191] According to the FDA, "[b]ecause of the presence of natural bST in milk, no milk is 'bST-free,' and a 'bST-free' labeling statement would be false."[192] The Guidance thus states that producers may not use such statements even voluntarily. The FDA also suggests that any statement implying a difference in the milk would be false, given the FDA's conclusion that "there [are no] measurable compositional differences" between the two types of milk.[193] The FDA determined, however, responding in part to inquiries from food companies, that companies could use any statements that "are truthful and not misleading" in their labeling.[194] Thus, "food companies that do not use milk from cows supplemented with rbST may voluntarily inform consumers of this fact in their product labels or labeling."[195] The FDA also asserted that its Guidance document was "intended to give states assistance in formulating their own labeling laws."[196]

In response, at least two states—Vermont and Ohio—enacted labeling laws. The Vermont law compelled processors of milk

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190 Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6279–80 (Feb. 10, 1994) (approval pursuant to FDA's authority over drugs used on animals).

191 *Id.* at 6280 (emphasis added).

192 *Id.*

193 *Id.*

194 *Id.*

195 *Id.*

196 Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 633 (6th Cir. 2010).

products produced with the use of rbST and offered for retail sale in Vermont to label them as such, offering four labeling options to meet the statutory mandate.[197] The Vermont statute was challenged by dairy producers as infringing their right not to speak.[198] The Second Circuit upheld the challenge, enjoining the Vermont statute.[199]

Ohio's Department of Agriculture, by contrast, promulgated a regulation prohibiting dairy processors from making claims about the absence of rbST in their milk and required producers to include a disclaimer along with any claim that rbST was not used in the production of the milk.[200] Dairy-processor trade associations challenged this action as violating their commercial free speech rights by compelling them to use the disclaimer.[201] The Sixth Circuit, though cognizant of the earlier ruling by the Second Circuit, concluded that Ohio's bans on composition claims and production claims regarding rbST were invalid.[202]

The crux of the matter with respect to voluntary labeling of milk, then, is what is "misleading." The FDA noted that "both the presence and the absence of information are relevant" to this determination.[203] "Thus, [in the FDA's view,] certain labeling statements about the use of rbST may be misleading unless they are accompanied by additional information."[204] Accordingly, the FDA concluded that statements about the "difference in the way milk is produced," such as that the milk came "from cows not treated with rbST," would be permissible only with a disclaimer to make clear that "milk from untreated cows is [not] safer or of higher quality than milk from treated cows."[205] According to the FDA, such a reference to the identity of milk as milk is necessary to provide "proper context" for even a truthful statement

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197 VT. STAT. ANN. tit. 6, § 2754(c) (repealed 1998); *see* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 69–70 (2d Cir. 1996) (holding Vermont's statute requiring notification and labeling unconstitutional).

198 Int'l Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246, 251–52 (D. Vt. 1995), *rev'd*, 92 F.3d 67 (2d Cir. 1996).

199 *Amestoy*, 92 F.3d at 74.

200 *Boggs*, 622 F.3d at 634.

201 *Id.* at 635.

202 *Id.* at 650.

203 Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994).

204 *Id.*

205 *Id.*

about production methods that "has the potential to be misunderstood by consumers."[206]

In evaluating the potential to mislead, both the Second Circuit and the Sixth Circuit considered the FDA's position that "there is no significant difference between milk from [rbST-] treated and untreated cows,"[207] but the two courts came to opposite conclusions. The circuit split has not been resolved.[208] Meanwhile, many producers have bowed to consumer pressure and have begun voluntarily to label their milk to inform consumers that synthetic hormones were not used in its production.

b. Lean Finely Textured Beef (LFTB)

The regulatory history of LFTB extends over four decades and involves both the FDA and the USDA. In 1974, the FDA declared food-grade ammonium hydroxide safe for human consumption.[209] In 1993, the USDA approved Beef Products, Inc.'s method of "separating lean beef from fatty, boneless trimmings" and using material from the trimmings in ground beef.[210] In 2001, "[t]he FDA and USDA approve[d] BPI's pH Enhancement System to treat lean beef with ammonium hydroxide as a processing aid meant to eliminate pathogens" otherwise present in higher concentration in trimmings.[211] Several years later, the USDA announced that "BPI's ammonia treatment destroys E. coli 'to an undetectable level'" and exempted BPI from routine E. coli testing.[212] Meanwhile, LFTB became "so ubiquitous that anyone who ate ground beef . . . likely consumed it . . . ."[213] It turned out, however, that ground beef made from trimmings processed with sufficient ammonia to kill the pathogens was unpalatable, and trimmings treated with little enough ammonia to be palatable carried a higher risk of contamination.[214] As news of the LFTB saga emerged, consumer disgust grew. By early

206 *Id.*

207 Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 70 (2d Cir. 1996) (quoting VT. STAT. ANN. tit. 6. § 2754 (repealed 1998)).

208 Chen, *supra* note 33, at 215 (describing a "stalemate").

209 *See* FDA, SELECT COMMITTEE ON GRAS SUBSTANCES (SCOGS) OPINION: AMMONIUM HYDROXIDE (1974), *available at* www.fda.gov/ForConsumers/ConsumerUpdates/ucm260862.htm.

210 Andrews, *supra* note 99.

211 *Id.*

212 *Id.*

213 *Id.*

214 *See supra* notes 106–07 and accompanying text.

2012, "McDonald's announce[d] that it ha[d] stopped adding LFTB to its burgers."[215]

One major purchaser of LFTB was the USDA itself, with the ground beef destined for use in the school lunch program. The USDA was attracted by the lower cost of LFTB compared to other ground beef.[216] But the use of LFTB led to problems. After "find[ing] E. coli O157:H7 in BPI products for a third time" in 2009, USDA officials responsible for the school lunch program halted shipments of LFTB to the school lunch program for a time.[217] At this point, school districts had neither knowledge of the product's use in school lunches nor a choice in the matter.[218] The USDA announced in March 2012 that "it [would] allow school districts . . . to opt out of serving LFTB-supplemented ground beef."[219] Soon thereafter, several school districts announced that they had opted out of using LFTB in school lunches.[220] Meanwhile, the USDA itself was still "plan[ning] to buy 7 million pounds of LFTB . . . in the coming months for the national school lunch program,"[221] apparently for schools that did not opt out.

Definitions are the key to understanding the USDA and the FDA's actions regarding the use of ammonia to kill pathogens. Although ammonia would appear to meet the statutory definition of a "food additive," both the USDA and the FDA consider it an incidental "processing aid"[222] that does not remain in food in significant levels

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215 Andrews, *supra* note 99. Numerous other fast-food restaurant chains and major supermarket chains followed suit. *Id.*

216 *Cf.* Dave Dreeszen, *USDA: Most School Districts Reject LFTB*, SIOUX CITY J. (June 5, 2012), http://siouxcityjournal.com/business/local/usda-most-school-districts-reject-lftb/article_d7b4b106-76dc-506f-81ba-d78619d245ab.html (ascribing to the USDA the view that beef that does not contain LFTB is expected to cost three percent more than beef that contains it).

217 Andrews, *supra* note 99. It is unclear when shipments to the school lunch program resumed.

218 Dreeszen, *supra* note 216 (stating that "virtually all districts last year received beef containing as much as 15 percent LFTB"). Prior to 2012, USDA simply purchased beef containing LFTB for the school lunch program and distributed it to school districts. *Id.*

219 Andrews, *supra* note 99.

220 *Id.*

221 *Id.*

222 FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products (U.S.D.A. 2013), *available at* http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1.pdf (listing ammonium hydroxide as both an Acidifier/Alkalizer and an Antimicrobial).

after processing or affect the food in a technical or functional way.[223] Because processing aids by definition do not remain in the finished food, they are not "ingredients" required by statute to be listed on the label.[224] Ammonia's classification as a processing aid persisted despite complaints[225] that consumers could smell and taste the substance in finished ground beef, suggesting that it did remain in the food in significant levels. Alternatively, because ammonium hydroxide is considered to be GRAS,[226] it is not a food additive. Thus, the strict review accorded to food additives is not required.

In April 2012, the USDA granted ground beef processors' requests for approval to label their products containing LFTB.[227] The USDA's action was not to *require* labeling reflecting the incorporation of LFTB into the finished product.[228] For meat, unlike most other foods, even voluntary labels must be pre-approved.[229] The USDA's announcement means simply that its "inspectors will certify labels such as 'Contains Lean Finely Textured Beef,' 'Contains Finely

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223 *See* Helena Bottemiller, *Slimegate: Should USDA Require Labeling for LFTB?*, FOOD SAFETY NEWS (Apr. 3, 2012), http://www.foodsafetynews.com/2012/04/slimegate-should-usda-require-labeling-for-lftb/.

> In a USA Today Op-Ed, former USDA Food Safety and Inspection Service administrator Dr. H. Russel Cross declared that '[t]here is no need for labeling LFTB—because nothing is being added that is not beef.' Likewise, in a recent video to help combat 'a frenzy of misinformation' about LFTB, American Meat Institute spokeswoman Janet Riley added a similar justification for not labeling LFTB: 'Both citric acid and ammonium hydroxide are natural processing aids, not additives or ingredients because they don't remain in the product.'

Id.

224 21 U.S.C. § 601(n)(9) (2012).

225 *See supra* note 105 and accompanying text.

226 21 C.F.R. § 184.1139(c) ("[Ammonia] is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use: (1) The ingredient is used as . . . a pH control agent as defined in § 170.3(o)(23) of this chapter . . . (2) The ingredient is used in food at levels not to exceed current good manufacturing practice.").

227 Andrews, *supra* note 99.

228 *USDA Grants LFTB Labeling on Ground Beef Products*, AGWEB (Apr. 9, 2012), http://www.agweb.com/article/usda_grants_lftb_labeling_on_ground_beef_products/ ("[The] USDA has received applications from companies that would like to label their products that include lean, finely textured beef (LFTB). Because USDA considers LFTB an all-beef product, it has never required that it be labeled.").

229 9 C.F.R. § 317.4(a) (2013).

Textured Beef,' or 'Contains Lean Beef Derived from Beef Trimmings,' and stamp them with USDA approval."[230]

3. Food Packaging

Food packaging materials fall within the jurisdiction of the FDA and the USDA by virtue of the definition of "food additives" in section 321(s): "The term 'food additive' . . . includ[es] any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food . . . ."[231] The upshot of this extraordinarily broad definition is that substances that affect food, even via packaging, are food additives, and hence become "food" for purposes of the FDA's regulatory jurisdiction.[232] As seen earlier in other contexts, the statutory escape clause is the GRAS provision,[233] which the FDA and the USDA have employed here as well to avert the strict regulation of food additives. The FDA and the USDA's views of the safety of additives used in packaging appear to hinge on the belief that "indirect" additives used in food packaging migrate into food only in negligible quantities and have very little effect on the food itself.[234] This view is open to question, given advances in the scientific evaluation of such additives and the likelihood of significant cumulative exposure over a lifetime of consuming packaged foods.[235] As with other controversies involving GRAS determinations, the agencies rely here on the testing and representations of the food industry regarding the safety of indirect

230 Jim Avila, *BPI Endorses USDA Voluntary Labeling of LFTB or 'Pink Slime*,' ABC NEWS (Apr. 3, 2012, 7:53 pm), http://abcnews.go.com/blogs/headlines/2012/04/bpi-endorses-usda-voluntary-labeling-of-lftb-or-pink-slime/.

231 21 U.S.C. § 321(s) (providing exceptions not relevant here).

232 *See* Natick Paperboard Corp. v. Weinberger, 389 F. Supp. 794 (D. Mass. 1975), *aff'd* 525 F.2d 1103 (1st Cir. 1975) (unsuccessfully challenging the FDA's authority to regulate use of polychlorinated biphenyls in food packaging).

233 21 U.S.C. § 321(s).

234 *See* Food Additives; Threshold of Regulation for Substances Used in Food-Contact Articles, 60 Fed. Reg. 36582 (July 17, 1995) (reciting evolution of regulatory policy regarding food contact substances); *see also* Monsanto v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979) (holding that the FDA Commissioner had discretion to "find migration 'insignificant' even giving full weight to the public health and welfare concerns that must inform his discretion").

235 *See* FOOD ADDITIVES 32 (A. Larry Branen et al. eds., 2d ed. 2002) ("When the risks or benefits of food additive use are considered, estimation must be made of the long-term or lifetime consumption of the additive. These substances may have cumulative effects on health, may interact with other biological or chemical compounds in the body, or may elicit different responses in consumers of different ages or health status.").

additives used in packaging. This approach has come to a head recently in connection with the use of BPA in food packaging materials and the use of the Modified Atmosphere Packaging (MAP) process to enhance the apparent freshness of packaged foods.

a. Bisphenol A (BPA)

BPA is widely used in food containers and packaging. In 2008, the FDA issued a draft report concluding that BPA is safe for use in food contact substances.[236] According to the report, after examining scientific studies the "FDA . . . concluded that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses."[237] Even this statement suggests that some harmful effects of BPA were known at the time; scientific evidence has continued to mount since the FDA's 2008 decision.[238] Had the FDA classified BPA as a food additive,[239] the substance would have been "deemed . . . unsafe" and its use subject to a strict premarket approval regime.[240] Use of the substance would have amounted to adulteration unless producers made the requisite showing of safety to obtain a regulation establishing conditions for safe use.[241]

Shortly following the 2008 announcement, the Natural Resources Defense Council (NRDC) filed a petition to force the FDA to undertake regulatory action with respect to BPA.[242] Though the FDA has 180 days to respond to such a petition, no response was forthcoming after eighteen months.[243] The FDA's inaction was

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236 FDA, DRAFT ASSESSMENT OF BISPHENOL A FOR USE IN FOOD CONTACT SUBSTANCES (Aug. 14, 2008), *available at* http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-0038b1_01_02_FDA%20BPA%20Draft%20Assessment.pdf.

237 *Id.* at 2. According to some reports, the studies FDA relied on "were paid for by the chemical industry." Meg Kissinger, *FDA Does About-Face on Exposure to BPA*, J. SENTINEL (Jan. 15, 2010), http://www.jsonline.com/watchdog/watchdogreports/81724607.html.

238 Simon, *supra* note 118.

239 *See* 21 U.S.C. § 321(s) (2012).

240 *See id.* § 348.

241 *See id.* § 348(a)(2) (requiring regulation); *id.* § 348 (c)(3) (prohibiting issuance of a regulation "if a fair evaluation of the data before the Secretary . . . fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe").

242 NRDC, Citizen Petition (FDA, Oct. 21, 2008), *available at* http://docs.nrdc.org/health/files/hea_08102001a.pdf.

243 Sarah Janssen, *NRDC Lawsuit Finally Prompts FDA to Agree to Determine Safety of BPA,* NRDC STAFF BLOG (Dec. 7, 2011), http://switchboard.nrdc.org/blogs/sjanssen/nrdc_lawsuit_finally_prompts_f.html.

somewhat surprising in light of its announcement in 2010 that, despite the 2008 decision

> it was concerned about the chemical's effects on fetuses, infants and children. The agency said it would work to reduce exposure to the chemical, which is found in the urine of 93% of Americans tested. But it stopped short of a ban, saying more studies are needed to better know the chemical's effects.[244]

At that point, the NRDC filed suit to force the FDA to respond.[245] To settle the NRDC lawsuit, the FDA agreed in late 2011 to make a decision regarding BPA by March 31, 2012.[246] Meanwhile, "strong consumer backlash" against BPA caused "more companies [to feel] the heat and [begin] to respond" by phasing out BPA voluntarily.[247]

In its March 2012 letter denying the NRDC's 2008 petition to ban the use of BPA in all food contact substances, the FDA stated:

> In assessing the safety of a food additive, the central question of [the] FDA's evaluation is whether the use is "safe," i.e., whether there is reasonable certainty that, in the minds of competent scientists, the substance is not harmful under the intended conditions of use.
>
> . . . .
>
> [The] FDA has determined, as a matter of science and regulatory policy, that the best course of action at this time is to continue our review and study of emerging data on BPA.[248]

This action inverts the statutory scheme from one requiring proof of safety prior to marketing to one allowing marketing pending further study of safety concerns.

Meanwhile, the FDA's parent agency, the U.S. Department of Health and Human Services, continues to advise parents on limiting their infants' exposure to BPA.[249] In July 2012, the FDA announced that BPA can no longer be used to make baby bottles or sippy cups.[250]

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244 Kissinger, *supra* note 237.

245 Janssen, *supra* note 243.

246 *Id.*

247 Simon, *supra* note 118.

248 Letter from David H. Dorsey, Acting Assoc. Comm'r for Policy & Planning, to Sarah Janssen and Aaron Colangelo, NRDC, at 2, 15 (Mar. 30, 2012), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2008-P-0577-0007 (follow "FDA OC Letter to Natural Resources Defense Council Petition Denial" hyperlink).

249 *Bisphenol A (BPA) Information for Parents*, U.S. DEP'T OF HEALTH & HUMAN SERVS. http://www.hhs.gov/safety/bpa/ (last visited Oct. 17, 2013).

250 Goetz, *supra* note 119.

The FDA contended that its decision indicated not that BPA was unsafe for use in these applications but rather that BPA "simply isn't 'used'" in them any longer.[251] It defies common sense to ban a substance on the ground that it is not being used in certain products rather than because it is unsafe. BPA is still permitted to be used in other food contact substances. In the face of consumer demand and in the absence of FDA regulation, at least eleven states have banned the use of BPA in certain types of containers.[252]

b. Modified Atmosphere Packaging (MAP)

Another area of concern is the use of carbon monoxide gas in packaging to keep beef looking red longer and other foods appearing fresh longer. The USDA classifies this process as GRAS. Thus, in USDA's view, labeling as to the use of MAP is not required.[253]

The use of carbon monoxide in food packaging has not been found to present health concerns.[254] As a result, food packaged in this manner is not likely to be actually "adulterated."[255] But because changes in color and texture, which serve as "visual evidence of spoilage," are "mask[ed]" by carbon monoxide and other gases, the use of MAP may induce consumers to purchase products they would otherwise consider too old.[256] Thus, the use of MAP potentially fits into the framework of economic adulteration of food, a topic central to the passage of the FDCA and other food-related statutes. Economic adulteration, which occurs when the product sold is not what it purports to be or is inferior to what it purports to be, is adulteration under the statutes and thus precludes sale of the product in interstate commerce. Accordingly, the USDA and the FDA would seem to have authority to address the issue.

But the USDA, with respect to meat, and the FDA, with respect to fruits and vegetables, have taken little action regarding the use of MAP. As in the case of genetic modification, the use of hormones,

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251 *Id.*

252 *Id.*

253 Burros, *supra* note 138 (stating that the FDA approved the process in 2004).

254 *Id.*

255 *See* 21 U.S.C. § 601(m)(1) (2012) (defining "adulterated" to mean that the meat product contains a "poisonous or deleterious substance which may render it injurious to health"); *id.* § 601(m)(2)(C) (defining "adulterated" to mean that the meat product "contains any food additive which is unsafe within the meaning of section 348 of this title").

256 EUR. FOOD INFO. COUNCIL, *supra* note 135.

and the use of ammonia to produce LFTB, the gases used in MAP are not considered food additives subject to pre-approval, nor are they considered ingredients required to be reflected in the product's labeling. This is so despite the fact that the safety of a substance is immaterial to the labeling requirements of the Act.[257] Instead, the FDA addresses safety concerns merely by requiring that MAP processes be part of a producer's Hazard Analysis and Critical Control Points (HACCP) plan.[258] This is a far cry from a prohibition on sale absent pre-market review or even from a labeling requirement.

C. Consequences of Agency Inaction

In sum, the FDA and the USDA responses to significant food production controversies have often been delay, inaction, and avoidance of regulatory responsibility. Consumers and advocacy groups have reacted angrily, resorting to actions such as boycotts and lawsuits to force either industry capitulation or regulatory action. When the industry has responded to consumer ire by voluntarily

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257 *See infra* text accompanying notes 325–26.

258 *See Hazard Analysis & Critical Control Points (HACCP)*, FDA, http://www.fda.gov/Food/GuidanceRegulation/HACCP/ (last updated July 5, 2013) ("HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product."). With respect to MAP, the 2009 Food Code provides:

> (I) Hazard Analysis and Critical Control Point (HACCP) Operation
>
> All food establishments packaging food in a reduced oxygen atmosphere must develop a HACCP plan and maintain the plan at the processing site for review by the regulatory authority. For ROP operations, the plan must include the requirements specified under ¶ 8-201.14(D). In addition, the HACCP plan may also include:
>
> (1) A complete description of the processing, packaging, and storage procedures designated as critical control points, with attendant critical limits, corrective action plans, monitoring and verification schemes, and records required;
>
> (2) A list of equipment and food-contact packaging supplies used, including compliance standards that may be required by the regulatory authority, i.e., a recognized third party equipment evaluation organization such as NSF International;
>
> (3) A description of the lot identification system;
>
> (4) A description of the employee training program;
>
> (5) A listing and proportion of food-grade gas(es) used; and
>
> (6) A standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 131, § 2(*I*).

changing its practices, the FDA has reacted favorably by endorsing industry action.[259] In other cases, state or local authorities have begun to act on their own.[260]

Neither solution is satisfactory. Voluntary industry action provides little assurance to consumers that companies won't reverse course or replace the challenged substances or processes with even more deleterious ones. State and local regulation creates problems for industry without assuring protection of most citizens.[261] Inter-circuit splits regarding permissible labeling as to processes of production leave both producers and consumers guessing.[262] The next Part argues that the FDA and USDA have authority to address many aspects of food production, and should exercise it.

III
USING EXISTING STATUTORY AUTHORITY TO ADDRESS FOOD PRODUCTION ISSUES

The FDCA and related statutes set forth a seemingly simple mandate for regulation of the food system. The statutes broadly prohibit the "introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated or misbranded."[263] In general, the adulteration provision relates to the safety of food products themselves, while the misbranding provisions relate to information provided on packages and labels.[264] But the two concepts overlap in that both focus, at least in part, on the prevention of so-called "economic adulteration."[265] In other words, a food may be "adulterated," even if it is perfectly safe to consume, if an inferior ingredient is substituted for a better one or if the product is made to appear better than it is.[266]

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259 *See* Simon, *supra* note 118.

260 *See* Goetz, *supra* note 119.

261 *But see* Strauss, *supra* note 13, at 303–07 (noting the benefits of state legislative action, including the possibility that state action may spur federal action).

262 *Cf. id.* at 307–08 (describing actions of trade associations and other stakeholders to fill regulatory void).

263 21 U.S.C. § 331(a) (2012) (general prohibition); *see also id.* § 342 (adulterated food); *id.* § 352 (misbranded food).

264 *Cf.* Chen, *supra* note 33, at 216.

265 *See* FORTIN, *supra* note 11, at 149.

266 The FDCA explicitly incorporates this concern in the definition of adulteration, one aspect of which is the addition to food of "any substance . . . so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is." 21 U.S.C. § 342(b)(1).

The statutes reach deep into the commercial food system. Prohibited acts include not only interstate sale of adulterated or misbranded foods but also ostensibly intrastate activities including the "adulteration or misbranding of any food."[267] Amendments in 1947 expanded the reach of the FDCA to "make it clear that [the Act] is not limited to the case where the act [of adulteration or misbranding] occurs while the article is held for first sale after interstate shipment."[268] This extension was necessary because

> [s]ome 20 percent of the seizures of adulterated and misbranded foods instituted during recent years involved cases where the adulteration clearly resulted from insanitary conditions or other causes during storage after interstate shipment. In a great many other cases it would have been impossible to prove that contamination or deterioration occurred before the interstate journey ended. Even where that fact eventually could have been established through investigations, the time required to complete such investigations frequently would have been such that much of the unfit material would have reached consumers' tables . . . before it could have been seized.[269]

Moreover, sanctions under the Act are significant. Persons who violate the adulteration or misbranding provisions of the Act are subject to fines and imprisonment.[270] Moreover, "[a]ny article of food . . . that is adulterated or misbranded when introduced into or while in interstate commerce . . . shall be liable to be . . . condemned in any district court of the United States . . . ."[271] Following condemnation, the "food . . . shall be disposed of by destruction or sale as the court may . . . direct."[272] Thus, producers and sellers who violate the Act risk loss of both liberty and property.

All these statutory provisions are in keeping with the intent of the 1938 Act to make the new law "meet the requirements of consumer

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267 *Id.* § 331(b); *see also id.* § 458(a)(2) (poultry); *id.* § 610(c) (meat).

268 H.R. REP. NO. 80-807, at 1 (1947). This amendment was necessary to counteract the decision in United States v. Phelps-Dodge Mercantile Co., 157 F.2d 453 (9th Cir. 1946), *cert. denied*, 330 U.S. 818 (1947) (holding that the 1938 Act did not reach contamination of a food while stored in a warehouse after shipment in interstate commerce). *Id.* at 2.

269 *Id.* at 2–3.

270 21 U.S.C. § 333.

271 *Id.* § 334(a)(1).

272 *Id.* In the case of food that is misbranded but not deleterious, the court may order that the food be properly labeled before being sold. *See id.* § 334(d)(1) (discussing food "being brought into compliance").

protection under modern conditions."[273] Both statutory text and Congress's avowed purpose support a robust reading of the FDA's and USDA's authority to regulate food production processes. Regulatory actions and court decisions, particularly those relatively contemporaneous with the statute's passage, are generally to the same effect.[274] Only recently have the agencies themselves, along with reviewing courts, taken a narrower view of regulatory authority.[275]

A. The Breadth of Existing Statutory Authority

The FDCA and related statutes provide broad authority to regulate food.

1. Definitions

In the first place, the definition of food—which establishes the jurisdiction of the Act with respect to the food system—extends to many items laypeople do not ordinarily think of as "food." The FDCA's definition reads: "[t]he term 'food' means (1) articles used for food or drink for man or animals, (2) chewing gum, and (3) articles used for components of any such article."[276] This definition goes well beyond traditional notions of "food" in that it extends to mostly anything that will be consumed by humans, even indirectly by virtue of having been consumed by animals that become food.

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273 H.R. REP. NO. 75-2139, at 1 (75th Cong., 3d sess. 1938).

274 *See, e.g.*, Kordel v. United States, 335 U.S. 345, 349 (1948) ("The high purpose of the [Food, Drug, and Cosmetic] Act to protect consumers who under present conditions are largely unable to protect themselves in this field would . . . be easily defeated [by a narrow construction of its provisions]. The administrative agency charged with its enforcement has not given the Act any such restricted construction. The textual structure of the Act is not agreeable to it."); *see also* United States v. Dotterweich, 320 U.S. 277, 281 (1943) ("The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."); United States v. Certified Grocers Co-op, 546 F.2d 1308, 1312 n.5 (7th Cir. 1976) (quoting *Dotterweich*, 320 U.S. 277, in case involving adulterated food).

275 Whether and to what extent the agencies' narrower view of their responsibilities under the Act is due to insufficient resources for broader enforcement is a question beyond the scope of this article. The FDA has cited insufficient resources as a reason for its stance: "Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for 'natural' at this time." Food Labeling: Nutrient Content Claims, General Principles, Definition of Terms: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101).

276 21 U.S.C. § 321(f).

Furthermore, courts have held "food" to include eggs rejected as food,[277] food packaging,[278] and "food additives" that are not themselves "food" or even "components" of food.[279] A food additive is defined broadly as

> 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, transporting, or holding food . . . [unless such substance is] 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 intended use . . . .[280]

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) regulate specific categories of food but within those categories are similarly broad in scope. For example, under FMIA

> [t]he term "meat food product" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats . . . . This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats . . . .[281]

and

> [t]he term "capable of use as human food" shall apply to any carcass, or part or product of a carcass, of any animal, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human food, or it is naturally inedible by humans.[282]

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277 *See* United States v. Technical Egg Products, Inc., 171 F. Supp. 326, 329 (N.D. Ga. 1959) (so long as an item retains a semblance of the identity it possessed as a food, it remains a food under the Act).

278 21 U.S.C. § 321(s) (defining "food additives" as explicitly including "any substance intended for use in . . . packaging . . . food").

279 *Id.*

280 *Id.*

281 *Id.* § 601(j).

282 *Id.* § 601(k).

Live animals destined to become food have been held to be "food" even before slaughter.[283] Similarly, under the PPIA,

> [t]he term "poultry product" means any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting products which contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry, and which are exempted by the Secretary from definition as a poultry product . . . .[284]

In addition, "[t]he term 'poultry' means any domesticated bird, whether live or dead."[285]

Other FDCA and related statute definitions establishing the parameters of food regulation are equally broad. For example, "labeling" includes "all labels and any other written, printed, or graphic matter (1) upon any article [of food] or any of its container or wrappers, or (2) accompanying such article."[286] Similarly, the term "safe," with respect to food, "refer[s] to the health of man or animal."[287]

The Acts' sweeping provisions are intended to reach whatever part of the process was responsible for the misbranding or adulteration of any product eventually sold as food.[288] For this intent to be realized, the statute must take effect as early in the food production chain as the wrong occurs, even if the item in question is not typically regarded as "food." Otherwise, neither the safety of food for human consumption nor the protection of consumers from economic harm can be assured.[289]

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283 *See* United States v. Tuente Livestock, 888 F. Supp. 1416, 1423 (S.D. Ohio 1995) (concerning the presence of animal drug residues in meat).

284 21 U.S.C. § 453(f).

285 *Id.* § 453(e).

286 *Id.* § 321(m); *see also id.* § 453(s) (poultry); *id.* §§ 601(o)–(p) (meat).

287 *Id.* § 321(u). FMIA does not define "safe" but in defining "adulterated" refers to definitions of safety in FDCA. *See id.* § 601(m) (referring to 21 U.S.C. §§ 346a, 348, 379(e), regarding pesticide chemicals, food additives, and color additives). The Poultry Products Inspection Act follows the same approach. *See id.* § 453(g).

288 *See, e.g.*, *Tuente Livestock*, 888 F. Supp. at 1426.

289 *Id.* at 1423.

2. Prohibitions

Violations of the adulteration and misbranding provisions do not turn on actual harm or on intent to harm or to deceive.[290] The statutory prohibitions on the sale of adulterated or misbranded food are broadly framed. Most traditional foods are presumed to be safe and are subject only to post-market prosecutions for adulteration or misbranding.[291] But the statutes employ a variety of mechanisms to reach less traditional foods, ingredients, additives, and processes.

a. Adulteration

"Adulteration" of food extends to food that (inherently) contains "any poisonous or deleterious substance" in sufficient quantity to render it "ordinarily injurious to health,"[292] food that has been held or packed in "insanitary conditions,"[293] and food that "consists in whole or in part of any filthy, putrid, or decomposed substance."[294] More broadly, adulteration also encompasses foods that contain "added" poisonous or deleterious substances[295] that "may render them injurious to health," "any food additive that is unsafe,"[296] any item "otherwise unfit for food,"[297] and any item economically adulterated by the "absence, substitution, or addition" of ingredients that make

290 *See, e.g.*, United States v. An Article of Food . . . 'Manischeiwitz . . . Diet Thins,' 377 F. Supp. 746, 749 (E.D.N.Y. 1974).

291 Meat, poultry, and eggs are an exception to the presumption of safety. For these foods, inspection is required prior to marketing. *See* 21 U.S.C. § 604 (requiring post mortem inspection of all carcasses and parts of cattle, sheep, swine, and other listed animals); *id.* § 455 (requiring post mortem inspection of all poultry); *id.* § 1034 (requiring continuous inspection whenever egg processing operations are being conducted. For meat and poultry labels must also be pre-approved. *See id.* § 607 (meat); *id.* § 457 (poultry).

292 *Id.* § 342(a)(1). The FDCA distinguishes between inherent and "added" poisonous or deleterious substances;" the latter are subject to a stricter safety standard than the former. *See* United States v. Anderson Seafoods, Inc., 622 F.2d 157 (5th Cir. 1980).

293 21 U.S.C. § 342(a)(4).

294 *Id.* § 342(a)(3).

295 *Id.* § 342(a)(1). "Added poisonous or deleterious substances" are not the same as "food additives." "Added substances" get into food through human activity but are not used intentionally in food processing. *Anderson Seafoods*, 622 F.2d at 161 (holding mercury in swordfish to be an "added substance"). Food "additives," on the other hand, are used intentionally to affect the characteristics of the food. 21 U.S.C. § 321(s).

296 21 U.S.C. § 342(a)(2)(C)(i).

297 *Id.* § 342(a)(3).

the product inferior to what it purports to be.[298] Nearly identical provisions appear in both the PPIA and FMIA.[299] Foods—including components of food—that fall into these categories are subject to stricter regulation, including pre-market controls.

Poisonous or deleterious substances that are added to foods "shall be deemed to be unsafe" and the food product thus adulterated unless the substance "is required in the production" of the food "or cannot be avoided by good manufacturing practice."[300] In that case, the "Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe . . . ."[301] When such a regulation is in effect, a food complying with its limits is not adulterated and may be sold.[302]

Food additives expected to become a component of a food or otherwise to affect the characteristics of a food "shall, with respect to any particular use or intended use . . . , be deemed to be unsafe" and hence adulterated.[303] Foods containing such additives are banned from sale unless a regulation is in effect specifying the conditions for use of the additive and the food product complies with that regulation.[304] As noted earlier, substances apparently meeting the definition of "food additives" but "generally recognized as safe" (GRAS) fall outside the definition of "food additives" under the FDCA.[305] Thus, foods containing such substances are not considered adulterated. Provisions of the FMIA and PPIA are to the same effect.[306]

b. Misbranding

"Misbranding" under the various Acts occurs when the labeling of the food is "false or misleading in any particular," not only when read as a whole.[307] Whether a label is "misleading" is determined not only

298 *Id.* § 342(b). In fact, section 342, read as a whole, extends the notion of "adulteration" to just about every imaginable problem that could occur with respect to food.

299 *See id.* §§ 453(g), 601(m) (defining adulteration in poultry and meat).

300 *Id.* § 346.

301 *Id.*

302 *Id.*

303 *Id.* § 348(a).

304 *Id.*

305 *See supra* note 291.

306 FMIA and PPIA incorporate FDCA's definition of food additives by reference. *Id.* §§ 453(g)(8), 601(m)(8) (poultry and meat).

307 *Id.* § 343(a)(1); *see also id.* §§ 453(h), 601(n) (poultry and meat).

on the basis of "representations made or suggested by statement, word, design, device, or any combination thereof, but also [on] the extent to which the labeling . . . fails to reveal facts material in light of such representations . . . ."[308] The test for a label's ability to mislead is the "reasonable consumer."[309]

Courts have interpreted the misbranding provision strictly, finding misbranding "if it appears that any one representation is false or misleading."[310] According to the Supreme Court,

> [d]eception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection or ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.[311]

Not only affirmative representations but also the omission of material facts may result in a finding that the label is misleading.[312] Foods may be condemned as misbranded even if they are not deleterious[313] or inferior.[314]

The broad statutory authority described in this section contrasts markedly with the agencies' hands-off posture with respect to the food controversies related in Parts I and II. The next section explores one aspect of the inconsistency between current regulatory approach and existing statutory authority. Specifically, the Article argues that the FDA's and USDA's adoption of the doctrine of "substantial equivalence" is without support in statutory provisions relating to food. The "substantial equivalence" approach infects determinations of both adulteration and misbranding.

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308 *Id.* § 321(n).

309 *See* Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed. Reg. 78002, 78003-04 (Dec. 20, 2002) (adopting reasonable consumer standard).

310 United States v. An Article of Food . . . 'Manischiewitz . . . Diet Thins,' 377 F. Supp. 746, 748–49 (E.D.N.Y. 1974).

311 United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 443 (1924) (construing the 1906 Act).

312 21 U.S.C. § 321(n).

313 *Manischiewitz*, 377 F.Supp. at 749.

314 *Ninety-Five Barrels*, 265 U.S. at 443.

B. Materiality of Fact Versus Substantial Equivalence of Food Products

As noted, the agencies' approach to many process-related controversies involving food has been to consider whether the end-product food in question is or is not substantially the equivalent of an existing or traditional food.[315]

1. Adulteration

An example involving potential adulteration is the longstanding federal policy to "regulate genetic engineering products no differently than those achieved through traditional [plant breeding] techniques."[316] According to FDA's 1992 Statement of Policy, foods produced using GE technologies

> are regulated within the existing framework of the [FDCA], FDA's implementing regulations, and current practice, utilizing an approach *identical* in principle to that applied to foods developed by traditional plant breeding. The regulatory status of a food, *irrespective of the method by which it is developed,* is dependent upon objective characteristics of the food and the intended use of the food (or its components). 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 new methods are used.[317]

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315 Van Tassel, *supra* note 6 (manuscript at 2) (noting that this approach "cripples the FDA's ability to regulate" with respect to novel food production technologies, focusing on nanotech ingredients in particular).

316 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986); *see also* Chen, *supra* note 33, at 215 (noting similarities between rbST cases and the GMO Policy Statement).

317 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22984–85 (May 29, 1992) (emphasis added). Several years earlier, the USDA, FDA, and several other agencies cooperated in the development of a Coordinated Framework for Regulation of Biotechnology, which stated that

> [a]gencies involved with regulating agriculture, foods, medical devices, drugs, biologics and pesticides have had extensive experience with products that involve living organisms in their manufacture and/or ultimate use including releases into the environment for these purposes. By the time a genetically engineered product is ready for commercialization, it will have undergone substantial review and testing during the research phase, and thus, information regarding its safety should be available. The manufacture by the newer technologies of food, the development of new drugs, medical devices, biologics for humans and animals, and pesticides, will be reviewed by FDA, USDA and EPA in essentially the same manner for safety and efficacy as products obtained by other techniques. The new products that will

The Policy Statement reflects FDA's belief that new plant varieties developed using GE technology are no different from new varieties developed using Gregor Mendel's nineteenth century plant breeding technology. This position is surprising because the point of GE technology is not primarily to select and encourage beneficial traits already present in some expressions of the plant but rather to introduce genetic material from another organism entirely—including such things as the biological pesticide, bT—into the plant's genetic material.[318] This is a modification of a different order. But the FDA treats bT corn as indistinguishable from non-GMO corn because it is all "corn."[319] It would not be surprising if the FDA eventually approved genetically engineered salmon, despite considerable opposition, on the grounds that however they were bred, they are "salmon."[320] In fact, the FDA has stated that

> [A] change in the composition of a food may or may not result in material changes in the attributes of the food. FDA has required labeling in cases where the absence of "material" information leads the consumer to assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not.
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> . . . .
>
> FDA has not found that foods from GE organisms, as a class, present different or greater safety concerns than their conventional

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be brought to market will generally fit within these agencies' review and approval regimens.

Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 25304 (June 26, 1986).

318 *See, e.g.*, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 23005 (discussing the issue of "whether FDA or EPA would have jurisdiction when plants are modified to express pesticidal substances"); *see also* Ric Bessin, *Bt-Corn: What It Is and How It Works*, UKAG (Jan. 2004), http://www2.ca.uky.edu/entomology/entfacts/ef130.asp.

319 Some farmers report that animals understand the difference: cows will not eat stalks of bT corn, for example, because the stalks are too tough. Conversation with Luke Linenbringer, Callaway County, Missouri Cattle Farmer, during meeting of Sustainable Agriculture Group in Columbia, Mo. (Sept. 6, 2012).

320 The FDA has yet to decide whether to approve the request, which has been under evaluation for several years. But approval seems likely in the near future. *See* Sydney Lupkin, *Genetically Engineered Salmon Nears FDA Approval*, ABCNEWS (Dec. 28, 2012), http://abcnews.go.com/Health/genetically-modified-frankenfish-nears-fda-approval-debate-heats/story?id=18078157 ("The Food and Drug Administration has determined genetically engineered salmon won't threaten the environment, clearing it of all but one final hurdle before it shows up on shelves throughout the nation—and igniting a final 60-day debate on whether it poses health risks before it's officially approved.").

> counterparts. Nor has FDA found that, as a class, they differ materially in nutritional value, organoleptic properties, or functional characteristics. Therefore, FDA does not consider the fact that a food was made using genetic engineering, in and of itself, to be a material difference . . . .
>
> On the other hand, if a particular GE-food is materially different from foods from its non-GE counterpart, then FDA could require that such a difference be identified in the food labeling. The absence of material information in labeling would make the product misbranded. Thus, for example, if an animal were genetically engineered so that food from the animal had significantly higher or lower levels of protein content, FDA would likely conclude this is a material fact. This difference in protein content levels would then have to be described in the labeling of foods made from the GE animal.[321]

One explanation for FDA's focus on the product rather than the process by which it was produced is that the food product itself is not "treated" in the sense that a pesticide is applied to it or a substance added to it. Instead, the modification occurs at an earlier step in the process—the DNA of the plant or animal is genetically modified or the cow is injected with synthetic hormones. The FDA apparently views this as different from treatments applied directly to the resulting food product—here, the tomato, the salmon, or the milk.[322] The FDA's focus on the end product may have caused it to articulate its regulatory authority in terms of "material difference" of the resulting products.

But it is at least arguable that the use of GE technology and synthetic hormones, as well as the processing of beef into LFTB, introduce "deleterious" substances or dangerous additives into the food supply.[323] Food contact substances, such as BPA and the gases in MAP, are clearly encompassed within the definition of food additives. The statutes specifically require more stringent safety regulation for such substances than for traditional foods, and for good reason. Consumers' lack of information as to methods of production often impedes their ability to assess food safety risks. In fact, products the FDA and the USDA consider to be "substantially equivalent" to each

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321 FDA, BACKGROUND DOCUMENT: PUBLIC HEARING ON THE LABELING OF FOOD MADE FROM THE AQUADVANTAGE SALMON 5 (Aug. 2010), *available at* www.fda.gov/ForConsumers/ConsumerUpdates/ucm222608.htm.

322 I am grateful to Susan A. Schneider for this insight.

323 Van Tassel, *supra* note 6 (manuscript at 17–19) (discussing the scientific uncertainty that attended the introduction of several food technologies and the lag time before the extent of hazards posed by such technologies was known).

other may present differing safety issues. For example, the use of LFTB became a safety issue when the level of ammonia, which was critical to ameliorate the higher likelihood of contamination of trimmings, was reduced to improve palatability. Consumers were not informed that the product included LFTB in the first place, nor were they informed that the LFTB process had changed in a way that made the final product potentially much more dangerous to human health. As a result, they were unable to evaluate the safety of the product. If this is so, consumers are correct to consider information about the production process highly material. Consumers' caution is validated by the statute's focus on reducing even the possibility of harm to humans from food. The statute does so by allowing the use of additives and food contact substances only after promulgation of a regulation establishing conditions for safe use.

2. Misbranding

An example of the "substantial equivalence" approach involving labeling is the FDA's finding "that there was no significant difference between milk from [hormone-]treated and untreated cows."[324] From this finding, the FDA "concluded that under the Federal Food, Drug, and Cosmetic Act . . . , the agency did not have the authority . . . to require special labeling for milk from rbST-treated cows."[325] The FDA's approach arguably deviates from the statutory standard for misleadingness of labeling: "facts material in the light of . . . representations [made on the labeling] or material with respect to consequences which may result from the use of the article to which

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324 Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated with Recominant Bovine Somatotropin, 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994).

325 *Id.* This view may have some superficial support in the statute, which focuses on the identity or definition of foods, imitation foods, and food additives. Section 343's provisions regarding misbranding, for example, regulate representations as to the definition and standard of identity of foods, 21 U.S.C. § 342(g) (2012), the quality and fill of containers, *id.* § 342(h), the labeling requirements for foods for which there is no definition or standard of identity, *id.* § 342(i), and the labeling of foods that are imitations of other foods, *id.* § 342(c). Section 346 regulates poisonous or deleterious substances added to foods, section 346(a) regulates pesticide residues in or on foods, and section 348 regulates food additives. Process-related concerns perhaps do not fit neatly within these categories, all of which focus on the composition of the food and largely ignore the way it came to be as it is. But these categories do not exhaust FDA's authority. As noted earlier, the FDA is broadly empowered to regulate adulterated and misbranded food. *See supra* Part III.A.

the labeling or advertising relates . . . under such conditions of use as are customary or usual."[326]

Similarly, the 1992 Statement of Policy states, with respect to GE foods, that

> [l]abels provide a variety of information about a food, including its name, ingredients, and nutritional profile. The following . . . key principles of food labeling . . . are applicable to the specific issue of the labeling of foods from GE animals, such as the AquAdvantage Salmon.
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> . . . .
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> [T]he law requires that the label include a name that accurately describes the basic nature of the food. In the 1992 policy on foods derived from new plant varieties and 2001 draft guidance on voluntary labeling of food from GE plants, FDA explained that . . . . changes to the name of the product are not appropriate . . . if the resulting GE food product is not materially different from its traditional counterpart (i.e., unless the GE food product differs in nutritional quality, taste, *etc.*).
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> FDA applied this reasoning when it reviewed submissions related to the FLAVR SAVR tomato. FDA concluded that the appropriate common or usual name of the product was "tomato," because the FLAVR SAVR tomato was not significantly different from other commercial varieties of tomatoes . . . .[327]

Federal courts have deferred to the FDA's view. In, *Stauber v. Shalala*, an early case involving rbST-derived milk, the court accepted the FDA's view that "a factual predicate to the requirement of labeling is . . . that a product differs materially from the type of product it purports to be."[328] The court concluded that "[i]n the absence of . . . a material difference between rbST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act."[329] In a later case involving the use of "recombinant deoxyribonucleic acid (rDNA) technology . . . to alter the genetic composition of organisms by mixing genes . . . to create new . . . plants for human and animal consumption," the court recited the just-quoted statements from *Stauber*.[330] The court then concluded that "[g]iven the[] facts" that "rDNA modification does not 'materially' alter foods, and . . . [that

326 21 U.S.C. § 321(n).

327 FDA, *supra* note 321, at 4.

328 Stauber v. Shalala, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995).

329 *Id.*

330 Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 169 (D.D.C. 2000).

FDA's] determination [on this point] is entitled to deference . . . [,] FDA lacks a basis upon which it can legally mandate labeling, regardless of the level of consumer demand."[331]

Interestingly, the *Bio-Integrity* court cited only *Stauber* on the issue of the FDA's authority to regulate GE foods. *Stauber* itself cites no authority at all for its "material difference" proposition. Perhaps the *Stauber* court was confused by the plaintiffs' argument as to why labeling was required. Plaintiffs asserted that "milk derived from rbST-treated cows [does differ] organoleptically from ordinary milk . . . and that these differences are 'material facts' requiring labeling."[332] Thus, both the *Stauber* plaintiffs and the court considered the difference between end products a "material fact;" they disagreed only on the question of whether the products in fact differed. But this is not the only kind of "material fact" comprehended within the statutory text. Section 321(n) provides in full as follows:

> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which 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.[333]

This provision focuses on information relevant to consumers in the broadest sense and says nothing at all about similarities between products produced by different methods. The FDA and federal courts have simply transformed the statutory phrase "material facts" into "material difference." The statute's focus on the relationship of representations made on labels to other facts about a given product has been supplanted by a test of the degree of similarity or equivalence between products produced using traditional methods as opposed to new ones.

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331 *Id.* at 179.

332 *Stauber*, 895 F. Supp. at 1193. Plaintiffs also argued that "widespread consumer desire for mandatory labeling of rbST-derived milk" was a "'material fact' requiring labeling." *Id.*

333 21 U.S.C. § 321(n) (2012).

Differing reactions to the FDA's Guidance document explain the discrepancy, recounted above in Part II.A.2.a, between the Second Circuit's decision in *International Dairy Foods Ass'n* v. *Amestoy* and that of the Sixth Circuit in *International Dairy Foods Ass'n v Boggs*. In *Amestoy*, the panel majority credited the FDA's "exhaustive studies" showing that "there are no human safety or health concerns associated with food products derived from cows treated with r[b]ST."[334] The majority stated that

> it is undisputed that neither consumers nor scientists can distinguish r[b]ST-derived milk from milk produced by an untreated cow. Indeed, the . . . record . . . contains no scientific evidence from which an objective observer could conclude that r[b]ST has any impact at all on dairy products. It is thus plain that Vermont could not justify the statute on the basis of "real" harms.[335]

Also critical to the *Amestoy* majority's approach was the view that "consumer interest alone [is] [in]sufficient to justify requiring a product's manufacturers to publish the functional equivalent of a warning about a production method that has no discernable [sic] impact on a final product."[336] The majority plainly was concerned that "there is no end to the information that states could require manufacturers to disclose about production methods."[337] According to the majority, "consumers interested in such information should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it."[338] This advice is given without apparent recognition of the irony that the majority's requirement of a disclaimer to accompany voluntary labeling may make such consumer reactions considerably less likely. Judge Leval, dissenting in *Amestoy*, viewed the FDA's Guidance differently. Judge Leval found "alarming and dangerous" the suggestion that "a government agency's failure to find a health risk in a short-term study of a new genetic technology should bar a state from requiring simple disclosure of the use of that technology."[339]

The Sixth Circuit panel in a later case also involving milk went further. The district court had concluded that claims that milk was produced without the use of synthetic hormones were "inherently

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334 International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 (6th Cir. 1996).

335 *Id.* (citation omitted).

336 *Id.*

337 *Id.*

338 *Id.* at 74.

339 *Id.* at 76–77 (Leval, J., dissenting).

misleading."[340] The Sixth Circuit found this conclusion to be "belied by the record, . . . which shows that . . . a compositional difference *does exist* between milk from untreated cows and . . . milk from cows treated with rbST."[341] Moreover, "the failure to discover rbST in . . . milk [from treated cows] is not necessarily because the artificial hormone is absent . . . but rather because scientists have been unable to perfect a *test* to detect it."[342] Because there is "room" to conclude that "*some* compositional difference between the two types of milk may exist," the "evidence points to two distinct types of milk."[343] If this is the case, labeling requirements may shift suddenly as scientists develop tests capable of detecting less obvious differences between products produced using different technologies. For now, at least, a claim that "milk from cows never given rbST" is "rbST free" is "demonstrably true" and may "inform[] consumers of a meaningful distinction."[344] The Sixth Circuit, therefore, found Ohio's ban on composition claims to be an invalid infringement on producers' commercial free speech rights.[345]

The FDA's determination, even if scientifically sound, that products produced with the use of GE technology, artificial hormones, potentially dangerous packaging, and the like are "not materially different" in composition or nutritional value from conventionally-produced products hardly exhausts the universe of material facts that consumers find relevant in light of representations made on the labeling or in advertising of the food. Consumer demand for information about how their foods are produced, as reflected in numerous polls, proves that consumers consider these facts highly "material." Consumers do not view all milk as simply "milk;" many differentiate various types of milk precisely on the basis of how they were produced. The very fact that a market exists for milk produced without artificial hormones is evidence of that fact. Fittingly, the statute provides a basis for considering exactly these kinds of facts in

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340 Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 637 (6th Cir. 2010).

341 *Boggs*, 622 F.3d at 636 (emphasis added).

342 *Id.* at 637. This is essentially the argument Professor Van Tassel makes about the period of scientific uncertainty following the introduction of a new technology. Van Tassel, *supra* note 6 (manuscript at 2).

343 *Boggs*, 622 F.3d at 637 ("[T]he extent of this difference . . . is still very much an open question").

344 *Id.*

345 *Id.* at 639–40.

determining whether a product is misbranded when the label fails to reveal the use of artificial hormones, GE technologies, and the like.

The FDA's misreading of the statute, focusing exclusively on the name or identity and the chemical or nutritional composition of the food product, effectively precludes regulation of misbranding based on process-related concerns. Although the FDA's Interim Guidance on the Voluntary Labeling of Milk discusses both composition claims and production claims, the adoption of the "material difference" standard cleverly bars straightforward production claims, at least as to milk produced from cows not treated with rbST.[346] According to the FDA, the agency

> is concerned that the term "rbST free" may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Instead, the concept would better be formulated as "from cows not treated with rbST" . . . . However, even such a statement . . . has the potential to be misunderstood by consumers. . . . Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading.[347]

For this reason, the FDA suggested with respect to milk that the truthful statement "from cows not treated with rbST" should be placed in "proper context" to avoid being found "misleading."[348] Proper context, according to the FDA, would include, among other things, a statement that "[n]o significant difference has been shown between milk derived from rbST-treated cows and non-rbST-treated cows."[349] Thus, even a voluntary and truthful statement about the production process can safely be used in labeling only if effectively nullified by a statement of little relevance to consumers who have a wide range of reasons for preferring one type of milk to another.[350]

Similarly, in connection with the use of GE technology, the FDA reported that it

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346 Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994).

347 *Id.*

348 *Id.*

349 *Id.*

350 These reasons likely include concerns about animal rights, the environment, or modern farming practices, religious objections, cost concerns, and health concerns. Some of these concerns admittedly go beyond the core food safety and consumer protection matters at the heart of FDA's regulatory authority.

> 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, [such] foods . . . present any different or greater safety concerns than foods developed by traditional plant breeding. For this reason, the agency does not believe that the method of development of a new plant variety (including the use of new techniques including recombinant DNA techniques) is normally material information within the meaning of 21 U.S.C. 321(n) and would not usually be required to be disclosed in labeling for the food.[351]

The USDA responded similarly to allegations that LFTB is not beef. The agency announced that it would "provide schools with a choice to order [ground beef] product[s] either with or without Lean Finely Textured Beef."[352] The USDA further stated that "Lean Finely Textured Beef is a meat product derived from a process which separates fatty pieces from beef trimmings to reduce the overall fat content."[353] These statements at least imply that the USDA views LFTB as beef and considers ground beef that includes LFTB to be the equivalent of ground beef produced without LFTB. Ironically, a USDA official reportedly stated that he "[did] not consider the stuff to be ground beef."[354] The same official considered allowing LFTB to be included in ground beef without any indication on the label "to be a form of fraudulent labeling."[355] Bowing to consumer pressure, the USDA acquiesced in producers' voluntary labeling of ground beef as including LFTB.[356]

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351 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22991 (May 29, 1992). If the new plant variety presents "a safety or usage issue [such as introduction of a major allergen] . . . to which consumers must be alerted, that information must be provided. *Id.*

352 News Release, USDA, USDA Announces Additional Choices for Beef Products in the Upcoming School Year (Mar. 15, 2012), *available at* http://www.usda.gov/wps/portal/usda/usdamediafb?contentid=2012/03/0094.xml.

353 *Id.*

354 Andrews, *supra* note 99, at 124 (reporting that in 2002, the USDA microbiologist Gerald Zirnstein "coin[ed] the term 'pink slime' in an email to colleagues, adding, 'I do not consider the stuff to be ground beef, and I consider allowing it in ground beef to be a form of fraudulent labeling'").

355 Andrews, *supra* note 99; *see also* Moss, *supra* note 95 (detailing reductions in ammonia use and subsequent detection of E. coli in some samples). The USDA eventually revoked BPI's exemption from routine testing. *Id.*

356 *See* Andrews, *supra* note 99. As noted above, all labeling of meat and poultry products must be preapproved by the USDA. Hence, producers were not free to include this information in the absence of USDA acquiescence. Moreover, the classification of

The FDCA and related statutes speak only in terms of the "materiality" of facts. Consumer demand is a highly relevant proxy for materiality in this situation. Consumers have shown over and over that they care how their food is produced. The agencies' rejection of consumer demand as an appropriate basis for regulation of process-related concerns falls short of the governing statutes' mark.

C. The Importance of the Consumer Protection Focus of FDCA and Related Statutes

The FDCA, like the FMIA and PPIA, is a consumer protection statute. Failure to reveal material facts about production processes interferes with Congressional intent to promote the "honesty and fair dealing"[357] necessary to assure consumers they are getting what they expected when purchasing food. One indication of the high level of consumer interest in the processes by which food is produced is the fact that the organic sector is the fastest-growing grocery market segment in the United States.[358] But the availability of organic foods produced under strict standards and required to be certified is not an adequate solution to broader process-of-production concerns.[359] Consumers who purchase certified organic foods are assured that they are not purchasing foods produced using GE technology, artificial hormones, subtherapeutic antibiotics, and the like.[360] But the process-

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ammonium hydroxide as a processing aid meant that it was not an "ingredient" to be listed on food labels. *Id.*

357 *See supra* note 151 and accompanying text.

358 *See Industry Statistics and Projected Growth*, ORGANIC TRADE ASS'N (June 2011), http://www.ota.com/organic/mt/business.html; Dan Flynn, *Letter from the Editor: Organics*, FOOD SAFETY NEWS (Sept. 16, 2012), http://www.foodsafetynews.com/2012/09/letter-from-the-editor-organics/. Ironically, federal involvement in organic certification itself occurred in the wake of FDA inaction on that topic. *See, e.g.*, Charles P. Mitchell, *State Regulation and Federal Preemption of Food Labeling*, 45 FOOD DRUG COSM. L.J. 123, 125–26 (1990) (noting that "the FDA has never specifically addressed many important labeling issues," including "organic" claims, that "[s]everal states have filled the gap left by FDA's inaction concerning organic labeling," and that "the FDA has not objected to" state standards). Perhaps for this reason, although FDA's statutory jurisdiction would have authorized it to regulate organic food, Congress chose to assign all responsibility for organic food to the USDA. *See generally* Bones, *supra* note 57, at 440–41 (discussing the jurisdiction of the USDA and FDA).

359 *Cf.* Chen, *supra* note 33, at 217 (describing organic labeling as a "surrogate for the 'GM-free' . . . labels that FDA has never unequivocally endorsed"); *see also* Strauss, *supra* note 13, at 311–12.

360 *See* Organic Food Products Act of 1990, 7 U.S.C. §§ 6501–6523 (2012) (providing standards for organic products); *see also* Chen, *supra* note 33, at 222 (discussing standards in the U.S. and European Union).

related concerns discussed in this article extend significantly beyond matters addressed in the National Organic Program standards.[361] Thus, "organic" is not a perfect proxy for the range of concerns a particular consumer may have about food.[362] Organic food is also widely thought to be more expensive than conventionally-produced food and thus out of reach for many consumers. Many consumers may prefer to choose the specific process-related attributes of food they care about and are willing to pay a premium to obtain.[363] Indeed, public reaction to a recent study,[364] downplaying the nutritional advantages of organic foods, indicates that consumers consider a variety of factors in choosing which foods to purchase and eat.[365]

The House Report accompanying the 1938 bill noted that the 1906 Act "contain[ed] serious loopholes and [was] not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions."[366] The 1906 Act was "vague and ambiguous in its language regarding adulteration of food" and "did not provide for control over false advertising. . . . [T]he consumer was virtually without any protection in this area."[367] Meanwhile, "flagrant abuses in the market were growing."[368]

The FDCA, "a new and far more adequate food and drug law[,] came into being" after five years of struggle in Congress.[369] The House Report noted the intent "to extend the protection of consumers contemplated by the law to the full extent constitutionally possible."[370] The 1938 Act "insure[d] fair dealing in the interest of the

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361 *See* National Organic Program, 7 C.F.R. § 205 (2013).

362 *See generally* Chen, *supra* note 33, at 223 (discussing the potential of organic agriculture, through its focus on philosophical and aesthetic considerations, to overcome both economics and natural science as bases for policy-making).

363 *See, e.g.*, Nicholas D. Kristof, Op-Ed., *Where Cows Are Happy and Food is Healthy*, N.Y. TIMES (Sept. 8, 2012), http://www.nytimes.com/2012/09/09/opinion/sunday/kristof-where-cows-are-happy-and-food-is-healthy.html?src=recg.

364 *See* Crystal Smith-Spangler et al., *Are Organic Foods Safer or Healthier than Conventional Alternatives?: A Systematic Review*, 157 ANNALS OF INTERNAL MED. 348 (2012).

365 *See, e.g.*, Jamie Kopf, *Don't Give Up on Organic Food, Our Experts Urge*, CONSUMER REPORTS.ORG (Sept. 5, 2012), http://www.consumerreports.org/cro/news/2012/09/dont-give-up-on-organic-food-our-experts-urge/index.htm.

366 H.R. REP. NO. 75-2139, at 1 (1938).

367 CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL 5 (1970).

368 *Id.* at 5.

369 *Id.* at 23.

370 H.R. REP. NO. 75-2139, at 3.

consumer."[371] The FDCA "was well worth the five-year fight in terms of new protection offered to the American consumer."[372]

The Supreme Court has repeatedly recognized the consumer-protection purpose of the FDCA. According to the Court,

> [b]y the Act of 1906, as successively strengthened, Congress exerted its power to keep impure and adulterated foods and drugs out of the channels of commerce. The purposes of this legislation . . . 'touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.'[373]

As a consequence, "[r]egard for these purposes should infuse construction of the legislation."[374] Later, the Court noted that "[b]oth the text and the legislative history of the [1938 Act] plainly show that its purpose was *not* confined to a requirement of truthful and informative labeling," which had existed even under the 1906 Act.[375] Instead, requiring truthful labeling was inadequate to "protect the consumer from 'economic adulteration,' by which less expensive ingredients were substituted . . . so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold."[376]

The 1938 Act's provisions "thus reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of technically truthful labeling, the relative merits of a variety of products superficially resembling each other."[377] The legislative focus on consumer information and choice of products could hardly be clearer in extending beyond safety concerns to a wide range of factors that *consumers* consider "material." The fact that many consumers have indicated a preference for labeling as to GE technology, artificial hormones, antibiotics, chemicals in food packaging, and a host of other process-related concerns should prompt FDA to consider labeling requirements that go directly to the process by which food

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371 *Id.* at 5.

372 JACKSON, *supra* note 367, at 195.

373 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. 593, 596 (1951) (quoting United States v. Dotterweich, 320 U.S. 277, 280 (1943)) (internal citation omitted).

374 *Id.*

375 Fed. Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218, 230 (1943) (emphasis added).

376 *Id.*

377 *Id.* at 231.

was produced, rather than insisting that only the composition of the finished food product matters. Additionally, proper context for whether a representation is misleading should focus on the realities of the modern food system—how consumers acquire food today and what information consumers think they need to evaluate the safety and value of food products. Disclaimers indicating, for example, that foods produced without use of GM technology do not differ compositionally from GM foods, should not be required. Under the statute and regulations already in place, all foods are required to be properly identified by name, to be accompanied by a list of ingredients, and so on.[378] An additional statement that there is no compositional difference not only is not material but may actually be confusing. Such a statement seems intended to disparage the non-GE food or to rehabilitate the GE food in consumers' eyes, rather than to provide information upon which consumers can evaluate the products for themselves.

CONCLUSION

The FDCA and related statutes establish a broad mandate to ensure that America's food supply is both safe and fair. These statutes provide ample authority for FDA and USDA regulation of matters relating to the process by which foods are produced. As a result, these agencies' narrow focus on the composition and identity of foods is misplaced. Consumers deserve protection with respect to process-related attributes of food precisely because it is those attributes they are least able to judge for themselves. The FDA and USDA should abandon the notion that jurisdiction to regulate exists only when foods are significantly different from or are not substantially equivalent to traditional foods. That concept has no basis in the statutes' food provisions.

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378 *See generally* 21 U.S.C. §§ 343(b)–(m) (2012).