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Let's Stop Worrying and Learn to Love Transparency: Food and Technology in the Information Age

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LET'S STOP WORRYING AND LEARN TO LOVE TRANSPARENCY: FOOD AND TECHNOLOGY IN THE INFORMATION AGE

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I. INTRODUCTION

Food and technology have had a long and tempestuous relationship. Current methods of food production and processing in the industrialized world depend heavily on technological developments. However, all technologies are not created equal. Some can produce food that is safer, more sustainable, more nutritious, or longer lasting.[1] Some can have the opposite effect: increasing opportunities for adulteration,[2] increasing the difficulty in detecting food fraud,[3] and contributing to both foreseeable and unforeseeable health or ecological costs.[4] Increasingly sophisticated technologies often

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1. *See, e.g.*, Y. MOTARJEMI ET AL., FOOD SAFETY ISSUES: FOOD TECHNOLOGIES AND PUBLIC HEALTH 7 (World Health Organization July 25, 1995), *available at* http://www.who.int/foodsafety/publications/fs_management/en/foodtech.pdf (declaring that food technology should be recognized as a health technology as well); ROYAL SOCIETY NAMES REFRIGERATION MOST SIGNIFICANT INVENTION IN THE HISTORY OF FOOD AND DRINK (Sept. 13, 2012), http://royalsociety.org/news/2012/top-20-food-innovations/; Nadia Arumugam, *Best Food Innovations of 2012*, FORBES (Dec. 26, 2012, 12:09 PM), http://www.forbes.com/sites/nadiaarumugam/2012/12/26/best-food-innovations-of-2012/ (including in this list edible food packaging and drifting ocean fish farms).

2. *See, e.g.*, James Griffiths, *20,000 Kilos of Fake Beef Seized in Xi'an*, SHANGHAIIST (Sept. 14, 2013, 11:00 PM), http://shanghaiist.com/2013/09/14/20000_kilos_of_fake_beef_seized_in_xian.php; Patrick Boehler, *Bad Eggs: Another Fake-Food Scandal Rocks China*, TIME NEWSFEED (Nov. 6, 2012), http://newsfeed.time.com/2012/11/06/how-to-make-a-rotten-egg/.

3. *See, e.g.*, Daniel Kelley, *5 Food Frauds You Might Have to Watch For*, ESQUIRE (Jun. 12, 2013, 7:00 AM), http://www.esquire.com/blogs/food-for-men/food-frauds-to-watch-15574457; Shoshana Walter, *Farm Fakes: A History of Fraudulent Food*, MODERN FARMER (May 3, 2013), http://modernfarmer.com/2013/05/farm-fakes-a-history-of-fraudulent-food/.

4. *See, e.g.*, Crystal Gammon and Environmental Health News, *Weed-Whacking Herbicide Proves Deadly to Human Cells*, SCIENTIFIC AMERICAN (June 23, 2009), http://www.scientificamerican.com/article.cfm?id=weed-whacking-herbicide-p;

become less apparent to the average consumer. For example, consider irradiated meat or genetically modified foods as opposed to freezer storage or homogenization. Some food technologies, like freeze-drying, tend to attract consumers.[5] Others, like meat from cloned animals, tend to elicit negative reactions.[6] This wide variety in applications of technology to food, as well as the range of consumer responses, leaves industry stakeholders and regulatory bodies with difficult choices concerning when and where to involve consumers.

The astounding pace of technological innovation has outpaced developments in consumer participation, resulting in consumer frustration and an increasing sense of hostility between consumers on the one hand and industry and regulators on the other.[7] How can regulators and industry stakeholders foster innovation without alienating consumers? How can they develop and market innovative goods that consumers feel benefitted by? How can these goals be met in a climate that is often presented in a reductive binary: either technological innovation or transparency enabling consumer preference?

This paper compares United States ("U.S.") and European Union ("EU") approaches to the intensifying questions surrounding technology in the food industry. Juxtaposing the U.S. and EU is not meant to automatically elevate one approach above another, but to highlight the range of choices available. Through an evaluation of the role consumer concerns play in the adoption of currently marketed innovative food technologies, this paper shows that the developing field of nanotechnology presents an opportunity for proponents of technology in the food industry. This paper argues that regulators and industry stakeholders should embrace a conception of the consumer as intelligent, thoughtful, and invested in the potential benefits of technology. By acting on this view of consumers, regulators and the industry can repair their relationships with consumers and build development and regulatory protocols that serve all these groups better.

Maggie Koerth-Baker, *Listeria Evolved to Live in Your Fridge*, BOING BOING (May 5, 2011, 8:41 AM), http://boingboing.net/2011/05/05/listeria-evolved-to.html.

5. Steven Rinella, *A Love Affair with Freeze-Dried Food*, OUTSIDE (March 6, 2013), http://www.outsideonline.com/outdoor-adventure/culinary/A-Love-Affair-With-Freeze-Dried-Food.html (noting a steady increase in consumer sales).

6. James Meikle, *Public Strongly Against Cloned Animal Meat, Study Reveals*, GUARDIAN (June 5, 2008), http://www.theguardian.com/science/2008/jun/06/foodtech.food; Finlo Rohrer, *What are Attitudes to Clone Food in the US?*, BBC (Aug. 4, 2010), http://www.bbc.co.uk/news/world-us-canada-10871737.

7. *See* Elen Stokes, *You Are What You Eat: Market Citizens and the Right to Know About Nano Foods*, 2 J. HUMAN RIGHTS ENV'T 178, 179-80 (2011).

However, this paper suggests that industry stakeholders and regulators should embrace consumer preference by increasing transparency and involving consumers in key policymaking structures surrounding nanotech and other developing food technologies. As significant stakeholders in the food system, consumers should be educated, and their input should be valued. Some evidence presented in this paper suggests this inclusion will result in positive responses when a consumer benefit can be shown. If consumers feel they are participants in the development of new food technologies they are more likely to make calculated risks rather than rejecting the technology out of hand.

This paper does not seek to suggest a value—or lack thereof—of developing food technologies or to evaluate related scientific data. Rather, it proposes better integration of consumers into the process of developing and regulating new food technologies. This integration will, in turn, result in a more transparent process that can benefit industry stakeholders as well as consumers and regulators. As an analytic lens, this paper will compare approaches by the U.S. and the EU, which have long been in tension and have resulted in numerous international and bilateral trade disputes.

The analysis is structured as follows: this paper first discusses the current role of consumers in developing and regulating new food technologies, such as irradiation, artificial hormones, antibiotics, and genetically engineered crops. Then follows a survey of the current state of nanotechnology, which shows it is an area ripe for new approaches. The final section suggests new avenues of promoting consumer engagement with nanotech development, which can serve as a model for other developing food technologies.

II. CURRENT CONSUMER RELATIONSHIP TO FOOD TECHNOLOGIES

A. *Technological Development Drives Supply and Demand*

Technology has served as the primary shaper of food supply and demand throughout history, in a "boom and bust cycle".[8] For example, the development of irrigation and plows increased production but also resulted in erosion and soil infertility.[9] These issues were addressed with the development of crop rotation, cover crops, and manure-based fertilizers.[10]

8. JOHNS HOPKINS CENTER FOR A LIVABLE FUTURE, *Teaching the Food System: History of Food* (last accessed Dec. 18, 2013) [hereinafter *History of Food*], http://www.jhsph.edu/research/centers-and-institutes/teaching-the-food-system/curriculum/_pdf/History_of_Food-Lesson.pdf.

9. *Id.*

10. *Id.*

Further increases in food production resulted in increases to the population, which precipitated the need for additional production and catalyzed the development of refrigeration, synthetic fertilizers, monocultures, and significant food imports and exports.[11] The industrialized food system relies on economies of scale, and this incorporates the values of specialization, simplification, routinization, mechanization, standardization, and consolidation.[12]

The current food system has resulted in minimal off-the-shelf costs for many,[13] but also increased tension between consumers and food producers. Consumers are becoming more aware of marketing strategies aimed to get them to pay the same amount of money for a less costly product, or for products with little to no nutritional value.[14] The hidden cost of externalities—like skyrocketing chronic diseases and increasing awareness of environmental unsustainability of food production processes—and new issues—like superweeds, antibiotic resistance, and arsenic in chicken—have resulted in resurging consumer wariness of industry and regulator assurances.[15] Increasing attention is being paid to the rise of consumer distrust, which seems poised to increase as technology develops.[16] Many consumers feel current uses of technology in food are driven by profit, without regard to their social, environmental, ethical, or health preferences.[17]

Without a change in the way industry and regulators interact with consumers, consumers will likely continue to see food technologies as geared toward industry benefit rather than their own enrichment. This may lead to increased consumer backlash and rejection of new technologies.

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11. WILLIAM J. BERNSTEIN, A SPLENDID EXCHANGE: HOW TRADE SHAPED THE WORLD 12-14 (2009).

12. *History of Food*, *supra* note 8, at 13-14; *see also* JARED DIAMOND, GUNS, GERMS, AND STEEL 279 (1999).

13. Americans spend less than 9% of their incomes on groceries, almost a 30% reduction compared to the early 80s. Lam Thuy Vo, *What America Spends on Groceries*, NPR'S PLANET MONEY (June 8, 2012, 10:37 AM), http://www.npr.org/blogs/money/2012/06/08/154568945/what-america-spends-on-groceries.

14. *See, e.g.*, Michael Moss, *The Extraordinary Science of Addictive Junk Food*, NY TIMES (Feb. 20, 2013), http://www.nytimes.com/2013/02/24/magazine/the-extraordinary-science-of-junk-food.html.

15. *See, e.g.*, Maria Lee, *Risk and Beyond: EU Regulation of Nanotechnology*, 35 EUR. L. REV. 799, 800, 816-18 (2010).

16. Stokes, *supra* note 7, at 178-79.

17. *Americans Lack Trust in and Knowledge of Food Industry, Finds New FoodThink White Paper*, PR NEWSWIRE (March 19, 2013), http://www.prnewswire.com/news-releases/americans-lack-trust-in-and-knowledge-of-food-industry-finds-new-foodthink-white-paper-199063621.html (noting that 81% of US consumers express distrust of the food industry).

To illustrate the current tensions, this paper will examine the reception of several significant food technologies: irradiation, artificial hormones, routine antibiotics in animal agriculture, and genetically engineered crops. Each section will compare the responses of European Union and United States industry and regulators.

1. Irradiation

Exposing food products to ionizing radiation kills pests, delays ripening, and reduces some microbes; this extends shelf life and decreases contamination.[18] Originally used extensively on astronaut food, irradiation did not expand into the consumer market until the 1980s.[19] While it is considered safe within certain parameters by both the EU and U.S., consumers expressed concerns over whether approved doses would leave irradiated food radioactive or alter nutrition, taste, or texture, as well as whether manufacturers would use the technology as a substitute for sanitary practices.[20]

While U.S. consumers were initially wary, several studies suggested educating them on the potential benefits of irradiation, especially in comparison with the alternatives, would result in increased acceptance.[21] While the Food and Drug Administration ("FDA") now requires labeling of some irradiated foods, it responded to consumer concerns by making it harder to identify which foods were irradiated.[22] In 1984, it originally proposed no labeling requirement.[23] In 1997, it decreased label visibility and

18. *Food Irradiation*, ENV'T PROTECTION AGENCY, http://www.epa.gov/radiation/sources/food_irrad.html (last updated Feb. 7, 2013).

19. Jo´zsef Farkasa and Csilla Moha´csi-Farkas, *History and Future of Food Irradiation*, 22 TRENDS IN FOOD SCI. & TECH. 121, 122 (2011).

20. *See e.g.*, Samuel S. Epstein and Wenonah Hauter, *Preventing Pathogenic Food Poisoning: Sanitation, Not Irradiation*, 31 INT'L J. HEALTH SERV. 187 (2001); PUBLIC CITIZEN, FOOD IRRADIATION AND GLOBAL TRADE: WHAT IRRADIATION MEANS FOR FARMERS AND RANCHERS IN THE UNITED STATES AND THROUGHOUT THE WORLD (2003), *available at* www.citizen.org/documents/tradereport.pdf.

21. Michael Boland and Sean Fox, *Food Irradiation and Public Health*, U. MINN. FOOD POLICY RESEARCH CTR. (Nov. 2012), https://conservancy.umn.edu/bitstream/157629/1/FPRC_Issue%20Brief_Irradiation_UDC%202013.pdf.

22. FDA, *Food Irradiation: What You Need to Know*, http://www.fda.gov/Food/FoodScienceResearch/ToolsMaterials/ucm216924.htm (last updated Nov. 7, 2014).

23. WASHINGTON ASSOCIATED PRESS, *FDA Proposes Softening Irradiated Food Labels*, USA TODAY (Apr. 4, 2007) [hereinafter *FDA Proposes*], http://usatoday30.usatoday.com/news/health/2007-04-04-food-radiation_N.htm.

exempted disclosure of irradiated ingredients.[24] In 2007, it proposed allowing irradiated food labels to say "pasteurized" or "cold pasteurized" instead of "treated by radiation" or "treated by irradiation."[25] Further, the FDA has rejected various requests for public hearings by consumer advocacy organizations, while expanding approved uses of irradiation.[26]

In the EU, the government responded to consumer concerns in 1999 by permitting irradiation only where necessary, non-hazardous, beneficial to consumers, labeled, and not replacing proper manufacturing practices.[27] EU rules also require inspection of irradiation facilities and devices.[28] Member states are allowed to further restrict or ban the practice as they see fit.[29] These different approaches have resulted in vastly different utilization of the technology. In 2010, the U.S. irradiated over 100,000 tons of food, eleven times the amount irradiated in the EU.[30]

2. Artificial Hormones in Meat Animals

Synthetically produced growth hormones sparked intense disagreement between the European Union and the United States, including a World Trade Organization ("WTO") dispute.[31] These hormones are relatively inexpensive in their artificial form and can increase producer profits significantly by promoting rapid muscle and fat growth.[32] However, they come at a cost. Because treated cattle require more energy-dense feed to support this faster growth, feed supplements began including meat and bone meal—a risk

24. Food & Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 306, 111 Stat. 2296 (1997).

25. *FDA Proposes*, *supra* note 23.

26. Irradiation in the Production, Processing, and Handling of Food, 76 Fed. Reg. 20509 (Apr. 13, 2011) (to be codified at 21 CFR pt. 179); Peyton Ferrier, *Irradiation of Produce Imports: Small Inroads, Big Obstacles*, USDA ERS (June 16, 2011), http://www.ers.usda.gov/amber-waves/2011-june/irradiation-of-produce-imports.aspx.

27. Council Directive 1999/2, 1999 O.J. (L 66/16) (EC); Council Directive 1999/3, art. 4, 1999 O.J. (L **66**/24) (EC).

28. *Id.*

29. *Id.*

30. Tamikazu Kume and Setsuko Todoriki, *Food Irradiation in Asia, the European Union, and the United States: A Status Update*, 62 RADIOISOTOPES 291 (2013). In the European Union, the most common irradiated foods are frog parts, poultry, and spices; in the US, spices, grains, fruits, and meats are routinely irradiated. *Id.* at 296-97.

31. Ladina Caduff, *Growth Hormones and Beyond* 1-2 (Swiss Federal Institute of Technology Zurich, Working Paper No. 8-2002, Aug. 2002), *available at* http://www.ib.ethz.ch/docs/working_papers/wp_2002_08.pdf.

32. Renee Johnson and Charles E. Hanrahan, *The U.S.-EU Beef Hormone Dispute*, CONGRESSIONAL RESEARCH SERVICE, 1 (Dec. 6, 2010), *available at* http://www.fas.org/sgp/crs/row/R40449.pdf.

factor for BSE ("Mad Cow Disease").[33] Consumer concerns regarding these hormones related not only to BSE, but also to cancer and reproductive harm in humans[34] and animal welfare.[35] Europeans were particularly concerned after several "hormone scandals," including the discovery of endocrine disruptors in baby food from cattle fed hormone growth stimulants.[36]

U.S. consumers opposed to these hormones did not gain traction with regulators, despite some support from the General Accounting Office ("GAO").[37] The United States allows added growth hormones in cattle and sheep production without labeling.[38] While safe residue levels have been established, a 2010 audit found the United States Department of

33. Judith Ferera, *Environment: Mad Cows And Growth Hormones Part Of The Same Problem*, INTER PRESS SERVICE (March 25, 1996), http://www.ipsnews.net/1996/03/environment-mad-cows-and-growth-hormones-part-of-the-same-problem/.

34. *See, e.g.*, SCI. COMMITTEE ON VETERINARY MEASURES RELATING TO PUB. HEALTH, *Assessment Of Potential Risks To Human Health From Hormone Residues In Bovine Meat And Meat Products*, EUROPEAN COMMISSION (April 30, 1999), *available at* http://ec.europa.eu/food/fs/sc/scv/out21_en.pdf.

35. Hormone use tends to correspond with industrialized CAFOs, which have a reputation for inhumane animal treatment. *See, e.g.*, *What Are The Animal Welfare Impacts of Using Hormone Growth Promotants in Beef Cattle?*, RSPCA AUSTRALIA, http://kb.rspca.org.au/What-are-the-animal-welfare-impacts-of-using-hormone-growth-promotants-in-beef-cattle_459.html (last updated Nov. 12, 2014).

36. TIM JOSLING, TRADE DISPUTES AND THE DISPUTE SETTLEMENT UNDERSTANDING OF THE WTO 260 (James C. Hartigan, ed., 1st ed. 2009) ; RECONCILING ENVIRONMENT AND TRADE 279 (Edith Weiss Brown, et al., eds., 2008); G.M. Fara et al., *Epidemic of Breast Enlargement in an Italian School*, 2 LANCET 295 (1979).

37. *See* Samuel S. Epstein, *None of Us Should Eat Extra Estrogen*, LA TIMES (March 24, 1997), http://articles.latimes.com/1997-03-24/local/me-41521_1_hormone-levels; Jayson L. Lusk and John A. Fox, *Consumer Demand for Mandatory Labeling of Beef from Cattle Administered Growth Hormones or Fed Genetically Modified Corn*, 34 J. Ag. & Applied Econ. 27 (2002), *available at* http://ageconsearch.umn.edu/bitstream/15506/1/34010027.pdf (finding that 85 percent of respondents wanted mandatory labeling of beef produced with growth hormones); GAO, RECOMBINANT BOVINE GROWTH HORMONE: FDA APPROVAL SHOULD BE WITHHELD UNTIL THE MASTITIS ISSUE IS RESOLVED, REPORT TO CONGRESSIONAL REQUESTERS (Aug. 6, 1992), *available at* http://www.gao.gov/assets/220/216521.pdf.

38. *Steroid Hormone Implants Used for Growth in Food-Producing Animals*, FDA.GOV, http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055436.htm (last updated Feb. 8, 2011).

Agriculture's ("USDA") testing program inadequate to ensure compliance.[39] Recent efforts to improve that testing have yet to be evaluated for efficacy.[40]

During the first BSE scare in the 1990s, the EU banned imported meat from cows treated with these hormones.[41] The U.S. disputed this action with the WTO, which ruled against the EU and allowed punitive sanctions.[42] From the WTO perspective, the EU was making rules that were more restrictive than necessary to protect its citizens' health, and the policy was thus labeled as hidden protectionism.[43] Similar clashes have erupted with the use of rBGH in dairy cows[44] and a hormone-like drug called ractopamine in beef, pork, and turkeys.[45] While consumer concerns have not made much of a ripple regarding U.S. policy, increasing trade resistance to the hormone-like drugs recently prompted the USDA to implement a program labeling meats as "Never Fed Beta Agonists," hoping these meats will find less trade resistance.[46]

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39. U.S. DEP'T OF AGRIC. INSPECTOR GENERAL, AUDIT OF THE FSIS NATIONAL RESIDUE PROGRAM FOR CATTLE (March 25, 2010).

40. *See* Helena Bottemiller, *USDA to Ramp Up Drug Residue Testing for Meat and Poultry*, FOOD SAFETY NEWS (July 2, 2012), http://www.foodsafetynews.com/2012/07/usda-to-ramp-up-drug-residue-testing-for-meat-and-poultry/.

41. *Hormones in Meat – Introduction*, EUROPEAN COMM'N, http://ec.europa.eu/food/food/chemicalsafety/contaminants/hormones/index_en.htm (last updated Dec. 4, 2007).

42. Johnson & Hanrahan, *supra* note 32.

43. *Dispute Settlement: European Communities—Measures Concerning Meat and Meat Products (Hormones)*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm (last updated May 9, 2014).

44. Press Release, Consumer Policy Inst., U.S. and Europe Agree to Disagree on Safety of Dairy Hormone (June 30, 1999), *available at* http://consumersunion.org/news/u-s-and-europe-agree-to-disagree-on-safety-of-dairy-hormone/.

45. *See, e.g.*, Helena Bottemiller, *FDA Petitioned to Lower Ractopamine Limits for Meat, Review Health Impacts*, FOOD SAFETY NEWS (Dec. 21, 2012), http://www.foodsafetynews.com/2012/12/fda-petitioned-to-lower-ractopamine-limits-for-meat-review-animal-health-impact/.

46. *See* Helena Bottemiller, *Escalating Trade Dispute, Russia Bans Turkey Over Ractopamine Residues*, FOOD SAFETY NEWS (Feb. 8, 2013), http://www.foodsafetynews.com/2013/02/escalating-trade-dispute-russia-bans-turkey-over-ractopamine-residues/; Cathy Siegner, *USDA Introduces Certification Program for Meat Without Growth-Enhancing Drugs*, FOOD SAFETY NEWS (Nov. 14, 2013), http://www.foodsafetynews.com/2013/11/new-usda-certification-program-may-increase-exports-for-livestock-producers-who-dont-use-growth-enhancing-drugs/.

3. Antibiotics in Animal Agriculture

During the middle of the previous century, studies found that antibiotics could be used not only to treat sick animals, but also to prevent diseases prevalent in the crowded industrial animal feed operations.[47] Somehow, these antibiotics also increase feed conversion efficiency, resulting in ballooning use.[48] Increased antibiotic use coincided with consumer concerns surrounding antibiotic resistance, animal welfare, harm from residues, and whether they would be substituted for sanitary conditions.

The FDA approved routine feed-based antibiotic use in the 1950s based on these studies alone.[49] Similar to growth hormones, antibiotics are subject to residue limits and random testing.[50] The FDA did not solicit public comment regarding these approvals and waived regulations they could have enforced to require a showing of safety regarding these new uses.[51] After a 1969 United Kingdom ("UK") committee concluded that such uses contributed to antibiotic resistance in humans, the FDA convened a task force to address the issue.[52] In 1977, it attempted to withdraw several approvals, but was blocked by industry pressure.[53] Industry representatives claimed the FDA did not have sufficient scientific evidence of harm.[54] A 1980 study from the National Academy of Sciences found that:

> [E]xisting data could neither prove nor disprove the postulated hazards to human health from subtherapeutic antimicrobial use in animal feed. However, the report cautioned that "[t]he lack of data linking human illness with subtherapeutic levels of antimicrobials must not be equated with proof that the proposed hazards do not exist. *The research necessary to establish and measure a definitive*

47. Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VT. L. REV. 1007, 1010 (2013).
48. *Id.*at 1012.
49. *Id.* at 1010.
50. 21 C.F.R. § 556.1(a) (2010).
51. Heinzerling, *supra* note 47, at 1010.
52. Food & Drug Admin., *Guidance for Industry: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* 5-6 (April 13, 2012), *available at* http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf.
53. *Id.* at 6.
54. *Id.* at 6-7.

> *risk has not been conducted and, indeed, may not be possible.*"[55]

The following three decades produced additional domestic and international support for restricting sub-therapeutic antibiotic use in animals, including recommendations from the GAO, World Health Organization ("WHO"), and Codex Alimentarius,[56] as well as consumer groups.[57] Despite this, only 20% of antibiotics used in the United States from 2009 to 2010 were used by humans: over 70% were given in animal feed and water, with just 3% injected therapeutically.[58] The most recent attempts to address antibiotic overuse have come in the form of voluntary measures, which some argue will not be effective.[59]

The EU has responded to these realizations more quickly, but with varied success, and still much more slowly than might have been expected. For instance, in the 1990s, they banned selected antibiotics;[60] they increased the ban in 2006 to include all antibiotic use for growth promotion.[61] As part of the effort, the government also sponsors an annual EU Antibiotic Awareness Day to draw attention to the importance of their careful use.[62]

However, these policies still allow antibiotic use for disease prevention, which is administered the same way and in the same doses as for growth promotion.[63] Due to the allowances for disease-preventing antibiotics, actual

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55. *Id.* at 7 (emphasis added).

56. *Id.*at 8-14.

57. Helena Bottemiller, *FDA Denies Petition to Ban Certain Antibiotics*, FOOD SAFETY NEWS (Nov. 10, 2011), http://www.foodsafetynews.com/2011/11/fda-denies-petition-to-ban-certain-antibiotics/.

58. *Know The Facts About Antibiotic Resistance and Animal Agriculture*, KEEP ANTIBIOTICS WORKING (June 2012), http://www.keepantibioticsworking.com/new/Library/UploadedFiles/KAW_brochure_June2012.pdf.

59. Lydia Zuraw, *Will FDA's Voluntary Plan Actually Reduce Antibiotics in Animal Feed?*, FOOD SAFETY NEWS (Dec., 12, 2013), http://www.foodsafetynews.com/2013/12/fda-finalizes-guidance-for-phasing-out-antibiotics-in-food-animals/.

60. *The Antibiotic Ban in Denmark: A Case Study on Politically Driven Bans*, ANIMAL HEALTH INST., http://www.ahi.org/issues-advocacy/animal-anitbiotic-ban-in-denmark-a-case-study-on-politically-driven-bans/. (last visited Nov. 19, 2014).

61. *Animal Nutrition - Feed Additives - Basic Legislation*, EUROPEAN COMM'N, http://ec.europa.eu/food/food/animalnutrition/feedadditives/legisl_en.htm (last updated June 23, 2008).

62. Press Release, European Commission, European Antibiotic Awareness Day 2013: Key Facts on the Fight Against Antimicrobial Resistance in the EU (Nov. 15, 2013), http://europa.eu/rapid/press-release_MEMO-13-994_en.htm.

63. Dan Charles, *Europe's Mixed Record on Animal Antibiotics*, NPR'S THE SALT (March 23, 2012, 4:53 PM),

use varies.[64] However, since the 90s, Denmark has successfully cut its use in half.[65] Even the Netherlands—which used comparable amounts to the U.S.—is finally seeing a decrease.[66]

4. Genetically Engineered Crops

Compared to irradiation, hormones, and antibiotics, genetic engineering ("GE")[67] presents a wider range of possible applications to food—the combination of foreign genes that may be inserted into a base crop's genetic code is almost endless. This carries with it a corresponding breadth of potential concerns, including human safety, allergens, environmental impact, cross breeding with conventional seeds, superweeds, and increased monocultures and pesticide use. The few consumers introduced to GE crops early in their development expressed enthusiasm for their development, but wanted studies completed regarding the above issues—and they opposed large-scale production.[68] They favored strict regulation but did not trust agencies on their own—they wanted input from public health officials, environmental groups, and taxpayers.[69]

In 1986, when biotechnology was in its infancy, the Reagan White House developed the "Coordinated Framework"—assigning current laws administered by the FDA, USDA, and the Environmental Protection Agency ("EPA") to foods developed with biotechnology, on the assumption that they

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http://www.npr.org/blogs/thesalt/2012/03/23/149221287/europes-mixed-record-on-animal-antibiotics.

64. *Id.*

65. *Id.*

66. *Id.*

67. This term may be used to reference direct genetic manipulation using biotechnology and includes what are commonly referred to as GMOs – genetically modified organisms.

68. Alison Peck, *Does Regulation Chill Democratic Deliberation? The Case of GMOs*, 46 CREIGHTON L. REV. 653, 668 (2013) ("[A] majority of respondents supported equal or increased government support for biotechnology research, and most supported small-scale field tests. When asked about large-scale environmental releases (short of commercial release), however, respondents were more skeptical: fifty-three percent said firms should not be able to make such releases, even 'if the risks of environmental danger are judged to be very small.'") (citing Office of Tech. Assessment, New Developments in Biotechnology: Public Perceptions of Biotechnology (May 1987), 83-84 & 87-88).

69. *Id.* at 668-69 ("When asked whether they would believe statements about the risk of a biotech product from various groups, respondents were more inclined to believe university scientists, public health officials, and environmental groups than federal agencies.").

present no unique risks.[70] These and other key decisions were implemented without meaningful public input.[71] Until a groundswell of public demand, the FDA discouraged even most voluntary labeling as potentially confusing and misleading.[72] In 2011, the USDA fast-tracked approvals for new strains,[73] while 60% to 70% of foods other than fresh fruits and vegetables used GE ingredients.[74] Meanwhile, decades into the development and use of GE crops, fewer than half of U.S. consumers knew about such products in 2013, and only one quarter believed they had eaten GE foods.[75]

Consumers who have learned about these foods are demanding information but receiving intense industry opposition.[76] Nearly half of American states have introduced mandatory labeling proposals.[77] Several local governments are considering, or have already, banned or limited GE

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70. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *Issues in the Regulation of Genetically Engineered Plants and Animals* 1 (April 2004) [hereinafter PEW INITIATIVE], http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/food_biotech_regulation_0404.pdf.

71. Peck, *supra* note 68 (concluding that, "[T]he history of biotechnology development and public awareness of that technology raises doubts as to whether the public has had an opportunity to engage in meaningful democratic deliberation about biotech controls."); *see also* PEW INITIATIVE, *supra* note 70, at 18, 86 (noting that FDA processes have no minimum requirements for public participation and transparency; many current GE foods are put on to market after voluntary, confidential consultations between the agency and the product's developers).

72. Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, FDA.GOV, *available at* http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm059098.htm (last visited Nov. 19, 2014) ("A statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies that the labeled food is superior to foods that are not so labeled.").

73. *Petition Process Improvements*, USDA, http://www.aphis.usda.gov/biotechnology/pet_proc_imp.shtml (last modified March 5, 2012).

74. Maggie Caldwell, *5 Surprising Genetically Modified Foods*, MOTHER JONES (Aug. 5, 2013, 2:00 AM), http://www.motherjones.com/environment/2013/08/what-are-gmos-and-why-should-i-care.

75. William K. Hallman et al., *Public Perceptions of Labeling Genetically Modified Foods* 4 (Nov. 1, 2013), http://humeco.rutgers.edu/documents_PDF/news/GMlabelingperceptions.pdf.

76. CENTER FOR FOOD SAFETY, *State Labeling Initiatives*, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/state-labeling-initiatives (last accessed Dec. 21, 2013).

77. *Id.*

crops, including Hawaii's Big Island,[78] several California counties,[79] and the City of Los Angeles.[80] The industry spent millions of dollars to oppose mandatory labeling in just two states and is aiming for a federal ban.[81] To fill the gap between industry and government reticence on the one hand and consumer demand on the other, expensive niche retailers like Whole Foods are developing private labeling requirements,[82] leading to a sense that transparency is, for many dependent on the U.S. food system, an unaffordable luxury.

The EU countries first imported GE crops in 1996, near the height of the BSE scandals that shattered public trust in government food regulators.[83] Despite the opposition of consumer groups, environmental groups, and some scientists, the EU originally approved fourteen GE plants and was poised to approve thirteen more.[84] Member states, however, instituted their own bans and called for biotech manufacturer liability legislation before they would continue approvals or imports.[85] U.S. crop containment failures in 2000 and 2005 further eroded confidence in the technology.[86]

In response, the EU adopted additional regulations, including the Regulation on Novel Foods and Novel Food Ingredients, which requires labeling of many GE products.[87] It also created the European Food Standards Agency to conduct independent safety assessments.[88] While the EU was working to craft approval processes acceptable to member countries, the U.S.

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78. *Hawaii's Big Island Bans Biotech Companies & GMO Crops*, HUFFINGTON POST (Nov. 19, 2013, 10:01 PM), http://www.huffingtonpost.com/2013/11/19/big-island-bans-gmo_n_4305729.html.

79. Gabriela Pechlaner, *GMO-Free America? Mendocino County and the Impact of Local Level Resistance to the Agricultural Biotechnology Paradigm*, 19 INT'L J. OF SOC'Y OF AGRIC. & FOOD 445 (2012).

80. *Los Angeles May Become Largest GMO-Free Area in the US*, RT.COM (Oct. 24, 2013, 12:05 AM), http://rt.com/usa/los-angeles-gmo-ban-643/.

81. Stephanie Strom, *Food Companies Claim Victory Against Labeling Initiative in Washington State*, NY TIMES (Nov. 7, 2013), *available at* www.nytimes.com.

82. Stephanie Strom, *Major Grocer to Label Foods With Gene-Modified Content*, NY TIMES (March 9, 2013), *available at* www.nytimes.com.

83. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *U.S. vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food*, PEWTRUSTS.ORG 8 (Dec. 2005, 8), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Biotech_USEU1205.pdf.

84. *Id.* at 9.

85. *Id.* at 10.

86. *Id.* at 28, 33.

87. *Id.* at 9.

88. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *U.S. v. EU*, *supra* note 83, at 28.

launched another trade dispute.[89] The EU streamlined their approval process, but still required labeling and traceability.[90] A 2010 study indicates that 84% of EU citizens had heard of GE foods and 61% felt their development should not be encouraged, though these opinions vary from country to country.[91] While the EU has responded to international pressures to accept GE food technologies,[92] public concerns seem to have significantly influenced approvals and use in the EU market.[93]

B. *Regulator and Industry Assumptions Regarding Consumers*

The approaches of the U.S. and the EU, while different, are not an exclusive binary. However, the divergence between the approaches highlights the substance, causes, and effects of assumptions regarding consumers. The U.S. focuses its food regulation on immediate food safety concerns, rather than long-term effects or social or environmental concerns. The FDA, which regulates about 80% of the U.S. food supply,[94] has repeatedly disclaimed responsibility for incorporating such concerns in its regulations and guidance.[95] For example, when refusing to incorporate U.S. consumer comments regarding animal cloning in its policies, the FDA said,

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89. *Id.* at 10.

90. *Id.* at 13.

91. TNS OPINION & SOCIAL for the EUROPEAN COMM'N, SPECIAL EUROBAROMERTER 73.1: BIOTECHNOLOGY REPORT 13-32 (Oct. 2010) [hereinafter EUROBAROMETER], *available at* http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf.

92. For example, the EU has required member states to drop wholesale bans on GE products. *EU Tells Serbia to Drop GMO Ban in Order to Join WTO*, B92.NET (Oct. 17, 2013), http://www.b92.net/eng/news/business.php?yyyy=2013&mm=10&dd=17&nav_id=88036.

93. Today, ninety GE crop varieties can be grown in and exported from the U.S., while only two are approved for cultivation in the EU, with thirty-nine approved as imports. Gemma Masip et al., *Paradoxical EU Agricultural Policies on Genetically Engineered Crops*, 18 TRENDS IN PLANT SCIENCE 312, 320 (2013). Some studies suggest, though, that consumers do not actively avoid foods containing GE ingredients to the degree predicted. Susanne Sleenhoff and Patricia Osseweijer, *Consumer Choice: Linking Consumer Intentions to Actual Purchase of GM Labeled Food Products*, 4 GM CROPS AND FOOD: BIOTECHNOLOGY IN AGRICULTURE AND THE FOOD CHAIN 166 (2013).

94. *FDA Facts: Food Safety Modernization Act*, FDA (May 2012), http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM305765.pdf.

95. *See generally* U.S. Food & Drug Admin., FDA'S RESPONSE TO PUBLIC COMMENT ON THE ANIMAL CLONING RISK ASSESSMENT, RISK MANAGEMENT PLAN, AND GUIDANCE FOR INDUSTRY 5 (Oct. 28, 2009), http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm055491.htm.

> The agency is not charged with addressing non-science based concerns such as the moral, religious, or ethical issues associated with animal cloning for agricultural purposes, the economic impact of products being released in commerce, or other social issues unrelated to FDA's public health mission.[96]

In the U.S., the focus is thus on public health, or food safety. The Nutrition Labeling and Education Act provided the FDA with the additional mandate of providing nutrition and other labeling.[97] This facilitates some consumer ability to make choices between foods, but only foods that the FDA has decided are materially different.[98]

Public interest groups—such as the Center for Science in the Public Interest, Public Citizen, and the Consumer Federation—cooperate with other consumer groups on an international level, but do not have a formalized association with either the FDA or Congress. Their input must be given either in the form of lobbying, lawsuits, or the general public comment process, which is not available until a ruling is already in draft stage and the industry concerned has already been extensively consulted.[99] FDA officials often are hired after working at a high level in a food or drug manufacturing business.[100] This structure allows for consumer input only at the last moments of rule-making. Further, it results in a FDA that is more versed in the perspective of the business than the perspective of the consumer.

In contrast, EU food regulations consciously respond to consumer concerns. The European Commission has noted a need for increased consumer education and involvement in order to increase confidence in the market.[101] In fact, citing the increased responsibility placed on consumers by market liberalization, it developed a comprehensive strategy that includes

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96. *Id.*

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

98. *Id.*

99. *Comment on Proposed Regulations and Submit Petitions*, FDA.GOV, http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm (last visited Dec. 1, 2014).

100. *See* David Zaring, *Against Being Against the Revolving Door*, 2013 U. ILL. L. REV. 507 (2013) (discussing the crossover between public agency and private industry employees).

101. *Commission Communication to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, A European Consumer Agenda – Boosting confidence and growth*, at 9 COM (2012) 132 final (May 22, 2012), *available at* http://ec.europa.eu/consumers/strategy/docs/consumer_agenda_2012_en.pdf.

consumer education even during compulsory schooling years.[102] EFSA ("European Food Safety Authority"), an EU analogue to the FDA, oversees food safety.[103] In order to allow EFSA to assess and monitor how consumers perceive it, EFSA also carries out research among its key target audiences, performing routine assessments to see whether it is meeting its further goal of "communication and dialogue" to "reinforce confidence and trust in EFSA and the EU food safety system through effective risk communications and dialogue with partners and stakeholders."[104]

Consumer groups in the EU also benefit from formalized connections to the government. For instance, the European Consumer Organization ("BEUC") lobbies EU decision-making bodies on behalf of independent consumer groups throughout Europe.[105] A significant part of their funding comes from an EU grant for consumer organizations.[106] Perhaps even more significant is the European Consumer Consultative Group ("ECCG"), which was created by the European Commission to advise it on consumer issues and disseminate information to consumer groups.[107] To preserve the group's integrity, only individuals independent of both industry and government may serve on the ECCG.[108] The divergent consumer input structures between the U.S. and the EU mirror the differences between how these governments have dealt with developing food technologies.

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102. *Commission Staff Working Document on Knowledge-Enhancing Aspects of Consumer Empowerment*, at 17 COM (2012) 235 final (July 19, 2012) [hereinafter *Consumer Empowerment*], *available at* http://ec.europa.eu/consumers/strategy/docs/commission_staff_working_knowledge_enhancing_2012_2014_en.pdf.

103. *European Food Safety Authority*, EUROPA, http://europa.eu/about-eu/agencies/regulatory_agencies_bodies/policy_agencies/efsa/index_en.htm (last accessed Dec. 18, 2013).

104. *Who We Work With*, EFSA, http://www.efsa.europa.eu/en/aboutefsa/efsapartners.htm (last accessed Nov. 20, 2014).

105. *Who We Are,* BEUC, http://www.beuc.org/about-beuc/who-we-are (last accessed Nov. 20, 2014).

106. *How are We Financed?*, BEUC, http://www.beuc.org/about-beuc/financial-information (last accessed Nov. 20, 2014).

107. *European Consumer Consultative Group*, EUROPEAN COMM'N, http://ec.europa.eu/consumers/empowerment/eccg_en.htm (last accessed Dec. 19, 2013).

108. *European Consumer Consultative Group*, EUROPA, http://europa.eu/legislation_summaries/consumers/protection_of_consumers/co0010_en.htm (last accessed Dec. 19, 2013).

1. Issues Raised

In the preceding illustrations, several issues emerge as central to decisions of when and how to respond to consumer concerns: (1) distinctions between process and product, (2) a right to know what one eats, (3) free trade concerns, and (4) science-based regulation. The following sections address those issues.

a. *Process vs. Product*

Product information relates to a good as received by the consumer. An example of a product-related disclosure would be nutrition information: if a granola bar contains 3 grams of fiber, this is so regardless of the machines used to make it, the company's labor practices, or the types of pesticides used to grow the ingredients. Process information, on the other hand, addresses how the product got to be the way it is: Did its production harm workers, animals, or the environment? Is there a difference between this good and another one that appears identical? Examples of process information include organic, fair trade, and dolphin-safe labels.

The process/product distinction features prominently in international trade negotiations and U.S. food labeling regulation.[109] In international trade, process-based distinctions are viewed as suspicious, disguised protectionism rather than responses to legitimate market needs.[110] Under WTO rules, process-based measures elicit stricter scrutiny and require more justification than product-based measures.[111] U.S. rule makers have relied on this distinction when dismissing consumer wishes for more information.[112] U.S. industry groups have developed free-speech legal arguments by distinguishing process information as less substantial than product information.[113] On the one hand, they argue that mandatory process disclosures are not justified by consumer interest; on the other, they claim

109. Douglas A. Kysar, *Preferences For Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525, 540 (2004).
110. *Id.* at 545.
111. *Id.* at 545-47.
112. *See, e.g.*, Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 431 (2002) ("[B]iotechnology should not be regulated as a process, but rather that the products of biotechnology should be regulated in the same way as products of other technologies.") (quoting NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 25 (2000)) (internal quotation marks omitted).
113. Kysar, *supra* note 109, at 569. For further explanation, see the section on consumers' right to know. pg. 24 et seq.

that their own voluntary process-related disclosures should be exempt from the advertising regulations that apply to product-related information.[114]

Critics say the process/product distinction is artificial, reductionist, and difficult to apply.[115] Supporters claim the distinction protects consumers hampered by information limitations and naïveté.[116] In practice, the process/product distinction can function to restrict information, adding to problems of consumer confusion or lack of knowledge rather than solving them.[117] "Natural" food labels provide a prime example. A majority of Americans look for the label "natural" when they shop.[118] Most believe such food is produced without pesticides, herbicides, genetic engineering, or artificial ingredients.[119] Many further believe that a food labeled "natural" is closer to these ideals than one labeled "organic."[120] However, the FDA has not defined the term "natural" and only offers voluntary guidance for its use.[121] The past two years have seen over one hundred false advertising lawsuits over "natural" claims alone.[122] Some, like PepsiCo's Naked Juice, reached multi-million dollar settlements.[123] Public interest groups like the

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114. *Id.*

115. *Id.* at 540.

116. *Id.* at 537.

117. *Id.* at 641. ("This process/product distinction has been invoked to question the authority of an importing nation to ban or label products that are developed using processes deemed objectionable by its citizens; to rationalize ignoring overwhelming consumer support for mandatory labeling of food products that contain genetically engineered ingredients; and to narrow the constitutional conditions under which states may force manufacturers to disclose process information or to face legal challenges for disclosing false or misleading process information. *These efforts to restrict the informational environment of consumers exist uncomfortably within a global political climate that increasingly embraces market liberalism and the rhetoric of consumer choice as its fundamental guideposts.*") (emphasis added).

118. Mike Esterl, *Some Food Companies Ditch "Natural" Label*, WALL ST. J. (Nov. 6, 2013), http://online.wsj.com/news/articles/SB10001424052702304470504579163933732367084.

119. *What Does "Natural" Mean?*, PCC SOUND CONSUMER (Oct. 2011), http://www.pccnaturalmarkets.com/sc/1110/natural.html.

120. *Id.*

121. FDA, *What is the Meaning of "Natural" on the Label of Food?*, FDA.GOV, http://www.fda.gov/aboutfda/transparency/basics/ucm214868.htm (last updated May 8, 2014) ("From a food science perspective, it is difficult to define a food product that is 'natural' because the food has probably been processed and is no longer the product of the earth. That said, FDA has not developed a definition for use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.").

122. Esterl, *supra* note 118.

123. Rachel Tepper, *Naked Juice Class Action Lawsuit Settlement Over Health Claims Means $9 Million For Consumers*, HUFFINGTON POST (Aug. 28, 2013, 12:31 PM),

Center for Science in the Public Interest see these labels as deliberate deception: "There's a boatload of litigation and that is going to continue until companies stop conning people."[124] Such situations fuel consumer perceptions that the industry uses misleading process-related information to capitalize on consumer values without addressing their concerns.[125]

b. *Right to Know*

Consumer claims that they have, at minimum, a "right to know" what is in their food have followed closely on the heels of disclosures of previously hidden technologies in food production. The concept of a right to know has embedded itself in the American consciousness through its ties to freedom of the press, government transparency, workplace safety, carcinogen disclosure, and even consumer concerns about garment sweatshops.[126] "The consumer right to know can be characterized as 'the notion that the public has a basic right to know any fact it deems important about a food or a commodity before being forced to make a purchasing decision.'"[127]

Many NGOs ("Non-Governmental Organizations") and consumer groups support recognition of such a right, but the EU is one of the only governments to have endorsed such a policy with regard to food.[128] While the right to know carries great rhetorical power, its legal force in U.S. food regulation is all but eviscerated. Right-to-know food-labeling legislation has repeatedly failed in Congress.[129] Courts have framed the right to know as "mere consumer curiosity" in conflict with producers' free speech rights.[130]

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http://www.huffingtonpost.com/2013/08/28/naked-juice-class-action-lawsuit_n_3830437.html.

124. Esterl, *supra* note 118.

125. *See also* Aurora Paulsen, *Catching Sight of Credence Attributes: Compelling Production Method Disclosures on Eggs*, 24 LOY. CONSUMER L. REV. 280, 281-82 (2011) (concluding that failure to regulate process disclosures on egg cartons results in consumer deception and premium prices paid for eggs with bucolic images that imply a higher quality of product than the consumer receives).

126. Steve Keane, *Can a Consumer's Right to Know Survive the WTO?: The Case of Food Labeling*, 16 TRANSNAT'L L. & CONTEMP. PROBS. 291, 301 (2006).

127. *Id.* at 302.

128. *Id.* at 292.

129. *Id.* at 293.

130. Alliance for BioIntegrity v. Shalala, 116 F. Supp. 2d 166, 179 (D.D.C. 2000); Keane, *supra* note 126, at 314 ("[A]lthough the right to know concept theoretically factors into the legal analysis of food labeling, in reality, it is only relevant once a significant safety issue has been established."); Sally Noxon Vecchiarelli, *Mandatory Labeling Of Genetically Engineered Food: Constitutionally, You Do Not Have a Right to Know*, 22 SAN JOAQUIN AGRIC. L. REV. 215, 222 (2013).

Litigation surrounding labeling milk from cows administered production-increasing hormones ("rBST") resulted in holdings that limit a consumer's right to know to "material" product differences that have been shown as a possible cause of significant harm to the consumer.[131] Note, however, that some producers have used a similar analysis to fend off attempted voluntary labeling prohibitions[132] and some reasoning suggests even slight compositional differences in products may provide a legal foothold for consumer interest.[133]

On the other hand, the EU embraced a consumer right to know at the community's inception. While some European commentators suggest bolstering industry rights via international treaties, modeling the arguments on the U.S. industry's use of the Constitution,[134] EU consumers' political power has increased rather than waned:

> Legal support for the regulations is found in the 1997 Amsterdam Treaty, which expressly promotes the right to consumer information as separate and distinct from health and safety interests. From a political standpoint, European food scares from the late 1990s have affected the public consciousness about food safety such that the demand for information about non-traditional foods cannot go unanswered without political ramifications.[135]

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131. Keane, *supra* note 126, at 306 ("A fair interpretation of Stauber and Alliance, at least with respect to food labeling, is that consumers only have a right to know what could harm them. However, even when a colorable likelihood of harm can be established, the right to know turns out to be a rebuttable right.").

132. *See* Laurie J. Beyranevand, *Milking It: Reconsidering the FDA's Refusal to Require Labeling of Dairy Products Produced From rBST Treated Cows in Light of International Dairy Foods Association v. Boggs*, 23 FORDHAM ENVTL. L. REV. 102, 113 (2012). Some argue that there is no right to food choice at all, much less a right to know what you are eating. *See, e.g.*, Samuel R. Wiseman, *Liberty of Palate*, 65 ME. L. REV. 738, 744 (2013) (positing a right against forced consumption of any particular food).

133. Beyranevand, *supra* note 133, at 133-34; *see also* Paulsen, *supra* note 125, at 313-15.

134. Bernd van der Meulen and Eva van der Zee, *"Through the Wine Gate": First Steps Towards Human Rights Awareness in EU Food (Labelling) Law*, 8 EUR. FOOD & FEED L. REV. 41, 45-6 (2013) (advocating EU application of international human rights treaties to grant businesses "freedom of expression," analogous to the freedom of speech enjoyed by corporations in the United States). While US court rulings on corporate legal personhood paved the way for US industry legal arguments, it is unclear how the author envisions corporations could qualify as humans deserving of universal rights.

135. Keane, *supra* note 126, at 292.

Where food scares in the U.S. have been brushed aside after official assertions of safety, similar issues galvanized EU consumers, leading to the development of EFSA and the Novel Foods Regulation.[136] However, even with these protections, concerns linger regarding regulatory gaps, trade disputes, how EU rules will apply to new technologies, and whether current rules offer true choice to consumers.[137]

c. *Free Trade*

While U.S. consumers believe increased international trade is beneficial,[138] one encounters little discussion of the impact its rules have on domestic consumers. International trade rules focus on free trade as a way to increase efficiency and thus increase overall output and wealth; each area should focus on its specialties, which will result in increased efficiency from economies of scale.[139] Increased export profits will then enable the purchase

136. *See* Lizette Alvarez, *Consumers in Europe Resist Gene-Altered Foods*, NY TIMES, Feb. 11, 2003, at A3. Such food scares led directly to the formation of EFSA and the implementation of the Novel Foods Regulation. EUROPEAN FOOD SAFETY AUTHORITY, *About EFSA*, EFSA, http://www.efsa.europa.eu/en/aboutefsa.htm (last visited Oct. 17, 2006); Alison Ma, *Technology: Against the Grain: Controversy Around New Genetically-Modified Crops May Have Caught Biotech Companies by Surprise*, FIN. TIMES MANDATE, Oct. 15, 1996, *available at* 1996 WLNR 4261839; *Q&A on the Novel Foods Regulation*, EUROPEAN PARLIAMENT NEWS, (March 29, 2011, 11:31 AM), http://www.europarl.europa.eu/news/en/news-room/content/20101019BKG88150/html/QA-on-the-novel-foods-regulation. Some have expressed concerns that the Novel Foods Regulation unfairly prejudices products from developing nations. Anu Lähteenmäki-Uutela, *European Novel Food Legislation as a Restriction to Trade*, Oct. 25, 2007, *available at* http://ageconsearch.umn.edu/bitstream/7909/1/pp07la01.pdf.

137. Stokes, *supra* note 7.

138. *AMERICA'S PLACE IN THE WORLD 2013*, PEW RESEARCH CTR. (Dec. 3, 2013), *available at* http://www.people-press.org/files/legacy-pdf/12-3-13%20APW%20VI%20release.pdf.

139. Some argue that free trade in staple foods is the answer to world hunger, a view echoed by the 1986 US Agriculture Secretary: "[The] idea that developing countries should feed themselves is an anachronism from a bygone era. They could better ensure their food security by relying on US agricultural products, which are available, in most cases at much lower cost." Philip McMichael, *The Impact of Globalisation, Free Trade and Technology on Food and Nutrition in the New Millennium*, 60 PROC. NUTR. SOC. 215, 219 (2001). Others see this increase in trade of foodstuffs as problematic for its consequences of raising food prices. *See, e.g.*, Jim Harkness, *Free Trade Versus Food Democracy*, THE HILL'S CONGRESS BLOG (April 16, 2013, 5:20 PM), http://thehill.com/blogs/congress-blog/foreign-policy/294179-free-trade-versus-food-democracy.

of goods not produced domestically. Free trade aims to lessen and eventually eliminate restrictions on the sale of goods between different areas.[140]

Trade restrictions can be direct or indirect. Financial levies like tariffs that directly increase the price of an imported item are direct. However, labeling and other production requirements—such as the EU measures regarding hormones and genetic engineering—have been challenged internationally through the WTO as indirect restrictions on trade.[141] Such measures are not trade restrictions on their face, but could have that effect. For example, some WTO members argued that the U.S.'s recently proposed Country of Origin Labels ("COOL") lowered the value of their imported goods, because consumers automatically prefer domestic products.[142]

Each country proposing such regulations cites a specific internal, arguably consumer-oriented, rationale: EU member countries worried that allowing cultivation of genetically engineered crops without a robust liability structure in place would leave them unable to hold producers accountable for environmental or health harms that may later be discovered. Similarly, they expressed concerns over hormone use linked to BSE, cancer, and reproductive defects.[143] U.S. regulators claimed COOL would increase traceability in the event of safety issues and bring processed meats in line with labeling requirements for other goods.[144]

Each of these measures may also have some market influence. If these measures have such an effect, those who stand to profit will support them as well. While looking at who stands to gain from a policy can provide helpful information, automatically treating any market-influencing measure as suspect greatly increases the difficulty a country faces when implementing consumer wishes and addressing their concerns. Some free trade commentators have criticized this tendency, claiming that the goal should not be eliminating trade barriers per se: "Policymakers must realize that the objective is not simply a matter of removing barriers to trade, but promoting

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140. For a list of trade barrier examples *see Trade Barriers*, EUROPEAN COMM'N, http://madb.europa.eu/madb/barriers_crossTables.htm (last updated Nov. 28, 2013).

141. *See, e.g.*, *Labelling*, WTO, http://www.wto.org/english/tratop_e/envir_e/labelling_e.htm (last accessed Dec. 22, 2013).

142. *Vilsack: Let WTO Resolve Country-of-Origin Labeling*, FOOD SAFETY NEWS (Nov., 15, 2013), http://www.foodsafetynews.com/2013/11/vilsack-let-wto-resolve-country-of-origin-labeling/; Remy Jurenas and Joel L. Greene, *Country-of-Origin Labeling for Foods and the WTO Trade Dispute on Meat Labeling*, CONGRESSIONAL RESEARCH SERV., Sept. 16, 2013, at 14-15.

143. *See generally* Harkness, *supra* note 139.

144. *See* Jurenas & Greene, *supra* note 142.

trade in a way that would benefit the public."[145] Without tethering free trade discussions to the public good, the rules look like little more than political and industrial battering rams.

Free trade arguments have also appeared in U.S. domestic spats, but have lain dormant for several decades.[146] One Iowa Representative revived them during recent Farm Bill debates when he proposed that Congress interpret the Commerce Clause to mean that states cannot regulate interstate trade based on the means of production.[147] While this amendment was targeted specifically at state-level animal welfare laws—including a recent California law requiring that all eggs sold within its borders be produced by hens in humane facilities by 2015—it could also have put into effect a lowest common denominator rule for food safety and seed quality standards, as well as for state-level labeling requirements.[148] Proponents argued the amendment should pass to increase choice and lower prices for consumers,[149] while opponents claimed that it would impermissibly nullify choices that a state's citizens have made for themselves about the kinds of products they want to buy.[150] Similar discussions have taken place among EU member states, particularly Germany, France, and the UK.[151]

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145. Debra M. Strauss, *The Application Of TRIPs To GMOs: International Intellectual Property Rights And Biotechnology*, 45 STAN. J. INT'L L. 287, 319; Keane, *supra* note 126, at 301.

146. *See generally*, Paul T. Truitt, *Interstate Trade Barriers in the United States*, 8 LAW & CONTEMP. PROBS. 209 (1941), *available at* http://scholarship.law.duke.edu/lcp/vol8/iss2/2; Steven G. Craig and Joel W. Sailors, *Interstate Trade Barriers and the Constitution*, 6 CATO J. 819 (1987), *available at* http://object.cato.org/sites/cato.org/files/serials/files/cato-journal/1987/1/cj6n3-6.pdf. Federal bodies rarely mediate interstate trade disputes, but a few cases have been decided at the Supreme Court level. David R. Francis, *A War Between the States: Home-Grown US Trade Barriers Costly*, CHRISTIAN SCIENCE MONITOR (Sept. 20, 1984), http://www.csmonitor.com/1984/0920/092015.html.

147. Steve King, *The Protect Interstate Commerce Act Offers State Trade Solution*, BEEF USA, http://www.beefusa.org/ourviewscolumns.aspx?newsid=2620 (last accessed Dec. 22, 2013).

148. Lauren Bernadett, *Proposed King Amendment Threatens Broad Spectrum of Food Issues*, FOOD SAFETY NEWS (Nov. 19, 2013), http://www.foodsafetynews.com/2013/11/proposed-king-amendment-threatens-broad-spectrum-of-food-issues/.

149. King, *supra* note 147.

150. Anne Lieberman, *King Amendment to House Farm Bill Ignores Consumer Trends*, THE HILL'S CONGRESS BLOG (June 20, 2013, 7:00 PM), http://thehill.com/blogs/congress-blog/economy-a-budget/306637-king-amendment-to-house-farm-bill-ignores-consumer-trends.

151. Natalie Chen and Dennis Novy, *Many Trade Barriers Remain High in the EU*, VOX (Jan. 27, 2009), http://www.voxeu.org/article/zero-tariffs-and-high-trade-costs-eu-technical-barriers-trade; UNICE INTERNAL MARKET WORKING GROUP, *It's the Internal*

d. *Science-Based Regulation*

The approach dubbed "science-based regulation" requires proof of actual harm in order to place limitations on a product or process. This principle appears within WTO mechanisms and U.S. food and agriculture policies. In the abstract, it sounds undeniable that this would provide a needed, objective standard against which to make international and domestic rules. However, it assumes a product or process is safe until shown otherwise. This means the burden is on those concerned about the product, those who may not have enough evidence of long-term harm until after a product has been widely distributed. With food, unless the harm is acute and immediate, proof of harm will likely not be possible until the product has been distributed and consumed for some time.

Many contrast science-based regulation with the precautionary principle, which requires proof of safety before distribution if there is a significant risk. EU regulations tend to favor this approach, which places the burden on the producer or promoter of the product. While both approaches lie on a spectrum and both have benefits and drawbacks, this juxtaposition shows why the food industry tends to favor the science-based approach: it requires less investment and effort up-front, lowers costs, increases market opportunities, increases market certainty, and exculpates them from liability for unforeseen consequences.[152]

Juxtaposing the burdens of each approach also shows why consumers tend to favor the precautionary approach: it requires that innovations are affirmatively shown to be safe before they are widely disseminated; it protects consumers from the effects of possibly detrimental technologies; and it gives consumers confidence that the long-term effects of new technologies have been taken into account. Because both approaches take into account scientific findings, the nomenclature may be somewhat misleading. "Ultimately, this is much less a discussion [] about whose approach is more 'science-based' than it is about establishing the right time

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Market, Stupid! A Company Survey on Trade Barriers in the European Union, UNICE 8 (May, 25, 2004), http://www.svensktnaringsliv.se/multimedia/archive/00000/A_company_survey_on_tr_375a.pdf. Assertions of national sovereignty in analogy to states' rights in the WTO have been rebutted by the consensual nature of the relationships. *See* CLAUDE E. BARFIELD, FREE TRADE, SOVEREIGNTY, DEMOCRACY: THE FUTURE OF THE WORLD TRADE ORGANIZATION (2002).

152. *See e.g.*, Michael Pollan, *Playing God in the Garden*, NY TIMES (Oct. 25, 1998), http://www.nytimes.com/1998/10/25/magazine/playing-god-in-the-garden.html ("Monsanto should not have to vouchsafe the safety of biotech food. Our interest is in selling as much of it as possible. Assuring its safety is the FDA's job.") (quoting Philip Angell, Monsanto's director of corporate communications).

to act to prevent harm in the process of accumulating evidence, and how to make manageable that point of action, be it early or late."[153]

Proponents tout science-based regulation as a filter that will sort out necessary measures from those based on unpredictable and varying social values. Social values, or consumer preferences, are suspect. They should not provide a basis for regulation, or even discrimination, because they could unnecessarily hamper economic vitality and can fluctuate. Industries should be allowed to develop and sell commodities without interference, unless there is significant and undeniable justification.

Recent scuffles over ractopamine, a drug that mimics the function of stress hormones in the bodies of animals that will be used for meat, exemplify objectivity concerns.[154] Producers like this drug because it causes more efficient conversion of feed to lean muscle weight, lowering the cost to produce each pound of meat.[155] Sources say it is fed to 60% to 80% of pork-producing pigs in the U.S.[156] Consumer organizations and some governments, including the EU, oppose its use as a potential public health hazard and on animal welfare grounds.[157] In 2012, the Codex Alimentarius Commission, whose standards are recognized by the WTO as a basis for trade disputes, placed the ractopamine bans of the EU, China, Taiwan, and Russia on unstable footing by setting maximum residue levels.[158] The sixty-nine to sixty-seven vote called into question the decision's objectivity and sound scientific basis.[159] Additionally, Codex used to adopt measures by consensus; resorting to votes on contentious issues leads to further lessening of confidence.[160]

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153. *Arguing about nothing? "Science-based" regulation of endocrine disruptors*, HEALTH & ENVIRONMENT (Jul. 21, 2013), http://healthandenvironmentonline.com/2013/07/21/arguing-about-nothing-science-based-regulation-of-endocrine-disruptors/.

154. *See, e.g.*, *Ractopamine Fact Sheet*, CTR. FOR FOOD SAFETY (Feb. 2013), http://www.centerforfoodsafety.org/files/ractopamine_factsheet_02211.pdf.

155. Burt Rutherford, *Codex Commission Adopts Global Standards For Ractopamine Hydrochloride*, BEEF (July 5, 2012), http://beefmagazine.com/health/codex-commission-adopts-global-standards-ractopamine-hydrochloride.

156. Helena Bottemiller, *Dispute over Drug in Feed Limiting US Meat Exports*, FOOD & ENV'T REPORTING NETWORK (Jan. 25, 2012), http://www.thefern.org/2012/01/dispute-over-drug-in-feed-limiting-u-s-meat-exports/.

157. *Ractopamine Fact Sheet*, *supra* note 154.

158. Helena Bottemiller, *Codex Adopts Ractopamine Limits for Beef and Pork*, FOOD SAFETY NEWS (July 6, 2012), http://www.foodsafetynews.com/2012/07/codex-votes-69-67-to-advance-ractopamine-limits-for-beef-and-pork/.

159. *Id.*

160. *Id.*

Industry groups are also influencing such scientific bodies.[161] Many science-based regulations and standards depend not on independent findings but on assessments provided by industry stakeholders themselves.[162] In addition to conflict of interest concerns, they also often omit costly human studies.[163] If a country or agency wants to set higher standards, that is seen as protectionism, rather than warranted caution.

These concerns have also surfaced regarding the FDA, which primarily evaluates evidence offered to it from other sources.[164] Similar concerns have been levied against EFSA.[165] Industry groups may also use the science-based regulation principle to naysay consumer choices based on criteria like environmental concerns or corporate control of foods by labeling these consumers as anti-science, or anti-technology.[166]

2. Assumptions

a. *What They Are*

i. U.S. Consumers should Accept Goods that Meet Minimum Standards

Addressing consumer discomfort with the current relationship of food and technology requires an evaluation of the assumptions behind current

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161. Kuei-Jung Ni, *Does Science Speak Clearly and Fairly in Trade and Food Safety Disputes? The Search for an Optimal Response of WTO Adjudication to Problematic International Standard-Making*, 68 Food & Drug L.J. 97, 97 (2013).

162. MARJELLE D. MASSON-MATTHEE, THE CODEX ALIMENTARIUS COMMISSION AND ITS STANDARDS 68 (2007).

163. European Food Safety Authority, *Safety Evaluation of Ractopamine: Scientific Opinion of the Panel on Additives and Products or Substances Used in Animal Feed,* 1041 EFSA J. 1, 24, 28 (2009), *available at* http://www.efsa.europa.eu/en/efsajournal/pub/1041.htm.

164. *See, e.g.*, Ramona Bashshur, *FDA and Regulation of GMOs*, ABA HEALTH ESOURCE (Feb. 2013), http://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1302_bashshur.html; *Do Seed Companies Control GM Crop Research?*, SCIENTIFIC AM. (Aug. 13, 2009), http://www.scientificamerican.com/article.cfm?id=do-seed-companies-control-gm-crop-research.

165. Martin Banks, *EFSA's Anniversary Hit by Protest over "Industry Capture" of Food Safety*, PARLIAMENT (Nov. 14, 2012), http://www.theparliament.com/latest-news/article/newsarticle/efsas-anniversary-hit-by-protest-over-industry-capture-of-food-safety/.

166. *See, e.g.*, NATIONAL FOREIGN TRADE COUNCIL, *Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science*, NFTC.ORG (May 2013), http://www.wto.org/english/forums_e/ngo_e/posp47_nftc_looking_behind_e.pdf.

policies. Based on the illustrative technologies and themes evaluated so far, the U.S. and EU seem to ascribe different functions and capabilities to consumers. U.S. policies allow choices among products that have met official minimum standards, but do not facilitate choices that look behind or second-guess these thresholds. This seems to imply that consumers have a low level of sophistication when choosing foods: they could not understand the issues at play even if they received the information. Further, consumers who wish to coordinate their social values with their food choices must purchase specialty products, the labeling and regulation of which has caused its own confusion and tensions. Industry groups have argued voluntary informational labeling itself is misleading without an acute safety threat.[167] The FDA has discounted concerns through suggested disclaimers, such as the one on rBST free milk: "No significant difference has been shown between milk derived from rBST-treated and non-rBST treated cows."[168] The use of the word "significant" here simply denotes immediate health effects. While consumers have a limited right to knowledge about their food, consumer choices that conflict with FDA minimum standards are tolerated at best. At worst—as with GE foods—such choices are intentionally frustrated, after being labeled irrational, reactionary, or anti-science.

ii. EU Consumers should Use their Purchasing Power to Make Social Choices

EU policies emphasize consumer education; they imply that consumers can and should make informed, intelligent choices.[169] The EU consumer empowerment plan specifically notes the importance of consumer education and choice in an increasingly global economy:

> The growing emphasis in policy-making on the freedom and responsibility of consumers to make their own informed choices means that consumer education is seen as a key tool in ensuring the smooth operation of markets. However, the

167. *See, e.g.*, Letter from FTC to Monsanto (April 21, 2007), *available at* http://milk.procon.org/sourcefiles/FTC_to_monsanto.pdf.

168. *Id.*

169. *See generally* Stokes, *supra* note 7 (asserting the growing need for EU structures to support these choices). Some say that retailers make the choices, not consumers, so consumers have only an indirect choice based on what retailers believe that they want. *See, e.g.*, Colin A. Carter and Guillaume P. Gruere, *Mandatory Labeling of Genetically Modified Foods: Does it Really Provide Consumer Choice?*, 6 AGBIOFORUM 2003, at 68, *available at* http://www.agbioforum.org/v6n12/v6n12a13-carter.pdf (last visited Nov. 21, 2014).

> development of consumer education practices, in formal or non-formal education, appears in most countries not to reflect this shift in emphasis.[170]

Further, EFSA's goal to increase consumer confidence in the EU food system acknowledges that regulators must work to deserve consumer trust; consumers are not irrational for finding official assertions less than comforting.[171]

EU policies also assume that purchasers can legitimately reflect social values in their decisions. When asked why they do not prefer various food technologies, EU consumers do not hesitate to say that they want to preserve the livelihoods of their farmers, or preserve biodiversity, or reduce pesticide use on their land—the kinds of value judgments that are not directly related to the safety of the food itself.[172]

b. *Where They Come From*

i. Economic Investments

Commentators suggest several reasons for these divergent assumptions: (1) economic investments, (2) market assumptions, and (3) industry power.[173] The U.S. invests significant resources into developing new technologies, including their applications to food. The government provides tax incentives for research and development,[174] grants funds for the development of specific technologies,[175] and develops technologies for

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170. *Consumer Empowerment*, *supra* note 102, at 16.

171. *Id.* at 6.

172. *See* EUROBAROMETER, *supra* note 91, at 18.

173. At least one commentator assesses U.S./EU differences in GE plant regulation as ultimately dependent on consumer preference and only peripherally connected to production commitments, attitudes toward mass production, and centers of political power. Anu Bradford, *The Brussels Effect*, 107 NW. U. L. REV. 1, 32 (2012). This analysis, however, ignores the low level of actual US consumer awareness. *See* NPD GROUP, *Over Half of U.S. Consumers Are Concerned About Genetically-Modified Foods, But the Definition of GMOs Is Unclear Among Consumers,* REPORTS NPD (Dec. 19, 2013), http://www.foodproductdesign.com/news/2013/12/gmo-concerns-steadily-grow-among-consumers.aspx.

174. *See generally* Jonathan Talley, *The Research and Development Tax Credit: Moderately Effective but Hampered by Politics*, 10 DEPAUL BUS. & COM. L.J. 77 (2011) (discussing U.S. R&D tax credits, which began in 1981).

175. *See U.S. Government Grants, About Us,* TECHNOLOGY GRANTS, http://us-government-grants.net/technology-grants (last accessed Dec. 22, 2013) (noting that for-profit corporations may receive grants if they are "conducting research" or "creating jobs").

military use that are then commercialized.[176] In contrast, the EU incentives for R&D have been criticized as too low[177] and have been re-evaluated over the past ten years.[178] By the time a given technology is ready to market, both the U.S. government and industry have already committed significant resources. It stands to reason that they would look for the broadest market possible, while the EU would not experience the same loss by preserving their status quo.

ii. Market Assumptions

U.S. regulators and judges tend to encourage developments in food technologies.[179] Innovation appears to promise increased consumer choice and decreased cost, as well as quality improvement.[180] This optimism seems to assume that any negative effects will be visible enough that the industry will have motivation to correct itself. It seems to further assume that any

176. *See* Dana Nicolau, *Innovation and Knowledge Transfer in Emerging Fields: The Case of Nanotechnology in Australia*, 2 NANOTECHNOLOGY L. & BUS. 384, 392 (2005) ("[T]he military market provided an important springboard for small companies in electronics and computers, and, later, in biotechnology."); James P. Chandler, *The Loss of New Technology to Foreign Competitors: U.S. Companies Must Search for Protective Solutions*, 27 GEO. WASH. J. INT'L L. & ECON. 305, 308 (1994) ("For the past 50 years, the major stimulus for U.S. technology research and development has been the design, development and production of weapons and space systems. Many commercial products today are the result of technologies developed for defense applications.").

177. *See* Simon Tilford, *Is EU Competition Policy an Obstacle to Innovation & Growth?*, CENTRE FOR EUROPEAN REFORM (Nov. 2008), http://www.cer.org.uk/sites/default/files/publications/attachments/pdf/2011/essay_competition_st_20nov08-1359.pdf.

178. *Placing Taxation at the Service of Research and Development*, EUROPA, http://europa.eu/legislation_summaries/taxation/l31047_en.htm (last updated Feb. 8, 2007).

179. *See generally* Marsha A. Echols, *Food Safety Regulation In The European Union And The United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525 (1998) (concluding that, "the U.S. regulatory approach doubts the safety of many traditional foods but embraces new technologies like genetic engineering and irradiation.").

180. This attitude appeared as early as the 1930s, when a court evaluated Bred Spred, a new product that looked like jam but contained very little fruit. Though consumers had no indication of this difference other than the absence of the word "jam" on the jar, the court refused to find the product misbranded, adulterated, inferior, or even an imitation of jam. *See* United States v. Ten Cases, More or Less, Bred Spred, Etc., 49 F.2d 87 (8th Cir. 1931) ("There is nothing harmful or deleterious in the product Bred Spred. It has some food value and some nutritive value."). *See also* MEREDITH A. HICKMAN, THE FOOD AND DRUG ADMINISTRATION 36 (2004).

damage caused will be readily identifiable and reversible—or at least that companies involved will be held responsible.

The EU embraces technical innovations in food more cautiously.[181] While they were originally more liberal in adopting hormones and GE crops, the EU reacted to unforeseen consequences by moving more cautiously thereafter. EU consumer education program materials suggest market liberalism is inevitable, leaving the government unable to implement all the restrictions it may see as valuable. Informing consumers becomes the new mechanism for protecting them, and relies on a view of the consumer as active in shaping the market, rather than as passively receiving from it.

iii. Industry Power

Assumptions about consumers' lack of sophistication in the U.S. mirror industry arguments that those who do not embrace their technologies are "rogue anti-technology campaigners"[182] or "cynical . . . scare campaign[ers]."[183] This perspective bleeds into government because the same people who work for the biotech and pharmaceutical companies behind the technologies take up positions of power in agencies like the USDA and FDA.[184] These individuals often move to the private sector, leading to what some see as the industry becoming its own de facto regulator. While there is a vigorous debate over whether this "revolving door" produces inappropriate bias, there is no debate over its existence.[185]

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181. *See* Echols, *supra* note 179, at 543 ("These influences in the EC tend to result in laws that accept the safety of traditional foods and production processes, like that for raw milk cheeses, but hesitate in the face of new technologies and novel foods."); Heidi Moore, *The US-EU Trade Deal Could Take Monsanto's GM Crops off the Table*, GUARDIAN (May 15, 2013, 9:30 AM), http://www.theguardian.com/commentisfree/2013/may/15/us-eu-trade-deal-monsanto-crops.

182. John Entine, *Exposing the Anti-GMO Legal Machine: The Real Story Behind the So-Called Monsanto Protection Act*, FORBES (April 2, 2013, 5:55 PM), http://www.forbes.com/sites/jonentine/2013/04/02/exposing-the-anti-gmo-legal-machine-the-real-story-behind-the-so-called-monsanto-protection-act/.

183. Henry I. Miller & Jeff Stier, *Mandatory Labeling Of Genetically Engineered Foods Deserves A Warning Label Of Its Own*, FORBES (Oct. 9, 2013, 6:00 AM), http://www.forbes.com/sites/henrymiller/2013/10/09/mandatory-labeling-of-genetically-engineered-foods-deserves-a-warning-label-of-its-own/.

184. *See, e.g.*, Judy Saransohn, *Under Bush, the Revolving Door Gains Speed*, WASHINGTON POST (Oct. 27, 2005), http://www.washingtonpost.com/wp-dyn/content/article/2005/10/26/AR2005102602454.html.

185. *See generally* Jason Iuliano, *Killing Us Sweetly: How to Take Industry out of the FDA*, 6 J. FOOD L. & POL'Y 31, 84-5 (2010) (discussing the approval process of artificial sweeteners as evidence of the conflicts of interest guiding high level FDA decisions),

The government-industry partnership in the U.S. begins early in almost any technology's development; many spring from academic-industrial partnerships, which attract government funding.[186] In addition to alleged agency capture, biotech and pharmaceutical industries—the main producers of controversial food innovations—also wield immense political and academic influence.[187] A recent Lancet study found multinational food corporations, many U.S. based, use tactics similar to the tobacco industry in order to undermine health policies and circumvent regulation.[188] Examples of these tactics include producing biased research, diverting health professionals and policy makers to promote their products, lobbying against regulations, promoting individual votes against regulations, and deflecting

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David Zaring, *Against Being Against the Revolving Door*, 2013 U. Ill. L. Rev. 507, 548-9 (2013) (concluding the crossover between public agency and private industry employees is not a touchstone of corruption, but that bureaucrats have incentives to do their regulatory jobs well to preserve their reputations, among other reasons); Elizabeth R. Glodé, *Advising Under the Influence?: Conflicts of Interest Among FDA Advisory Committee Members*, 57 FOOD & DRUG L.J. 293, 321-2 (2002) (concluding that the FDA must re-evaluate its conflict of interest criteria); James L. Zelenay, Jr., *The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?*, 60 FOOD & DRUG L.J. 261, 338 (2005) (asserting that the FDA does not have the needed independence from the industry).

186. *See* Jerome P. Kassirer, *Financial Conflict Of Interest: An Unresolved Ethical Frontier*, 27 AM. J.L. & MED. 149, 151 (2001) (discussing 1980s Bayh-Dole Act and its incentives for academic-industrial partnerships, which some claim are responsible for the rise of biotechnology); Eyal Press & Jennifer Washburn, *The Kept University*, ATLANTIC MONTHLY (Mar. 1, 2000, 12:00 PM), http://www.theatlantic.com/magazine/archive/2000/03/the-kept-university/306629/?single_page=true.

187. *See* Interview by Steven M. Sellers with Jerome Kassirer, MONEY & MEDICINE, Trial 34 (June 2012) ("I do worry a lot about ghostwriting [i.e., articles written by industry representatives but bylined by physicians], much more than I did when I was the editor [of the New England Journal of Medicine]. . . . And it's not just ghostwriting of review articles; it's even ghostwriting of clinical trials."); W. John Thomas, *The Vioxx Story: Would It Have Ended Differently In The European Union?*, 32 AM. J.L. & MED. 365, 376 (2006) ("[T]he pharmaceutical industry has the largest lobbying organization in Washington."); Bradford, *supra* note 173, at 32 ("Biotechnology is seen as a key for retaining the U.S. competitiveness in export markets . . . . Consequently, U.S. farmers and the entire biotechnology industry are influential players in the U.S. political process.") (internal citations omitted); Nicola Lucchi, *Governing Control over Human Genetic Resources: Promises and Risks*, 4 EUR. J. RISK REG. 254, 254-55 (noting the use of biotechnology in developing new pharmaceuticals).

188. Rob Moodie et al., *Profits and Pandemics: Prevention of Harmful Effects of Tobacco, Alcohol, and Ultra-Processed Food and Drink Industries*, LANCET, Feb. 12, 2013, at 670, *available at* http://www.fsp.usp.br/site/dcms/fck/Monteiro_Lancet_Profits%20and%20Pandemics-1.pdf.

attention from the health of their products by engaging primarily in unrelated philanthropic arenas.[189]

In the U.S., consumers are implicitly told to leave safety concerns to the FDA, despite the fact that the FDA process has little pre-market power to address long-term health implications. This leaves consumers vulnerable, as shown by the recent action against trans-fats.[190] Artificial trans-fats entered the U.S. food supply in the 1950s, and caused significant scientific alarm in the 1980s, but industry pressures have delayed meaningful FDA action until 2013.[191] Perhaps tellingly, food industry arguments in the EU reflect their government's opposing assumptions. Biotech trade representatives use these arguments to claim, as it relates to Europeans, "There is no evidence that opposition to GM food is a manifestation of a wider disenchantment with science and technology in general."[192] This effort to engage consumer approval directly seems to stem from the industry's sense of its lack of political clout in the EU.

C. *Nanotechnology Applications to Food*

It is in this convoluted food regulatory space that nanotechnology is beginning to come into its own. The concept of manipulating atoms on an extremely small scale has existed since at least the late 1950s, and throughout its ensuing development commentators encouraged tailored and cautious regulatory responses.[193] However, most consumers remain unaware of this developing technology, much less that over 1,600 products on the market include nano-materials.[194]

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189. *Id.* at 673-4.

190. Kristin Wartman, *Trans Fats: Deadly Consequences of FDA Inaction*, CIVIL EATS (Nov. 20, 2013), http://civileats.com/2013/11/20/trans-fat-travails/.

191. *Id.*

192. George Gaskell et al., *EUROPEANS AND BIOTECHNOLOGY IN 2005: PATTERNS AND TRENDS*, EUROBAROMETER 64.3 May 2006, at 3, *available at* http://ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf; *What do European Consumers Really Think about GM Foods?*, EUROPABIO, http://www.europabio.org/sites/default/files/facts/what_do_european_consumers_really_think_about_gm_foods.pdf (last accessed Dec. 23, 2013) (arguing that consumers should be given more opportunities to choose between GE and non-GE foods, with increased information being made available).

193. Stokes, *supra* note 7, at 180-81.

194. *See* Brita Belli, *Eating Nano*, E MAG. (Nov. 1, 2012), http://www.emagazine.com/magazine/eating-nano ("[E] ach of us likely consumes some amount of titanium dioxide (TiO2) nanoparticles each day, and children under 10 likely consume the greatest amounts . . . due to their higher intake of frosted foods, candy, gum and other sweets"); *see also* Stokes, *supra* note 7; Press Release, WILSON CTR., Inventory

> Nanoparticles are materials that are microscopic—significantly smaller than a red blood cell; and tens of thousands of times smaller than the width of a human hair. These particles can help deliver nutrients, ensure longer freshness of food, act as thickening agents or enhance taste or flavor. The problem is, scientists are still determining the health and environmental impact of these tiny particles, even as industry is forging ahead.[195]

The web of standards that may be imposed on developing technologies makes application of current measures to nanotechnology uncertain. Additionally, the growing global sense of consumers distrust of the food industry and of regulatory bodies suggests that new food technology should inspire new approaches to their development and regulation.

While the majority of consumer nanotech applications relate to durable consumer goods, many relate to food. One example is nano-sized titanium dioxide, which is present in "many processed foods, including Mentos, Trident and Dentyne gum, M&Ms, Betty Crocker Whipped Cream Frosting, Jello Banana Cream Pudding, Vanilla Milkshake Pop Tarts and Nestlé Original Coffee Creamer."[196] While some nano-sized materials exist in nature (like viruses, some milk proteins, and caramelized foods), nanotechnology enables the production and manipulation of materials not originally present in nano form.[197] While the chemical composition is the same, materials produced at nanoscale increase in surface area, which can increase reactivity and result in different properties than their conventional counterparts.[198] For instance, some opaque materials are transparent at

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Finds Increase in Consumer Products Containing Nanoscale Materials (Oct. 23, 2014), *available at* http://www.nanotechproject.org/process/assets/files/9241/nano_oct_2013_final_ver.pdf ; Andy Behar, *Study the Use of Nanoparticles in Food*, CNN (Feb., 14, 2013), http://www.cnn.com/2013/02/14/opinion/behar-food-nanoparticles/.

195. Belli, *supra* note 194.

196. Twilight Greenaway, *Nanoparticles in Your Food? You're Already Eating Them*, GRIST (Dec. 3, 2012, 8:40 AM), http://grist.org/food/nanoparticles-in-your-food-youre-already-eating-them/. Food applications of nanotechnology are often discussed in the following categories: (1) packaging, (2) cookware, (3) supplements, and (4) in foods themselves. Jill Richardson, *Meet the Four Categories of Nanofoods*, FOOD SAFETY NEWS (Nov. 22, 2010), http://www.foodsafetynews.com/2010/11/meet-the-four-categories-of-nanofoods/.

197. Greenaway, *supra* note 196.

198. *What is it & How it Works*, NANO.GOV, http://www.nano.gov/nanotech-101/what (last visited Jan. 25, 2015).

nanoscale; some materials that normally would be excreted after ingestion can migrate into various tissues at nanoscale and accumulate; some materials simply have a different texture or are lighter.[199] These different properties are precisely the reason they are being developed.[200] In fact, the United States government has allocated almost $21 billion to nanotechnology research.[201]

Like genetic engineering, nanotechnology has significant potential across the food and agriculture spectrum:

> Nanotechnologies are expected to contribute to materials with better, for instance[,] antimicrobial properties; and to "smart" packaging using sensors to indicate food spoilage. . . . Nanotechnologies are expected to enable encapsulation devices which protect sensitive food ingredients, improve their solubility and mask unpleasant tastes. They enable processing technologies such as particle stabilized emulsions which can contribute to novel food structures which have novel "mouth sensations." Nanotechnologies may contribute to highly sensitive sensor technologies to detect food pathogens and may be used to monitor crop growth.[202]

Many of these potential benefits could accrue to consumers directly in the form of superior products, whether in terms of nutrition, safety, or simply a new food experience. Further, food packaging developed with nanotechnology may significantly reduce food waste, helping to address world hunger.

Discussion of nanotechnology regulation has stalled based on industry apprehension that consumers are opposed to technology applications to food, or "concerns about concerns."[203] Food made with nanotechnology does raise

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199. *Nanocomposites*, NANOSONIC (2011), http://www.nanosonic.com/29/nanocomposites.html.

200. *Frequently Asked Questions*, NANO.GOV, http://www.nano.gov/nanotech-101/nanotechnology-facts (last accessed Dec. 23, 2013).

201. *Id.* According to a 2011 report, the US leads worldwide nanotech research, with Russia and China close behind. *Global Funding of Nanotechnologies & its Impact*, CIENTIFICA (July 2011), http://cientifica.com/wp-content/uploads/downloads/2011/07/Global-Nanotechnology-Funding-Report-2011.pdf.

202. Haico te Kulve et al, *Context Matters: Promises and Concerns Regarding Nanotechnologies for Water and Food Applications*, 7 NANOETHICS 17, 22 (2013) (internal citations omitted).

203. *Id.* at 22, 23 (noting that such concerns are "largely about the perceptions by advocates of nanotechnologies (such as industry) about possible negative perceptions of

health and safety concerns, and some question the magnitude of the actual benefits:

> [P]ossible health and safety issues includ[e], for example, the possible migration of nanomaterials in food packaging or possible toxic effects of nanoparticles used to improve taste or the nutritional value of food products. Occasionally other issues are mentioned, such as possible environmental impacts of nanomaterials, i.e. impacts of disposed nanomaterials. In addition, some voices do not refer directly or indirectly to health or environmental risks, but are skeptical about the performance of future products and their economic feasibility.[204]

Assessing these concerns presents additional difficulty because of the breadth of nanotechnology: engineered nanomaterials comprise a broad category, with wide-ranging potential concerns and possibilities. One engineered nano-material may be quite harmful, while another completely benign. Informed citizens cite several concerns reminiscent of other technologies discussed: long-term health effects, environmental repercussions, how the technology's development is controlled, and how risks would be assessed and distributed.[205] These concerns do not reflect anti-technology sentiment. In fact, consumers polled were more interested in nanotechnology in food than in GE technology in food, but still wanted more transparency.[206] They cite what they saw as past failures of regulators to take into account their interests (e.g., BSE, asbestos, Agent Orange) as an impetus for such concerns.[207]

Many nanotechnology commentators have discussed the lack of consumer engagement and transparency by industry promoters of GE foods as a pitfall to be avoided with the introduction of nanotechnology.[208] However, industry proponents and governments have largely ignored this insight. In the mid-2000s, several countries—including the UK, U.S.,

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consumers, so concerns about concerns, rather than examining actual data of consumer perceptions. Expectations about negative consumer responses are supposed to affect the way how the food industry approaches nano-based applications, namely by keeping silent about the respective activities.") (internal citations omitted).

204. te Kulve, *supra* note 202, at 23.

205. Georgia Miller, *Nanotechnology and the Public Interest: Repeating the mistakes of GM foods?*,7 INT'L J. TECH. TRANSFER & COMMERCIALIZATION 274, 275-76 (2008).

206. *See generally id.*

207. *Id.* at 276.

208. *See id.*

France, and Germany—experimented with "public engagement exercises," but none connected to actual decision making.[209]

Not only are nanotechnology developers refusing to identify and target socially desirable developments, less than one half of one percent of worldwide technology research funding goes to research of health and environment risks.[210] Even among Swiss and German companies, which serve some of the most eco-conscious consumers, new nanotechnologies are rarely assessed for risk.[211]

Nanomaterials are effectively un-tracked and un-regulated in most of the world. Despite vast development investments, no country has implemented a nano-specific approval or regulatory regime.[212] As of the end of 2014, the EU requires labeling of nanotech-enhanced food and cosmetics.[213] The still-developing science makes it unclear, though, exactly how products will be regulated or which will be subject to approval under the Novel Foods Regulation.[214]

In the U.S., no government body to date has developed requirements for engineered nanomaterials. The FDA does not even track nanotech used in food products.[215] The U.S. regulates nanotech materials just like their

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209. *Id.* at 279.

210. Miller, *supra* note 205, at 277.

211. *Id.* at 278.

212. Several countries have disallowed engineered nanotech particles in foods labeled "organic": Canada, UK, Austria, Australia. In the US, the Organic Crop Improvement Association has banned nano in organics; while the National Organic Standards board recommended in 2010 that nanotech be disallowed in organics, no final stance seems to have been taken. NATIONAL ORGANIC STANDARDS BOARD, *Formal Recommendation to the National Organic Board*, Oct. 28, 2010, *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5087795; *Canada Bans Nanotechnology in Organics*, ORGANIC & NON-GMO REPORT (May 2010), http://www.non-gmoreport.com/articles/may10/canada-bans-nanotechnology-organics.php.

213. *See Communication from the Commission to the European Parliament, the Council, & the European Economic & Social Committee on the Second Regulatory Review on Nanomaterials*, COM (2012) 288 final (Oct. 3, 2012); *see also* Nicola Barrett, *European Union Regulation of Nanotechnology in the Food Industry*, 8 NANOTECHNOLOGY L. & BUS. 252 (2012).

214. *See generally* Daniela Marrani, *Nanotechnologies and Novel Foods in European Law*, 7 NANOETHICS 177 (2013) (noting the EU's incremental regulatory approach, which subjects nanomaterials to the same kinds of rules as other products unless new risks are found to require different rules, as well as the lack of international agreement on definitions and risk assessments, which may lead to trade disputes).

215. Belli, *supra* note 194 ("Following is a recent email exchange with Sebastian Cianci, a spokesperson at the FDA: E Magazine: What can you tell me about the prevalence of nanomaterials in our food supply? Sebastian Cianci: FDA does not have a list of food products that contain nanomaterials. E: Where are nanomaterials most often

larger counterparts, unless the manufacturer voluntarily identifies a material difference.[216] Despite repeated assertions that public information and engagement will encourage development of nanotechnology, governments and industry are largely ignoring the so-called lessons of the GE food controversies.[217] Efforts by public interest groups to this end have met with failure,[218] and consumer information regarding nanotechnology developments has actually been declining.[219] Retailers have similarly failed to demand life-cycle safety or environmental impact studies. Experiences with genetic engineering and other technologies seem to have brought discussion of nanotech in food to a standstill.

III. A NEW MODEL FOR CONSUMER ENGAGEMENT IN DEVELOPING FOOD TECHNOLOGIES

A. *Responses to Current Assumptions*

1. United States

While U.S. consumers are expected to accept goods that meet minimum safety standards due to an inability to adequately evaluate additional issues,[220] this paper has shown this approach is lacking. Widely-

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found within food products? In colorings or additives? S.C.: FDA does not maintain a list of food products that contain nanomaterials so we cannot reliably answer this question.").

216. FDA, *Guidance for Industry*, 2014 CTR. FOR FOOD SAFETY & APPLIED NUTRITION 4, 5 ("As with all food substances, this guidance also is intended to recommend that you consult with us regarding a significant change in manufacturing process for a food substance already in the market, irrespective of your conclusion about whether that change affects the safety or regulatory status of the food substance. It is prudent practice for you to do so, particularly when the change in manufacturing process involves emerging technology. . . . The consequences (to consumers and to the food industry) of broadly distributing a food substance that is later recognized to present a safety concern have the potential to be significant.")

217. Miller, *supra* 205, at 277 (2008); *see, e.g.*, Carla Almeida, *Brazil Struggles to Regulate Emerging Nanotechnology*, SCIDEVNET (Sept. 9, 2013), http://www.scidev.net/global/technology/feature/brazil-struggles-to-regulate-emerging-nanotechnology.html.

218. For example, in 2006, a coalition of consumer and environmental groups petitioned the FDA for labeling and testing of new nano-enhanced products. In 2011, it sued for a response to the petition. Complaint at 2, International Center for Technology Assessment et al., v. Hamburg, Docket No. 3:11-cv-06592 (N.D. Cal. 2011).

219. Caroline Scott-Thomas, *Consumers Less Aware of Nanotech as Media Coverage Falls*, FOOD NAVIGATOR (Dec. 3, 2013), http://www.foodnavigator.com/Financial-Industry/Consumers-less-aware-of-nanotech-as-media-coverage-falls.

220. *See generally* Wartman, *supra* note 190; Heinzerling, *supra* note 47.

cited risk-communication expert David Ropeike, diagnoses this situation as the "malady of Fear of Fear," noting that, contrary to popular belief,

> Choice makes risks feel voluntary. It makes us feel empowered, more in control of our health and safety, and that makes any risk feel less scary. Time and time again, when people are given choice—as labeling would do—their fears are reduced and they engage in risks they fight tooth and nail when the risk feels imposed.[221]

Unnecessarily restricting consumer decision-making by excluding information is counterproductive. It encourages skepticism and distrust. Assumptions of consumer unwillingness or inability to engage in calculated risks also hamper consumer efforts to make choices that implement their social or ethical values.[222] This "lowest common denominator" approach can also mislead by portraying food choices as black and white, safe or unsafe, resulting in consumer inaction, due perhaps to a false sense of security or bystander apathy.[223]

Finally, focusing developments in the food industry on patented or patentable technologies may not be beneficial from a consumer standpoint. A frequent claim arises: granting and protecting government-granted monopolies (i.e., patents on crops or other food-related technologies) is the only way to promote innovations that will address consumer tastes and market needs, like increased production to meet growing world nutrition demands. However, this claim may prove unsubstantiated if empirically analyzed.[224]

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221. David Ropeik, *GMO Labeling: An Open Letter to BigAgTech CEOs*, HUFFINGTON POST (Nov. 6, 2013, 1:39 PM), http://www.huffingtonpost.com/david-ropeik/gmo-labeling_b_4224023.html.

222. *See, e.g.*, Dorothy Du, Note, *Rethinking Risks: Should Socioeconomic and Ethical Considerations be Incorporated into the Regulation of Genetically Modified Crops?*, 26 HARV. J.L. & TECH. 375, 76 (2012).

223. *See* Wartman, *supra* note 190; Heinzerling, *supra* note 47(discussions of trans fats and antibiotic resistance); *see also* Alison Peck, *Does Regulation Chill Democratic Deliberation? The Case of GMOs*, 46 CREIGHTON L. REV. 653, 685 (2013).

224. *See* Emily Marden & R. Nelson Godfrey, *Intellectual Property and Sharing Regimes in Agricultural Genomics: Finding the Right Balance for Innovation*, 17 DRAKE J. AGRIC. L. 369, 391 (2012) ("[B]oth regimes that grant IP and those that mandate the sharing of such resources are necessary for continued innovation in the agricultural genomics space. . . . The collective impact on innovators by these fragmented and complex regimes has not been conclusively documented and remains difficult to unravel for developers and academic commentators alike."). For an overview of plant patent history, seed market consolidation, and reduction in biodiversity, and other issues related to plant patents, *see* Allyson Martin, *Seed Savers v. Monsanto: Farmers Need a Victory*

2. European Union

While the EU seems to operate from a different starting point than the U.S., saddling consumers with the responsibility to implement social choices through their individual choices brings its own set of concerns. First, labeling alone may not be enough to facilitate an informed decision. For instance, a consumer may see "made with Nanotechnology" but not know how that information should be used. A recent pamphlet from an EU biotech trade organization, EuropaBio, noted that consumers may be interested in purchasing technologically enhanced food products with additional information, such as whether the technology resulted in lower pesticide residue, or involved a more environmentally friendly process.[225]

Second, a consumer may lack superior options or feel inundated with so many important choices that she may become overwhelmed rather than empowered. Alternatively, consumers may feel satisfied with doing the best they can even when that "best" is bounded by production and distribution mechanisms that conflict with their values. Some academics discuss this phenomenon as a growing "consumer burden" resulting from liberal trade and regulatory policies.[226] This suggests that even the EU's aggressive education plans may not assure consumers a meaningful way to enact their social values or make purchases consistent with their ethical concerns.

3. How to Think about Consumers

Consumers can react viscerally when they feel information has been deliberately hidden from them, even if they would have accepted the change with an adequate up-front explanation. These considerations suggest that industry and government should shift to thinking of consumers as true stakeholders rather than simply purchasers and digesters of products.

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for Wilting Biodiversity, 24 DEPAUL J. ART, TECH. & INTELL. PROP. L. 95 (2013). A research project by the National Bureau of Economic Research concluded that plant patents may in fact result in market concentration and uniformity of available varieties, using rose plants as a case study. Petra Moser and Paul W. Rhode, *Did Plant Patents Create the American Rose? in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY REVISITED 413 (Josh Lerner & Scott Stern, eds., 2012).

225. EUROPEAN ASSOC. FOR BIOINDUSTRIES, *What do European Consumers Really Think about GM Foods?*, EUROPABIO, http://www.europabio.org/sites/default/files/facts/what_do_european_consumers_really_think_about_gm_foods.pdf (last accessed May 22, 2014).

226. *See, e.g.*, CONFRONTING CONSUMPTION (Thomas Princen et al., eds., 2002); JULIE GUTHMAN, WEIGHING IN: OBESITY, FOOD JUSTICE, AND THE LIMITS OF CAPITALISM (2011).

Nutritional science has been and still is developing its understanding of the significant connection between food and health, so consumers often find the old adage, "you are what you eat" still resonates with them. Thus, access to information about and control over food choices becomes ever more important to consumers. Consumers have exhibited heightened awareness of food sensitivities and allergies, as well as the environmental impacts of their food choices. Many with the means and time to do so have made efforts to opt out of the current food system in the U.S. (e.g., growing popularity of farmers markets; growth in sales of Organic, Fair Trade, and Kosher labeled foods). These shifts indicate a public that feels it deserves to see how it would be benefitted by new developments.

B. *Mechanisms for Forward Motion*

The current U.S. approach to food technologies has been largely ad hoc and has resulted in consumer uncertainty and distrust. Some may say that these developing technologies are all so different from each other that no adequate alternative exists. Regardless of the diversity of concerns or technologies at issue, however, keeping in mind Ropeike's assessment of risk may prove instructive.[227] He claims that sound decisions regarding new, evolving, or difficult-to-characterize risks demand accurate and careful communication of the magnitude of the risks as best understood, even if they are uncertain.[228]

Industry actors can respond to consumer discontent by making their cases for the use of new technologies in foods, showing that the technologies are not benefitting companies at the expense of consumer values. Regulators can insist on sharing information and facilitate meaningful consumer input. Food-applicable technologies will only develop and proliferate, and government and industry actors may be able to address this by adopting proactive, communicative regimes for development and regulation of new technologies used in food. These regimes should involve both information communicated to consumers and facilitation of meaningful consumer input. Descriptions of several suggested components follow.

227. George M. Gray and David P. Ropeik, *Dealing With The Dangers Of Fear: The Role Of Risk Communication*, HEALTH AFFAIRS, Nov./Dec. 2002, at 106, 115.
228. *Id.*

1. Invigorate GRAS Implementation by Enabling Pre-Market Notice and Review

While pharmaceutical products must pass pre-market FDA review, food products are not generally subject to such scrutiny. However, in 1958 Congress responded to consumer concerns regarding increased additive use in foods by enacting the Food Additives Amendment.[229] It requires approval of "substances used in packaging, transport, processing, preparation, and other processes that might either affect or migrate into food."[230] Some commentators argue that GRAS, one of the exceptions to this rule, has made the rule all but ineffective.

A substance is GRAS if "generally recognized, among experts qualified by scientific training and experience to evaluate [their] safety . . . to be safe under the conditions of [their] intended use."[231] The FDA has implemented GRAS using various procedures since its enactment, but currently a food producer who wishes to assert that an additive is GRAS is not even required to alert the FDA—the process is voluntary.[232] This means that new additives, whether used in the food, its packaging, or elsewhere, may not even be on the FDA's radar, much less approved for use or evaluated according to the statutory exception's requirements.

While the FDA began a comprehensive review of GRAS substances in 1970, this halted due to lack of resources.[233] Now the FDA reviews GRAS substances only when specific issues are raised.[234] With some food additive petitions taking over a decade to complete the petition process, food companies have every incentive to identify an additive as GRAS if any argument can be made that it meets this vague standard. Facing possible penalties down the road can make much more business sense than submitting to an uncertain approval process that can take over half of the patent length.[235] Mitigating or removing this perverse incentive should be a primary goal of food system reform. Requiring mandatory pre-market notice and publication of claimed GRAS status seems to be a reasonable start.[236] Even

229. Laurie J. Beyranevand, *Generally Recognized As Safe?: Analyzing Flaws in the FDA's Approach to GRAS Additives,* 37 VT. L. REV. 887, 894 (2013).
230. *Id.*
231. 21 U.S.C. § 321(s) (2012).
232. Beyranevand, *supra* note 133, at 906.
233. Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 449 (2008).
234. *Id.*
235. Peter Barton Hutt, *Regulation of Food Additives in the United States*, *in* FOOD ADDITIVES 199, 205 (A. Larry Branen et al. eds., 2d ed. 2001).
236. As a corollary, the food additive approval process may also require reform to become a viable option.

a published notice requirement would provide a foothold for consumer awareness and response.

2. Labeling New Technologies is a Minimum Threshold

Foods containing, processed with, or packaged using new technologies should be labeled in order to facilitate consumer awareness and traceability in the case of unforeseen consequences. Those who oppose increased labeling requirements argue that required information labels can become de facto warning labels, which may cause unwarranted negative responses. On the other side, voluntary labeling statements have caused just as much, if not more, confusion to consumers. Consumers make purchases based on the information available to them regarding safety, nutrition, and environmental and ethical concerns. This is the case even if that information is unregulated or implied, and very few consumers are aware of which statements are regulated, which are not, and just what that means for their reliability.[237] The case of industrialized egg production provides a salient illustration:

> [M]any consumers are paying premiums for eggs adorned with images of farms without knowing what those illustrations mean. Other consumers are declining to pay for eggs with superior nutritional or safety qualities because they do not have enough information about how eggs are produced to know that those added qualities are important, or they do not trust that labeling indicating those qualities is truthful. Thus, there is a breakdown in the relationship between consumer preference and the types of eggs consumers ultimately choose. Such a breakdown indicates a market failure, because egg prices are not reflecting actual demand for food qualities, such as increased nutrient content. Indeed, one may conclude that there is a lower supply of high-quality food products (e.g., cage-free or free-range eggs) than there would be if this information asymmetry were remedied.[238]

Without labeling new technologies, packaging implies that the contents are what they always have been in the past, creating misinformation through

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237. *See* FDA, *What is the Meaning of "Natural" on the Label of Food?, supra* note 121.

238. Aurora Paulsen, *Catching Sight of Credence Attributes: Compelling Production Method Disclosures on Eggs*, 24 LOY. CONSUMER L. REV. 280, 317 (2011).

silence and assumptions or through provision of selective information.[239] Ideally, a labeling scheme would involve not just a notation about the new technology, but also assess its environmental or health impact, or note the lack of available information, with additional detail available in an online database or agency publication.[240]

3. Facilitate Pre-Market Consumer Input through Consultant Boards

Providing the information consumers need to make informed choices about their food requires knowing what kind of information consumers look for when they make purchases, and what their priorities are. It also requires balancing those interests with regulatory resources, research priorities, and industry needs. Consumer representative groups—similar to the ECCG—should be created and required to consult on labeling regimes and regulations regarding new technologies. Involving an independent board in this arena is an ideal way to balance the concerns of the industry for privacy and the need for consumer input—the members of the consultant board can easily abide by non-disclosure agreements when needed.

An additional and perhaps even more crucial arena for consumer involvement seems to be in allocating research funding.[241] The U.S. government directs substantial funds to directly and indirectly subsidize technology development; engaging consumer input regarding the social utility of funded projects could result in more efficient use of funds and a

239. For a detailed discussion of the potential for food labels to facilitate consumer choice, including health, environmental, and ethical issues, *see* J.C. Horvath, *How Can Better Food Labels Contribute To True Choice?*, 13 MINN. J.L. SCI. & TECH. 359 (2012) (this issue also dovetails with discussions regarding mandatory front of pack labeling limitations).

240. The EWG cosmetic rating system is a relatively easy to use and informative format that may present a helpful model for noting new food technologies and communicating risk in a helpful way. It rates each ingredient and product on two levels: hazard, and data availability. EWG'S SKIN DEEP DATABASE COSMETICS DATABASE, http://www.ewg.org/skindeep/faq/ (last accessed May 22, 2014). Hazard is rated from 0 to 10 and data availability is rated on five levels – ranging from "none" to "robust." *Id.* Data availability is reflected by the color that serves as a background to the hazard rating. *Id.*

241. *See, e.g.*, European Commission Services, *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields,* 2011 EURPOEAN RESEARCH, SCI. IN SOC'Y 10 ("In order to anticipate positive and negative impacts or, whenever possible, define desirable impacts of research and innovation both in terms of impact on consumers and communities. Setting of research priorities with their anticipated impacts needs to be subject to a societal review. This implies broadening the review of research proposals beyond scientific excellence and includes societal impacts.").

stimulation of research that would result in new food products responding directly to consumer needs or concerns. European studies looking at how to assess technology have already been conducted and could inform U.S. efforts.[242]

4. Reconsider International Trade Policies on Food Technologies

Agriculture and food-related intellectual property ("IP") issues have formed some of the most contested areas in current trade agreement negotiations. With WTO stagnation came an emphasis on bilateral agreements as the primary vehicle by which powerful trading entities like the U.S. and EU implement increased IP protections.[243] The U.S. is now negotiating two massive trade agreements: Trans Pacific Partnership ("TPP") and Transatlantic Trade and Investment Partnership ("TTIP") / Transatlantic Free Trade Area ("TAFTA").[244] These negotiations involve non-tariff barriers, which some fear will include bargaining away regulations and standards that consumers view as protections.[245] Domestic consumer organizations claim that leaked negotiation materials show TAFTA negotiations include efforts by each party to weaken protections.[246] Similar concerns were anticipated regarding TPP, whose chief agricultural negotiator is a former lobbyist for pesticide and agribusiness firms.[247]

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242. *See, e.g.*, BRIDGES BETWEEN SCIENCE, SOCIETY AND POLICY (Michael Decker and Miltos Ladikas eds., 2004).

243. *See* Kaitlin Mara, *Stronger IP Enforcement Finds A Home In Bilateral Trade Agreements*, INTELLECTUAL PROPERTY WATCH (APRIL 21, 2009, 12:09 PM), http://www.ip-watch.org/2009/04/21/stronger-ip-enforcement-finds-home-in-bilateral-trade-agreements/.

244. For a comparison, *see* Ulli Jamitzky, *TAFTA/TTIP and TPP in Comparison: Similar Interests, Unknown Outcomes*, *in* THE TRANSATLANTIC COLLOSSUS 44, 44 (Daniel Cardoso et al. eds., 2013).

245. Glyn Moody, *TAFTA/TTIP: What Are The Benefits? What Are The Costs?*, TECH DIRT (Apr. 18, 2014, 12:04 AM), http://www.techdirt.com/articles/20140417/09391926947/taftattip-what-are-benefits-what-are-costs.shtml.

246. Debbie Barker, *Trade Matters*, CENTER FOR FOOD SAFETY (May 2014), http://www.centerforfoodsafety.org/files/cfs_trade_matters_76070.pdf; *TAFTA COULD MAKE YOU SICK: A BACKDOOR FOR FOOD CONTAMINATION*, PUBLIC CITIZEN, http://www.citizen.org/documents/TAFTA-food-factsheet.pdf (last accessed May 22, 2014).

247. Marian Burros, *Agriculture Nomination Steams Greens*, POLITICO (Oct. 26, 2009, 4:47 AM), http://www.politico.com/news/stories/1009/28722.html. Almost 100 groups wrote to the Senate to protest his nomination. Marcia Ishii-Eiteman, *98 Organizations Oppose Obama's Monsanto Man, Islam Siddiqui, for US Agricultural Trade Representative*, ORGANIC CONSUMERS ASSOCIATION (Feb. 22, 2010), http://www.organicconsumers.org/articles/article_20276.cfm; *see also Trans-Pacific*

While international trade is perhaps the most inaccessible forum for consumers, it is arguably the most influential and should be a priority in any effort to address consumer concerns. International trade negotiations are anything but transparent, and some see them as a way for government and industry to enact rules that would never appeal to the public but present a potential profit opportunity.[248] These negotiations can include trade lobbyists but rarely involve consumer representatives or even Senators.[249]To remedy this imbalance a consumer group should be included anywhere industry lobbyists are included.

IV. CONCLUSION

Through this discussion of current trends and potential improvements to involving consumers in the development of food technologies, a significant disconnect has emerged. U.S. food technology policies operate on a largely voluntary basis in the ostensible belief that market forces will adequately safeguard consumers. However, this review has shown that industry actors continue to advance legal actions, lobbying campaigns, and initiatives that seek to expand their ability to avoid market downsides, to in effect alter the market. This should come as no great surprise, as 78% of surveyed managers admit that steady earnings from quarter to quarter and year to year are their primary motivation, even at the risk of long-term negative consequences.[250] It also underscores the importance of establishing institutions and processes that will involve consumer voices and values in the development of new technology applications to food.

Many commentators see consumer preference as an opposing force to technology in the food system. Discussions often focus on a specific issue, such as constitutional rights, then analyze whether consumers or industry have, or should have, the upper hand in that isolated context. However, as theories of profitable consumer engagement develop in the social media age,

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Partnership (TPP): Fast Track to a Gusher of Imported Fish, FOOD & WATER WATCH (April 2014), http://documents.foodandwaterwatch.org/doc/TPP_Imported_Fish.pdf; *Fast-Tracking Corporate Power: Investor-State Dispute Resolution and the TPP*, FOOD & WATER WATCH (Jan. 2014), http://documents.foodandwaterwatch.org/doc/Fast_Tracking_Corporate_Power.pdf.

248. David Brodwin, Op-Ed, *Obama's Pacific Trade Deal Is No Deal At All*, US NEWS AND WORLD REPORT (April 19, 2013), http://www.usnews.com/opinion/blogs/economic-intelligence/2013/04/19/trans-pacific-partnership-strikes-a-blow-against-growth-and-sustainable-development.

249. *Id.*

250. John R. Graham et al., *The Economic Implications of Corporate Financial Reporting*, 1-3 (Nat'l Bureau of Econ. Research, Working Paper No. 10550, 2004).

it seems increasingly likely that engaging consumers will improve a company's bottom line.[251]

Decisions in this arena should not, however, rely solely on market vitality. While transparency brings benefits, they may be insufficient motivation for some. Best efforts to be responsive to consumers in a world of fast changing technologies must include mandatory measures incorporating consumer input.

251. *See, e.g.*, V. KUMAR, PROFITABLE CUSTOMER ENGAGEMENT: CONCEPT, METRICS AND STRATEGIES (2013).