A Science-Based Endeavor: Interpreting Contamination Prevention in The Food Safety Modernization Act

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I. INTRODUCTION

On January 4, 2011, President Barack Obama signed the FDA Food Safety Modernization Act (the "Act")[1] into law, enacting the largest overhaul of the food industry since the Federal Food, Drug, and Cosmetics Act of 1938.[2] In granting the Food and Drug Administration (FDA) greater systematic oversight of all food production facilities,[3] the Act authorizes the FDA to implement prevention standards to combat

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1. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified in scattered sections of the U.S. Code).

2. *See, e.g.*, Les Schnoll, *The Food Safety Modernization Act: A Public Health Imperative—Why New Legislation is Necessary*, QUALITYDIGEST.COM (Aug. 30, 2011), http://www.qualitydigest.com/inside/fda-compliance-column/food-safety-modernization-act-public-health-imperative.html

3. *See* 124 Stat. 3885.

food contamination outbreaks.[4] Specifically, Title I, Section 103 of the Act, mandates that the FDA "establish science-based minimum standards" to conduct hazard analysis and employ preventative controls.[5] Although this directive seems straightforward, the term "science-based" represents the only qualitative description of the regulations that the Act contains.[6]

The Act's pervasive impact on the food industry will likely cause food production companies and public health advocates to scrutinize both the guidance documents[7] and the final promulgated regulations thoroughly.[8] The U.S. Supreme Court has held[9] that agency construction of statutes the agency administers must conform to congressional intent if that intent is clear.[10] Various methods of statutory construction serve to ascertain congressional intent, including an assessment of the plain meaning of the statute's text, analysis of the legislative history, and examination Congress's underlying purpose.[11] This Comment uses these

4. *See Background on the FDA Food Safety Modernization Act (FSMA)*, U.S. FOOD & DRUG ADMIN. (July 19, 2011), http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM263773.pdf.

5. Federal Food, Drug, & Cosmetic Act § 418(n)(1)(A), 21 U.S.C. § 350g(n)(1)(A) (2011).

6. *See id*.

7. Federal Food, Drug, & Cosmetic Act § 701(h), 21 U.S.C. § 371(h) (2006 & Supp. 2011).

8. *See* Mike Adams, *Senate Bill S 510 Vote Imminent—Procedural Vote Passes 74-25*, NATURALNEWS.COM, Nov. 18, 2010, http://www.naturalnews.com/030440_Food_Safety_Modernization_Act_Senate.html (outlining organizations opposed to the Senate version of the Act).

9. *See* Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court as well as the agency must give effect to the unambiguously expressed intent of Congress."); *see also* Estate of Cowart v. Nicklos Drilling Co., 505 U.S. 469, 475 (1992) (citing Demarest v. Manspeaker, 498 U.S. 184, 190 (1991)) (holding that the judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent).

10. *Chevron* further held that "when a statute is silent or ambiguous with respect to the specific question, the issue for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 842. The Supreme Court later clarified this language in holding that reasonable, permissible, or rational constructions are accorded *Chevron* deference. *See* Holly Farms Corp. v. N.L.R.B., 517 U.S. 392, 398 (1996); Kristine Cordier Karnezis, Annotation, *Construction and Application of "Chevron Deference" to Administrative Action by United States Supreme Court*, 3 A.L.R. FED. 2D 25 (2005). However, the question of whether "science-based" is rational construction under the Act is beyond the scope of this Comment. This Comment will solely examine clear congressional intent and proper adherence to this intent.

11. *See* William N. Eskridge, Jr. & Philip P. Frickey, *Statutory Interpretation as Practical Reasoning*, 42 STAN. L. REV. 321, 324 (1990); *see also* Lawrence M. Solan, *Private Language, Public Laws: The Central Role of Legislative Intent in Statutory Interpretation*, 93 GEO. L.J. 427 (2005); Peter L. Strauss, *The Courts and the Congress: Should Judges Disdain Political History?*, 98 COLUM. L. REV. 242 (1998); Caleb Nelson, *What Is Textualism?*, 91 VA. L. REV. 347 (2005).

methods to clarify the term "science-based," establishing some definition to the regulations the FDA should promulgate in order to withstand a challenge in court.

This Comment's analysis of the plain language of the text indicates the importance of objective standards and use of the scientific method. Examination of the legislative history of the Act demonstrates that legislators understood "science-based" to connote use of experts and in-plant evaluations similar to that enumerated in Hazard Analysis and Critical Control Point (HACCP) methodology, data collection similar to that employed by the Food Safety and Inspection Service, and information technology utilization as advocated by the FDA Science Board. Additional examination of Congressional purpose reveals legislators expected "science-based" regulations to comply with World Trade Organization Sanitary and Phytosanitary standards. Taken together, these methods of statutory interpretation[12] provide a clearer view of Congress's "science-based" regulatory mandate to the FDA.

II. BACKGROUND

A. A Brief History of Food Safety Regulation in America

The history of food regulation in America and the problems with food safety persisting today explain Congress's motivation in writing and passing the FDA Food Safety Modernization Act. Consequently, to understand the potential impact of this Act, it is important to discuss the historical development of food safety regulation law in the United States. Food safety regulation in the United States began slowly, but public outcry over unsanitary meat products in the early 20th century resulted in the passage of the Pure Food and Drug Act of 1906.[13] This legislation was limited in its ability to adapt to the modernizing food industry, and in 1938, Congress enacted the Federal Food, Drug, and Cosmetics Act.[14] An examination of these Acts[15] and later history of food safety measures

12. Although various other theories of statutory interpretation exist, this Comment focuses on "archeological" theories to ascertain congressional intent. *See* William N. Eskridge, Jr., *Gadamer/Statutory Interpretation*, 90 COLUM. L. REV. 609, 611 (1990).

13. *See* DONNA J. WOOD, STRATEGIC USES OF PUBLIC POLICY: BUSINESS AND GOVERNMENT IN THE PROGRESSIVE ERA 70 (Edwin M. Epstein ed., 1986) (discussing how muckraking journalists brought unsanitary meat production conditions to public attention)); *see also* Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).

14. *See* Vincint A. Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 50 Food & Drug L.J. 65, 67 (1995); *see also* Federal Food, Drug, and Cosmetics Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

15. The Acts discussed in this Comment also contain implications for drug, cosmetic, and medical device regulation; however, this Comment will focus on developments in food safety.

in America will help to clarify legislative intent in adopting the FDA Food Safety Modernization Act and the nature of the safety plans that the FDA must administer.

Prior to the 20th century, the U.S. Federal Government regulated food production and distribution to a minimal extent.[16] In the late 1800s, public awareness of health hazards in the food industry dramatically increased.[17] Contaminated food, milk, and water caused many food-borne infectious diseases during this time, including typhoid fever, tuberculosis, and scarlet fever.[18] Muckraking journalists, most notably, Upton Sinclair, brought these unsanitary food production conditions to light.[19] Sinclair's novel, *The Jungle*, provided a vivid description of the unsanitary and inhumane conditions in the Chicago meatpacking industry, shocking readers.[20] One foul description read:

> [T]he meat would be shoveled into carts, and the man who did the shoveling would not trouble to lift out a rat even when he saw one—there were things that went into the sausage in comparison with which a poisoned rat was a tidbit. There was no place for the men to wash their hands before they ate their dinner, and so they made a practice of washing them in the water that was to be ladled into the sausage. There were the butt-ends of smoked meat, and the scraps of corned beef, and all the odds and ends of the waste of the plants, that would be dumped into old barrels in the cellar and left there. Under the system of rigid economy which the packers enforced, there were some jobs that it only paid to do once in a long time, and among these was the cleaning out of the waste barrels. Every spring they did it; and in the barrels would be dirt and rust and old nails and stale water—and cartload after cartload of it would be taken up and dumped into the hoppers with fresh meat, and sent out to the public's breakfast.[21]

16. *See Significant Dates in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN. (Oct. 14, 2010), http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm.

17. *See id*.

18. *See* JAMES HARVEY YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906 40 (1989).

19. *See* WOOD, *supra* note 13, at 70.

20. James Harvey Young, *The Pig That Fell into the Privy: Upton Sinclair's* The Jungle *and the Meat Inspection Amendments of 1906*, 59 BULL. OF THE HIST. OF MED. 467, 467 (1985) (detailing how the history of *The Jungle* helped to spur passage of the 1906 Food and Drugs Act).

21. UPTON SINCLAIR, THE JUNGLE 162 (Penguin Books 2006) (1906).

In response to these types of writings, American meat purchases, both domestic and foreign, fell by one-half.[22] As a result, Congress passed the Pure Food and Drug Act[23] and the Meat Inspection Act in 1906.[24]

The Pure Food and Drug Act of 1906 (the "1906 Act") represented the first wave of regulation over food production.[25] The 1906 Act prohibited the adulteration or misbranding of food.[26] Specifically, the 1906 Act deemed food to be adulterated if "any substance has been mixed or packed with it so as to reduce or lower or injuriously affect its quality or strength," or "if it contain[ed] any added poisonous or other added deleterious ingredient which may render such article injurious to health."[27] The 1906 Act considered food to be misbranded if it was "labeled or branded as to deceive or mislead the purchaser," or if "the contents [were] stated in weight or measure, they [were] not plainly and correctly stated on the outside of the package."[28] In addition, the 1906 Act tasked the Bureau of Chemistry with the responsibility of examining food for mislabeling or alterations.[29]

The Bureau of Chemistry, however, struggled to meet its new responsibilities.[30] The 1906 Act did not provide the Bureau of Chemistry any new staff or funding.[31] Furthermore, judicial decisions narrowed the capacity of the Bureau of Chemistry to enforce the statute by requiring high standards for proof of fraudulent intent.[32] Under the framework of the 1906 Act, the government did not have "the power simply to

22. *See* PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 51 (2003).

23. Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified in scattered sections of the U.S. Code).

24. Federal Meat Inspection Act, Pub. L. No. 59-382, 34 Stat. 669 (1906) (codified in scattered sections of the U.S. Code).

25. *See* HILTS, *supra* note 22, at 56.

26. 34 Stat. 768.

27. *Id.*

28. *Id*.

29. *See* Wallace Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420, 425 (1981).

30. *See* HILTS, *supra* note 22, at 56 (observing that the Bureau of Chemistry found it difficult to meet the Congressional mandates of the Pure Food and Drug Act of 1906 because of the way in which the Act was worded, and the lack of resources allocated to the Bureau).

31. *Id.*

32. *See, e.g.*, United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914) (holding that the burden falls on the government to show a relationship between the chemical additive and the harm it allegedly caused in people, and that the mere presence of such additives is not sufficient to render the food illegal); *see also* United States v. Forty Barrels & Twenty Kegs of Coca-Cola, 241 U.S. 265 (1916) (holding that the introduction of caffeine in the later stages of syrup production made it an "added ingredient" in any sense of the term and the removal of harmful ingredients, even if vital to the identity of the product, did not constitute adulteration).

determine that the law was violated; it required that the government take each offender to court and prove that each particular food . . . was adulterated or mislabeled, and by what standard it was making that judgment."[33]

In an attempt to better fulfill the goals of the 1906 Act, the Bureau of Chemistry's regulatory powers were reorganized under a new Department of Agriculture body, the "Food, Drug, and Insecticide Administration," later shortened to the "Food and Drug Administration" (FDA).[34] But this reorganization could not overcome the 1906 Act's shortcomings.[35] According to one scholar, "The 1906 [Act] was built on the idea that false claims must be prosecuted, rather than addressing the real issues of whether food. . .put on the market [was] safe. . . ."[36]

By the 1930s, the weaknesses of the 1906 Act prompted the FDA to recommend that Congress enact a completely revised bill.[37] The need to enact new legislation became accentuated after an untested product, Elixir Sulfanilamide, caused the deaths of 107 people in 1937.[38] Ultimately, Congress passed the Food, Drug, and Cosmetic Act in 1938 (the "1938 Act").[39] In the 1938 Act, Congress provided detailed provisions that restricted adulteration and misbranding of food.[40] Whereas the 1906 Act did not establish definitions or standards of food identity, the 1938 Act authorized administrative establishment of these definitions.[41] Pursuant to the 1938 Act, if a quality standard was established for a particular food and that food fell below the standard, the food must be labeled as sub-standard or be held misbranded.[42] The 1938 Act also deemed a product to be misbranded if "its container is so made, formed, or filled as to be misleading."[43] Selling one food under the name of another was also prohibited by the 1938 Act.[44] The 1938 Act authorized authority to promulgate standards of fill for containers, and prohibited substances added to make "the product appear better or of greater value than it is."[45] The 1938 Act also established the remedy of

33. HILTS, *supra* note 22, at 54.
34. *Id*. at 74.
35. *See id*. at 68.
36. HILTS, *supra* note 22, at 68.
37. *See Significant Dates in U.S. Food and Drug Law History*, *supra* note 16.
38. *See id*.
39. *See id*.
40. David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 25 (1939).
41. *See id*. at 25.
42. *See id*. at 29.
43. *See id*. at 30.
44. *See id*. at 29.
45. *Id*. at 27.

court injunctions and authorized factory inspections.[46] The 1938 Act was a milestone in American food safety oversight and continues to serve as the basic food safety statute today.[47]

The FDA's forceful administration of the 1938 Act contributed to the legislation's success, and judicial interpretations of the 1938 Act tended to strengthen and broaden the FDA's power.[48] In the 1950s and 1960s, the FDA was widely successful in bringing hundreds of lawsuits against nutrition claims that it viewed as false or misleading.[49] With this new power, the FDA also established food standards and lists of ingredients that could lawfully be included in products.[50] A series of laws addressing pesticide residue, food additives, and color additives gave the FDA tighter control over chemicals that may enter the food market.[51] In addition, manufacturers had the duty to establish the safety of such chemicals.[52]

Subsequent amendments to the 1938 Act addressed additional food safety concerns.[53] The Miller Amendment of 1948 affirmed that the FDA had the authority to regulate goods crossing state lines that had reached the consumer.[54] The Food Additives Amendment of 1958 required manufacturers to establish the safety of new food additives, and the FDA published the first list of substances generally recognized as

46. *See Significant Dates in U.S. Food and Drug Law History*, *supra* note 16.

47. *See* Wallace F. Janssen, *The Story of the Laws Behind the Labels*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2010), http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm.

48. *See* CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL 220 (1970); *see also* Kordel v. United States, 335 U.S. 345 (1948) (holding that product literature which met the product at the location of the sale constitutes labeling and is thus subject to the labeling provisions of the 1938 Act even though such literature did not physically accompany the product); United States v. Urbuteit, 335 U.S. 355 (1948) (same).

49. *See* Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 67 (1984) (citing V.E. Irons, Inc. v. United States, 244 F. 2d 34 (1st Cir. 1957); United States v. Nutrition Serv., Inc. 227 F. Supp. 375 (W.D. Pa. 1964)).

50. *See* JACKSON, *supra* note 48, at 22. In the years following the 1938 Act, food technology advanced and the number of possible ingredients grew exponentially. *Id.* In response, the FDA developed recipe standards for foods, which included lists of ingredients that could lawfully be included in a product. *Id.* If food products varied from the lawful recipes, they would have to be labeled as an imitation. *Id.*

51. *See* JACKSON, *supra* note 48, at 220.

52. *See* MELVIN J. HINICH AND RICHARD STAELIN, CONSUMER PROTECTION LEGISLATION AND THE U.S. FOOD INDUSTRY 34 (1980).

53. *See* Janssen, *supra* note 47.

54. Miller Amendment, 21 U.S.C. § 350e (1948); Color Additives Amendment, 21 U.S.C. § 379e (1960) (requiring manufacturers of new food and color additives to establish that the additives are safe); Fair Packaging and Labeling Act, 15 U.S.C. § 1451 (1966) (requiring all consumer products in interstate commerce to be honestly and informatively labeled).

safe in the same year.[55] Similarly, the Color Additive Amendment of 1960 required manufacturers to establish the safety of food color additives.[56] In 1988, Congress designated the FDA as an agency within the U.S. Department of Health and Human Services, with a Commissioner appointed by the President.[57] Thus, as the 20th century progressed, the FDA acquired significant responsibility in food safety regulation.[58]

B. The FDA Food Safety Modernization Act

Despite the FDA's expanded responsibilities and authority, the agency continued to struggle against preventing food contamination outbreaks.[59] Each year in the United States, about 48 million people get sick, 128,000 are hospitalized, and 3,000 die as a result of foodborne diseases.[60] The lack of preventative measures became especially pronounced during the summer of 2010 with various publicized contamination events.[61] These outbreaks resulted in the recall of half a billion eggs that caused salmonella, and a peanut butter recall connected to food poisoning.[62] Shortly after these outbreaks, the push for preventative measures to protect against food contamination grew among consumer groups and various members of Congress.[63]

Although congressional efforts to advance preventative measures enjoyed some bipartisan support, the ultimate product, the FDA Food Safety Modernization Act (the "Act"), did not pass through Congress

55. Food Additives Amendment, 21 U.S.C. § 348 (1958).

56. Color Additives Amendment, 21 U.S.C. § 379e (1958 & Supp. 1960).

57. *See Significant Dates in U.S. Food and Drug Law History*, *supra* note 16.

58. *See* HILTS, *supra* note 22.

59. *See* RENÉE JOHNSON, CONG. RESEARCH SERV., R40403, FOOD SAFETY IN THE 111TH CONGRESS 1 (2010).

60. U.S. FOOD & DRUG ADMIN., *supra* note 4; *see also* Schnoll, *supra* note 2.

61. U.S. FOOD & DRUG ADMIN., *supra* note 4.

62. *See* Bryan Walsh, *Food: The Senate Passes a Food-Safety Bill, But the Problem Isn't Going Away*, TIME, Nov. 30, 2010, *available at* http://ecocentric.blogs.time.com/2010/11/30/food-the-senate-passes-a-long-awaited-food-safety-reform-bill-but-the-problem-isnt-going-a/#ixzz1amdxjqL3; *see also* JOHNSON, *supra* note 54, at 2.

63. Alison Young, *Food Safety Groups Slam USDA Egg Graders at Farms in Recall*, USA TODAY, Sept. 3, 2010, *available at* http://www.usatoday.com/yourlife/food/safety/ 2010-09-02-eggregulations2_ST_N.htm ("Rep. Rosa DeLauro, who chairs the House Appropriations Agriculture subcommittee, last month sent a letter to Agriculture Secretary Tom Vilsack asking, among other things, about the egg graders' awareness of conditions at Wright County Egg. She's waiting on answers. It has never been more clear that we need to pass strong FDA food safety legislation this year,' said DeLauro, D-Conn. 'In the long term, a single food agency is needed that focuses exclusively on protecting our food supply.'").

easily.[64] Food wholesalers, farm organizations, and cooperatives opposed the expansion of FDA regulatory power.[65] Some advocates for small farms and organic food producers said this type of legislation would destroy their industry under a mountain of paperwork.[66] The small government ideals remained a driving force behind many Republicans who believed that the cost of this type of food safety act for both the government and consumers would be too high.[67] Nevertheless, Representative John Dingell (D-MI) introduced the first attempt at granting the FDA more preventative enforcement power on June 8, 2009.[68] H.R. 2749, entitled "The Food Safety Enhancement Act," was referred to the House Committee on Energy and Commerce, and, after committee amendment and general floor debate, the bill passed the House of Representatives by a vote of 283-142 on July 30, 2009.[69]

Although this bill was referred to the Senate on August 3, 2009, the Senate did not take any further action on it.[70] Rather, Senator Dick Durbin (D-IL) introduced a new bill on March 3, 2009, S.510, entitled "The FDA Food Safety Modernization Act."[71] Senator Jon Tester (D-MT) and Senator Kay Hagen (D-NC) advocated for a "Tester Amendment" to this bill to exempt producers with less than $500,000 in annual sales who sell most of their food locally.[72] Despite the Tester Amendment exemption for small farmers, Senator Tom Coburn (R-OK) strongly opposed the legislation and forced a vote on an amendment to ban all earmark spending through 2013 in attempts to prevent the bill

64. *See* Walsh, *supra* note 62.

65. *H.R. 2751—FDA Food Safety Modernization Act*, OPEN CONGRESS, http://www.opencongress.org/bill/111-h2751/show (last visited Oct. 31, 2012).

66. Gardiner Harris and William Neuman, *Senate Passes Sweeping Law on Food Safety*, N.Y. TIMES, Nov. 30, 2010, *available at* http://www.nytimes.com/2010/12/01/health/policy/01food.html.

67. Helena Bottemiller, *Update: Food Safety Bill Clears Full Senate*, FOOD SAFETY NEWS, Nov. 30, 2010, *available at* http://www.foodsafetynews.com/2010/11/s510-clears-key-vote-debate-to-resume-today/ (stating that during debates over the Act, Senator Tom Coburn (R-OK) argued that the bill "fails to address systemic problems with federal food safety oversight and will increase the cost of food as well as leave the states with unfunded mandates").

68. *Bill Summary and Status 111th Congress (2009-2010) H.R. 2749*, THOMAS (LIBRARY OF CONGRESS), http://thomas.loc.gov/home/thomas.php (last visited Nov. 11, 2011).

69. *H.R.2749—Food Safety Enhancement Act*, OPEN CONGRESS, http://www.opencongress.org/bill/111-h2751/show (last visited Dec. 1, 2011).

70. *See id.*

71. *See Bill Summary and Status 111th Congress (2009-2010) S. 510*, THOMAS (LIBRARY OF CONGRESS), http://thomas.loc.gov/home/thomas.php (last visited Nov. 12, 2011).

72. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.).

from passing.[73] Ultimately, the bill passed in the Senate with a vote of 73-25 on November 30, 2010.[74]

However, a constitutional concern arose after the bill's passage. S.510 contained a tax provision; yet all revenue raising provisions must originate in the House of Representatives.[75] To solve this problem, the House attached the language of the Food Safety Modernization Act to H.R. 3082, the Full Year Continuing Appropriations Act, on December 8, 2010.[76] The Senate, however, rejected the Full Year Continuing Appropriations Act for objections to earmarks.[77] Instead, the Senate resurrected H.R. 2751, a "Cash for Clunkers" bill that had originated in the House and replaced the bill's language with that of the Food Safety Modernization Act.[78] The Senate passed this restructured bill through unanimous consent on December 19, 2010, which the House subsequently passed by a vote of 215-144 on December 21, 2010.[79] President Obama signed the Food Safety Modernization Act into law on January 4, 2011.[80]

The final version of the Food Safety Modernization Act (the "Act") enables the FDA to implement compliance standards designed to prevent food contamination and grants the agency the power to enforce these standards.[81] As Michael R. Taylor, Deputy Commissioner for Foods at the FDA, stated:

> The law directs the FDA to issue a rule requiring comprehensive preventive controls for most facilities. In the future, each facility will have to produce a written analysis identifying the hazards associated with the foods it handles and the processes used to manufacture them. The required documentation will describe the controls the facility has

73. 156 CONG. REC. S8259-02 (daily ed. Nov. 30, 2010) (statement of Sen. Tom Coburn).

74. *S.510—FDA Food Safety Modernization Act*, OPEN CONGRESS, http://www.opencongress.org/bill/111-s510/show (last visited Nov. 23, 2011).

75. U.S. CONST. art. I, § 7.

76. *See* 156 CONG. REC. D1170-01 (daily ed. Dec. 8, 2010).

77. *See Bill Summary and Status 111th Congress (2009-2010) H.R. 3082*, THOMAS (LIBRARY OF CONGRESS), http://thomas.loc.gov/home/thomas.php (last visited Oct. 31, 2012) (noting H.R. 3082 later passed without the language of the FDA Food Safety Modernization Act).

78. Jamie Dupree, *Food Safety Bill Lives*, THE ATLANTA JOURNAL-CONSTITUTION (Dec. 19, 2010, 8:39 PM), http://blogs.ajc.com/jamie-dupree-washington-insider/2010/12/19/food-safety-bill-lives/.

79. *H.R.2751—FDA Food Safety Modernization Act*, OPEN CONGRESS, http://www.opencongress.org/bill/111-h2751/show (last visited Oct. 31, 2012).

80. Elizabeth Weise, *Obama Signs Legislation to Improve Food Safety*, USA TODAY, Jan. 5, 2011, *available at* http://www.usatoday.com/news/nation/2011-01-04-food-safety_N.htm.

81. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.).

> implemented to prevent the identified hazards, including a plan for monitoring the controls and correcting problems when failures occur.[82]

Key aspects of the Act emphasize prevention, inspection and compliance, response, regulations on foreign imports, and enhanced partnerships with other government agencies (both domestic and foreign).[83]

The Act requires the FDA to establish comprehensive, science-based preventive controls across the food supply.[84] This mandate includes: (1) requiring food facilities to implement a written preventative plan; (2) establishing science-based minimum standards for the safe production and harvesting of fruits and vegetables; and, (3) issuing regulations to protect against the intentional contamination of food.[85] As noted above, in the food facilities' preventative safety plans, the facilities must evaluate the hazards that could affect food safety and implement preventive steps to minimize or prevent these hazards.[86] The facilities must also indicate how they will monitor these safety controls, maintain routine records of the monitoring, and specify what actions they will take to correct problems that arise.[87] In addition, the FDA must establish produce safety standards. In establishing mandatory produce safety standards, the FDA must consider naturally occurring hazards, as well as those that may be introduced either intentionally or unintentionally.[88] Moreover, the FDA must address soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water.[89] The FDA will also have authority to prevent intentional contamination and must establish science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points.[90]

However, these preventive control standards can improve food safety only to the extent that producers and processors comply with the standards. Consequently, the Act includes provisions that provide the FDA with new tools for inspection and compliance, including: (1) establishing a mandated inspection frequency; (2) allowing FDA

82. Michael R. Taylor, *Will the Food Safety Modernization Act Help Prevent Outbreaks of Foodborne Illness?*, NEW ENG. J. MED. (2011), *available at* http://www.nejm.org/doi/full/10.1056/NEJMp1109388#t= article.

83. U.S. FOOD & DRUG ADMIN., *supra* note 4.

84. *Id*.

85. *Id*.

86. *See* 124 Stat. at 3889.

87. *See id*.

88. U.S. FOOD & DRUG ADMIN., *supra* note 4.

89. *See* 124 Stat. at 3900 (stating soil amendments are materials added to the soil, such as compost).

90. *See* 124 Stat. at 3895.

access to records; and (3) requiring certain food testing to be carried out by accredited laboratories.[91] In addition, the FDA received a $50 million funding boost for 2012, $39 million of which is specifically designated for carrying out measures of the Food Modernization Act.[92] The frequency of food facility inspections will be based on the level of risk associated with the facility, and an increased risk level will result in immediate increase in inspection frequency.[93] All high-risk domestic facilities must be inspected within five years of the date of enactment and no less than every three years after that.[94] The FDA will have access to records and food safety plans, and food facilities must document the implementation of their plans.[95] To carry out certain food tests, the FDA must also establish a program for laboratory accreditation to ensure that U.S. food testing laboratories meet high quality standards.[96]

Section III of this Comment focuses on Title I, Section 103 of the Act, entitled "Hazard Analysis and Risk Based Preventative Controls." Section 103 of the Act amends the basic 1938 Act to mandate that food facilities implement "science-based" food safety plans.[97] Section 103 is critical because, "for the first time, [the] FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply."[98] The language of Section 103 enumerates, "Not later than 18 months after January 4, 2011, the Secretary shall promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under this section."[99] Thus, the remainder of this Comment will analyze the language of Section 103 to clarify and discover its meaning as the FDA plans to promulgate both guidance documents and regulations.

91. U.S. FOOD & DRUG ADMIN., *supra* note 4.

92. Caroline Scott-Thomas, *Food Safety Law Gets $39m Funding for 2012*, FOOD NAVIGATOR USA (Dec. 2, 2011) http://www.foodnavigator-usa.com/ Regulation/Food-safety-law-gets-39m-funding-for-2012.

93. U.S. FOOD & DRUG ADMIN., *supra* note 4.

94. *See* 124 Stat. at 3888.

95. *See id.* at 3886.

96. U.S. FOOD & DRUG ADMIN., *supra* note 4.

97. 124 Stat. at 3895.

98. *Food Safety Legislation Key Facts*, U.S. FOOD & DRUG ADMIN. http://www.fda.gov/Food/FoodSafety/FSMA/ucm237934.htm (last updated July 19, 2011).

99. 124 Stat. at 3895.

III. ANALYSIS

Congress's mandate to the FDA to promulgate safety regulations may seem relatively straightforward at first glance.[100] The Food Safety and Modernization Act (the "Act") clearly states that the FDA must establish food safety regulations and provides the final date for the publication of these regulations.[101] The Act also includes language to alleviate undue burdens on small food producing facilities.[102] However, the Act leaves some ambiguity involving the substantive nature of the regulations themselves.[103] The only qualitative description of the regulations that the Act specifies is that the regulations must be "science-based."[104] This terminology is broad and allows the FDA to determine the specifics of the regulations to be promulgated.[105]

The broad term "science-based" grants the FDA the power to determine the specific nature of the preventive regulations.[106] It does not provide substantive direction to the FDA regarding the specific content of the regulations, such as requisite probability levels or establishing burden of proof.[107] Because of the open-ended nature of this directive, there could be challenges in court regarding the meaning of the term "science-based," and whether the FDA regulations adhere to this meaning.[108] The FDA's regulations will have a great impact on food production companies, and these companies will likely scrutinize the regulations closely for overstepping the Congressional mandate.[109] On the other hand, public interest groups will examine the regulations for

100. *See id.*

101. *See id.* ("Not later than 18 months after January 4, 2011, the Secretary shall promulgate regulations.").

102. *See id.* (noting that the regulations shall "provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm").

103. *See* Shawn Stevens, *The Food Safety Modernization Act: Are We Almost There Yet?*, DEFENDING FOOD SAFETY (Nov. 15, 2011), http://www.defendingfoodsafety.com/2011/11/articles/food-safety-news/the-food-safety-modernization-act-are-we-almost-there-yet/.

104. *See* Shawn Stevens, *We Think We Have an Adequate Food Safety Plan, But How Will It Be Enforced?*, DEFENDING FOOD SAFETY (Sept. 28, 2011), http://www.defendingfoodsafety.com/2011/09/articles/food-safety-news/we-think-we-have-an-adequate-food-safety-plan-but-how-will-it-be-enforced/.

105. *See id.*

106. *See* Laetitia Mailhes, *The Food Safety Act Raises Questions*, CARE2.COM (Dec. 1, 2010, 9:36 AM), http://www.care2.com/greenliving/the-food-safety-modernization-act-raises-questions.html#ixzz1lEvKJ8Dg.

107. *See* 124 Stat. at 3895.

108. *See H.R.2751—FDA Food Safety Modernization Act*, *supra* note 79; *H.R.2749—Food Safety Enhancement Act*, *supra* note 69.

109. *See id.*

falling short of Congress's aim in protecting public health and safety.[110] The pervasive impact of these regulations could result in challenges to the scope of Congress's mandate to the FDA.[111] Challenges to agency authority in court are common.[112] The Supreme Court has established precedent in determining the level of deference that an agency receives when interpreting a statute the agency administers.[113]

Part III of this Comment seeks to clarify the broad term "science-based" as used by Congress to authorize the FDA to promulgate food safety regulations. Specifically, Part III will use the first prong of *Chevron* and the three archeological methods[114] of statutory interpretation—textualism, intentionalism, and purposivism—to discover the meaning of the term "science-based" within the context of the Act. First, Part III will establish the importance of discussing "science-based" under the first prong of *Chevron* using the three statutory interpretation methods as a framework. Next, Part III will examine the term "science-based" under each method of statutory interpretation and discuss the implications of each of these methods. Part III will clarify the range of meaning for the term "science-based" in the context of the FDA Food Safety Modernization Act.[115]

A. Agency Deference

The Supreme Court has established precedent for the standard of review that a court should apply to a government agency's interpretation of a statute that the agency administers.[116] In *Chevron U.S.A., Inc. v.*

110. *See id.*

111. *See, e.g.*, Helena Bottemiller, *Senate Food Safety Bill Moves Ahead*, FOOD SAFETY NEWS (Nov. 18, 2010), http://www.foodsafetynews.com/2010/11/food-safety-bill-advances-compromises-ironed-out/ (stating the widespread impact of the bill, and explaining why some were opposed to its passage).

112. *See, e.g.*, Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984); Estate of Cowart v. Nicklos Drilling Co., 505 U.S. 469 (1992); Skidmore v. Swift & Co., 323 U.S. 134 (1944); Christensen v. Harris Cnty., 529 U.S. 576 (2000); United States v. Mead Corp., 533 U.S. 218 (2001); Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs., 545 U.S. 967 (2005).

113. *See id.*

114. "Archeological" methods of statutory interpretation, as termed by William N. Eskridge, refer to a court's objective to "unearth and enforce the original intent or expectations of the legislature that created the statute." William N. Eskridge, Jr., *Politics Without Romance: Implications of Public Choice Theory for Statutory Interpretation*, 74 VA. L. REV. 275 (1988).

115. This Comment serves to establish the basic limits on the FDA's "science-based" regulations, and, while further analysis of the term "science-based" under the second prong of Chevron and under various other methods of statutory interpretation would also prove insightful, such analysis is beyond the scope of this Comment.

116. *See Chevron*, 467 U.S. at 842.

Natural Resources Defense Council, Inc., the Court enumerated a two-part analysis:

> First, always, is the question whether Congress has spoken directly to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court as well as the agency must give effect to the unambiguously expressed intent of Congress. If, however, the Court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction of the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific question, the issue for the court is whether the agency's answer is based on a permissible construction of the statute.[117]

The Court limited and clarified *Chevron* in two later decisions, holding that deference to an agency's interpretation only applies if it is the product of a formal agency process[118] in which the agency is authorized by Congress "to speak with the force of law."[119] In the case of FDA food safety regulations, the FDA would be accorded *Chevron* deference because the regulations it promulgates are currently in the notice-and-comment formal rulemaking process, and Congress authorized the FDA to speak with the force of law.[120]

The first prong of the *Chevron* analysis asks whether Congress has directly addressed the issue at hand, in this case, the meaning of the term "science-based."[121] Although the Court appears to favor agency deference in the ultimate holding of *Chevron*, the Court has often determined that Congress had indeed addressed the question at issue, requiring no need to defer to agency interpretation.[122] The methods that the Court uses to determine whether Congress directly addressed an issue are instrumental in making this determination. The Court has not relied on a single method of determining congressional intent, using both legislative history and plain meaning in various decisions.[123]

117. *Id.*

118. Formal agency processes include adjudication or notice-and-comment rulemaking. *See Mead Corp.*, 533 U.S. 218.

119. *Id.* at 229 (2001); *see also Christensen*, 529 U.S. 576 (2000).

120. *See* Press Release, Food & Drug Admin., Dockets Open for Comment (July 12, 2011), *available at* http://www.fda.gov/Food/FoodSafety/FSMA/ucm261689.htm.

121. *See Chevron*, 467 U.S. at 842.

122. *See, e.g.*, Sullivan v. Zebley, 493 U.S. 521 (1990) (noting that regulations "are simply inconsistent with the statutory standard"); Dole v. Steelworkers, 494 U.S. 26 (1990) (stating that deference to OMB interpretation of Paperwork Reduction Act is foreclosed by the Court's finding of clear congressional intent to contrary).

123. *See, e.g.*, Dunn v. CFTC, 519 U.S. 465, 473-74 (1997) (stating legislative history supports the Court's conclusion that the statute is clear and the agency's interpretation is untenable); *see also* Babbitt v. Sweet Home Chapter, 515 U.S. 687, 708 (1995)

Therefore, three archeological methods of statutory interpretation provide useful lenses in which to explore whether Congress "directly addressed" a particular issue.[124] The first of these is "textualism." Textualism involves an analysis of the text itself and puts great emphasis on the plain meaning of the language.[125] The second method is "intentionalism." Intentionalists "rely on the historical record of the lawmaking process," including reference to congressional records, committee hearings, and committee reports to determine congressional intent.[126] Finally, the third method is known as "purposivism." This method looks deeper into the purpose of the statute, and contemplates the statute's political history.[127] Each of these methods can be used to analyze the term "science-based" to clarify the meaning of FDA regulation requirements.

B. Textualism

An examination of the text of the Food Safety Modernization Act (the "Act") provides insight into the practical implications of a "science-based" regulation. The study and emphasis on the plain meaning of text to determine a statute's implication is "textualism."[128] As Justice Scalia stated, the goal of textualism is to determine "the intent that a reasonable person would gather from the text of the law, placed alongside the remainder of the corpus juris."[129] The Supreme Court sometimes relies upon this method to determine the meaning of a statute.[130] In

(concluding that "based on the text, structure, and legislative history of the ESA, that the Secretary reasonably construed the intent of Congress" in defining "harm"); K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 291 (1988) (stating that courts should look "to the particular statutory language at issue, as well as the language and design of the statute as a whole" in order to ascertain statute's "plain meaning"); Ohio Pub. Emps. Ret. Sys. of Ohio v. Betts, 492 U.S. 158, 171 (1989) ("[N]o deference is due to agency interpretations at odds with the plain language of the statute itself.").

124. *See* Eskridge & Frickey, *supra* note 11, at 324.

125. *See* Nelson, *supra* note 11, at 347; *see also* Eskridge & Frickey, *supra* note 11, at 340.

126. *See* Solan, *supra* note 11, at 427.

127. *See* Strauss, *supra* note 11, at 242; *see also* Eskridge & Frickey, *supra* note 11, at 332.

128. *See* John F. Manning, *Textualism and Legislative Intent*, 91 VA. L. REV. 419, 420 (2005) (discussing the ideas about legislative intent that follow from underlying textualist assumptions).

129. Antonin Scalia, *Common-Law Courts in a Civil-Law System: The Role of United States Federal Courts in Interpreting the Constitution and Laws*, *in* A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW 17 (Amy Gutmann ed., 1997).

130. *See, e.g.*, Nat'l R.R. Passenger Corp. v. Bos. & Me. Corp., 503 U.S. 407 (1992) (holding an agency's permissible construction of a silent or ambiguous statute is entitled to deference if not in conflict with the plain language of the statute); Pub. Emps. Ret. Sys. of Ohio v. Betts, 492 U.S. 158 (holding no deference to agency interpretation at odds with plain language of statute it administers); Demarest v. Manspeaker, 498 U.S. 184

determining the significance of statutory language, textualists recognize the importance of placing the text in context; however, textualists do not believe that legislative history plays any role in shaping that context.[131] Rather, textualists look to dictionaries, the statute as a whole, or other statutes in which similar language is used.[132] Analyzing the Act in this way will shed light on the difficultly presented by the term "science-based" in this context.

Looking solely at the text of Section 103 of the Act, the standard for the regulations that Congress requires of the FDA is minimal. A simple definition of the term "science" is "knowledge or a system of knowledge covering general truths or the operation of general laws especially as obtained and tested through scientific method."[133] Common understanding of the term recognizes the importance of objectivity, rather than subjectivity, in the meaning of "science-based" regulations. This broad characterization of the term provides the FDA with extensive authority to promulgate objectively founded regulations.

Section 103 of the Act does not contain many restrictive provisions alongside the term "science-based."[134] Aside from specifications stating that the regulations must accommodate all facility sizes and must not require that facilities hire third-party consultants, the Act does not greatly restrict the extent of FDA oversight.[135] If the FDA regulations, whether minimalistic or overly burdensome, meet the objectivity standard and fall within the few limitations set forth in Section 103, a textualist interpretation would likely deem the regulation satisfactory. Many judges and academics argue in favor of a purely textualist approach to statutory interpretation,[136] but this method can only provide a certain degree of direction for the regulations. An analysis of the legislative history of the Act will provide additional information for the meaning of the term "science-based," though texualists would dispute whether legislative history should contribute to the understanding of the term's meaning.

(1991) (holding administrative interpretation of statute contrary to its plain language is not entitled to deference); MCI Telecomm. Corp. v. Am. Tel. & Tel. Co., 512 U.S. 218 (1994) (holding agency's interpretation of statute is not entitled to deference when it goes beyond meaning that statute can bear).

131. *See* Scalia, *supra* note 129, at 23.

132. *See* William N. Eskridge, Jr., *The New Textualism*, 37 UCLA L. REV. 621, 669 (1990).

133. *Science Definition*, MERRIAM-WEBSTER DICTIONARY, http://www.merriam-webster.com/dictionary/science (last visited Oct. 31, 2012).

134. *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885, 3895 (2011).

135. *Id.*

136. *See, e.g.*, Scalia, *supra* note 129, at 23; Jonathan R. Siegel, *Textualism and Contextualism in Administrative Law*, 78 B.U. L. REV. 1023, 1026 (1998).

C. Intentionalism

Courts regularly use legislative history to clarify and articulate the meaning of a term in a statute.[137] In the case of vague terminology, Lawrence M. Solan argues, "When a statute is ambiguous, an interpretive effort is unavoidable."[138] Moreover, proponents of the use of intentionalism believe that legislative history is important because "[i]f the legislature is the primary lawmaker and courts are its agents, then requiring the courts to follow the legislature's intentions disciplines judges by inhibiting judicial lawmaking, and in so doing seems to further democracy by affirming the will of elected representatives."[139] Committee hearings, congressional reports, floor statements, and earlier versions of a bill provide evidence of the legislative process and congressional intent.[140] However, committee reports are the most widely utilized source of legislative history.[141] Justices avoid relying on floor statements cited in congressional reports and do not prefer to rely on floor statements alone, as these tend to reflect individualistic views.[142] Likewise, purely private understandings of legislators are not enforced through this method of analysis.[143] Public legislative records pertaining to the Food Safety and Modernization Act (the "Act") contain various references to the term "science-based" that can serve to help clarify the definition of this term.[144]

137. *See, e.g.*, NationsBank of N.C., N.A. v. Variable Annuity Life Ins. Co., 513 U.S. 251 (1995) (holding legislative history may indicate whether an agency's interpretation of a statute that is silent or ambiguous on the issue in question is reasonable for the purposes of *Chevron* deference); Reno v. Koray, 515 U.S. 50 (1995) (holding legislative history, particularly changes relating to the agency interpretation at issue, may be helpful in determining whether the agency's interpretation is plausible and entitled to deference); Clarke v. Sec. Indus. Ass'n, 479 U.S. 388 (1987) (holding legislative history may be indicative of the reasonableness of the agency's interpretation of a statute in determining whether that interpretation is entitled to deference).

138. Solan, *supra* note 11, at 485.

139. Eskridge & Frickey, *supra* note 11, at 326.

140. *See* Richard A. Posner, *Statutory Interpretation-in the Classroom and in the Courtroom*, 50 U. CHI. L. REV. 800, 819-20 (1983) (discussing a positive proposal on how to interpret statutes).

141. *See* Jane S. Schacter, *The Confounding Common Law Originalism in Recent Supreme Court Statutory Interpretation: Implications for the Legislative History Debate and Beyond*, 51 STAN. L. REV. 1, 15 (1998); *see also* ABNER J. MIKVA & ERIC LANE, AN INTRODUCTION TO STATUTORY INTERPRETATION AND THE LEGISLATIVE PROCESS 36 (1997).

142. *See* Schacter, *supra* note 141.

143. WILLIAM N. ESKRIDGE, JR., ET AL., LEGISLATION AND STATUTORY INTERPRETATION 296-97 (2000) (stating that it is "rare" for federal judges to make determinations based on information that is not publicly accessible).

144. *See* hearings cited *infra* notes 147, 149, 151.

First, various congressional records use the term "science-based" while referring to the Hazard Analysis and Critical Control Point (HACCP) methodology. HACCP is a risk control mechanism currently used both by the U.S. Department of Agriculture (USDA) to regulate meat production facilities and by the FDA to regulate seafood and juice production facilities.[145] In a hearing on April 2, 2009, before the Committee on Agriculture in the U.S. House of Representatives, Chandler Keys, representing JBS USA LLC,[146] described his own company's procedures after stating that he would assist Congress in establishing "science-based" measures.[147] The procedures used by JBS reflect risk assessment mechanisms as outlined in HACCP.[148] In an April 23, 2009 House hearing, James O. Regan of the National Cattlemen's Beef Association used "science-based" in reference to intervention and management strategies, stating "utilizing science-based principles and validating interventions used throughout the [beef production] process effectively controls the associated risks of E. coli."[149] These "science-based principles" are the same methods outlined in HACCP. At another House hearing on July 16, 2009, Robert G. Reinhard of the Sara Lee Corporation[150] plainly stated, "HACCP is a science-based proven food safety system that has enhanced the safety of the meat and poultry products produced in the United States."[151] Various references to "science-based" methods throughout food safety committee hearings refer to the methods used by HACCP, so a further examination of this methodology will clarify the meaning of this term.

145. Hazard Analysis and Critical Control Point (HACCP) Systems, 21 C.F.R. § 120.1 (2001).

146. JBS USA LLC is a large meat processing company. Visit the JBS website at http://www.jbssa.com.

147. *Hearing to Review Current Food Safety Systems: Hearing Before the H. Comm. on Agric.*, 111th Cong. 4 (2009) [hereinafter *April 2 Hearing*] (testimony of Chandler Keys, Head of Gov't Affairs & Indus. Relations, JBS USA LLC).

148. *Food Safety*, JBS, http://www.jbssa.com/Responsibility/FoodSafety/default.aspx (last visited Oct. 31, 2012).

149. *Hearing to Review Federal Food Safety Systems at the Department of Agriculture: Hearing Before the Subcomm. on Livestock, Dairy, & Poultry of the H. Comm. on Agric.*, 111th Cong. 34 (2009) [hereinafter *April 23 Hearing*] (testimony of James O. Regan, Senior Vice President of Research, Educ., & Innovation, Nat'l Cattlemen's Beef Assoc.).

150. Sara Lee is a food and beverage production company. *See* SARA LEE, http://www.saralee.com/ (last visited Oct. 31, 2012).

151. *Hearing to Review Current Issues in Food Safety: Hearing Before the H. Comm. on Agric.*, 111th Cong. 51 (2009) [hereinafter *July 16 Hearing*] (testimony of Robert G. Reinhard, Dir. of Food Safety & Regulatory Affs., Sara Lee Corp.).

HACCP methodology outlines a "systematic approach to the identification, evaluation, and control of food safety hazards."[152] Pillsbury and NASA jointly developed HACCP in the 1960s in a project aimed at keeping astronaut's food pathogen-free.[153] This program attempted to identify the processing points where food safety risks could be reduced to the greatest extent possible, much like the requirements of the FDA Food Safety Modernization Act.[154] According to the HACCP Principles and Application Guidelines:

> [T]he major infusion of science in a HACCP system centers on proper identification of the hazards, critical control points, critical limits, and instituting proper verification procedures. These processes should take place during the development and implementation of the HACCP plans and maintenance of the HACCP system.[155]

To be science-based, HACCP plans include "(1) expert advice and scientific studies and (2) in-plant observations, measurements, and evaluations."[156] For example, in the meat industry, "validation of the cooking process for beef patties should include times and temperatures needed to obtain an appropriate destruction of pathogenic microorganisms (i.e., enteric pathogens) and studies to confirm that the conditions of cooking will deliver the required time and temperature to each beef patty."[157]

Although HACCP standards play a role in clarifying the term "science-based," differences between this methodology and the regulations that the FDA will need to promulgate should be considered. HACCP has been widely successful in the meat industry; however, meat facilities produce a limited set of distinct products, as opposed to the wide variety of different products and facilities that the FDA will soon

152. U.S. FOOD & DRUG ADMIN., HAZARD ANALYSIS AND CRITICAL CONTROL POINT PRINCIPLES AND APPLICATION GUIDELINES (1997), *available at* http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm.

153. *See* William H. Serber & Richard F. Stier, *Happy 50th Birthday to HACCP: Retrospective and Prospective*, FOOD SAFETY MAG. (Jan. 2009), *available at* http://www.foodsafetymagazine.com/article.asp?id=3481.

154. *Id.* (stating that the seven principles that guide HACCP to eliminate food safety risks today are: (1) conduct a hazard analysis; (2) determine the CCPs; (3) establish critical limit(s); (4) establish a system to monitor control of the CCPs; (5) establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control; (6) establish procedures for verification to confirm that the HACCP system is working effectively; and (7) establish documentation concerning all procedures and records appropriate to these principles and their application).

155. U.S. FOOD & DRUG ADMIN., *supra* note 152.

156. *Id.*

157. *Id.*

regulate.[158] All meat production facilities use similar procedures and face similar risks, and therefore follow similar HACCP programs.[159] Meanwhile, the regulations under the Food Safety Modernization Act must operate in food facilities of all types and sizes.[160] While the HACCP methodology does not provide solutions for all aspects of food regulation, it is one process that could qualify as "science-based."

The term "science-based" also surfaces often in reference to the Food Safety and Inspection Service (FSIS).[161] The FSIS is a public health agency of the USDA responsible for overseeing the safe production of meat, poultry, and eggs.[162] In a House Agriculture Committee hearing on July 16, 2009, Patrick Boyle, President and CEO of the American Meat Institute, stated:

> FSIS assures processes are scientifically validated. Teams of expert auditors conduct periodic in-depth food safety assessments which can take days or weeks to complete and may involve extensive microbiological sampling of the plant's environment and finished products. Annually, FSIS conducts more than 8,000 microbiological tests to verify the production processes are under control. This is in addition to the several million microbiological tests that industry conducts each year.[163]

Later in the same hearing, Robert Reinhard of the Sara Lee Corporation described FSIS as a "modern science-based inspection service."[164] Further discussion of FSIS at an April 23, 2009 Agriculture Committee hearing reveals an emphasis on empirical science-based data collection, free from subjective influence.[165] FSIS administrator Alfred V. Almanza addressed the importance of uniformity in data collection, explaining:

> [T]he [Enforcement Investigation Analysis Officers (EIAOs)], they are all trained in the same manner. In fact, we just had a new enhanced training session for our EIAOs to be able to do it in a very uniform manner, whether it be in Virginia or whether it be clear

158. *See* Stevens, *supra* note 104.

159. U.S. FOOD & DRUG ADMIN., *supra* note 152.

160. *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.).

161. *See supra* notes 147, 149, 151.

162. *See* FOOD SAFETY & INSPECTION SERV., http://www.fsis.usda.gov/ (last visited Nov. 1, 2012).

163. *July 16 Hearing*, *supra* note 151, at 16 (testimony of Patrick Boyle, President and CEO, Am. Meat Inst.).

164. *July 16 Hearing*, *supra* note 151, at 48 (testimony of Robert G. Reinhard, Dir. of Food Safety & Regulatory Affs., Sara Lee Corp.).

165. *April 23 Hearing*, *supra* note 149, at 20 (testimony of Alfred V. Almanza, Admin., Food Safety & Inspection Serv.).

> across the country in California. We want a uniform way of food safety.[166]

"Science-based" terminology is found in reference to the FSIS throughout food safety legislative history, and analysis of the science methods used by this agency provides further insight to the term.

The FSIS is "the public health regulatory agency responsible for ensuring that domestic and imported meat, poultry and processed egg products are safe, wholesome and correctly labeled and packaged."[167] FSIS relies heavily on data collection to detect and respond to food contamination hazards.[168] FSIS methodology involves a data analytics technique called the Public Health Information System, a web-based application establishing an automated data-driven inspection system.[169] This system allows "analysts to identify trends that will automatically adjust domestic and import inspections and sampling, such as the relationship between *Salmonella* test results and inspection findings, notifying field and headquarters personnel about potential public health threats."[170] The reference to FSIS methodology using the term "science-based" in the legislative history suggests that data usage is an important aspect of this term.

Another use of the term "science-based" in the legislative history appears in reference to the importance of maintaining sufficient infrastructure to establish the proper "science-based" standards.[171] On April 23, 2009, Professor Michael Taylor testified:

> [A]s documented by the FDA Science Board, a group of independent experts from outside FDA, FDA's science base for food safety has eroded over the years; it has miniscule resources for applied food safety research; and it lacks the modern information systems that are essential to implementation of a science-based and preventive food safety program.[172]

As noted by Professor Taylor, the FDA Science Board issued a report stating that the FDA "does not have sufficiently extensive collaboration

166. *Id.*

167. Press Release, USDA Food Safety & Inspection Serv., Food Safety and Inspection Service's Public Health Information System (Sept. 3, 2010).

168. *Id.*

169. *Id.*

170. *Id.*

171. *See Keeping America's Families Safe: Reforming the Food Safety System: Hearing Before the S. Comm. on Health, Educ., Labor, & Pensions*, 111st Cong. 75 (2009) [hereinafter *October 22 Hearing*] (testimony of Kraig R. Naasz, President and CEO, Am. Food Inst.).

172. *April 23 Hearing*, *supra* note 149, at 53 (testimony of Michael R. Taylor, Research Prof., Dep't of Health Policy at George Washington Univ. Sch. of Pub. Health & Health Servs.).

with external scientists, thus limiting infusion of new knowledge and missing opportunities to leverage resources."[173] The report also noted that the FDA "has insufficient access to data and cannot effectively regulate products based on new science due to lack of a supportive IT infrastructure."[174] As Kraig Naasz, President and CEO of the American Frozen Food Institute stated in an October 22, 2009 Senate Committee hearing, "The single step that could most dramatically improve FDA's effectiveness in scrutinizing the safety of food imports would be to provide the agency modern information technology capabilities."[175] The emphasis in the legislative history on employing proper infrastructure to establish "science-based" standards further refines the meaning of this term.

Another possible meaning for the term "science-based," as described in the legislative history, could be FDA use of modern information technology and partnership formation with external scientists.[176] Collaboration with scientists outside of the FDA would ensure that the science employed would be the most current technologies available.[177] Up-to-date scientific data is key for standards promulgated under the Food Safety and Modernization Act,[178] and partnerships with other agencies, academia, and industry would help ensure that these standards are "science-based."[179] In addition, access and organization of data is crucial to establishing "science-based" principles, and adequate information technology is critical in reaching this objective.[180] Legislators' discussions of the importance of modern information technology, data analysis, and hazard analysis risk assessment in the context of "science-based" regulations suggest that these methods are important components of "science-based" regulations.

173. FDA SCIENCE BOARD, FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY 44 (2007).

174. *Id*.

175. *October 22 Hearing*, *supra* note 171, at 75 (testimony of Kraig R. Naasz, President and CEO, Am. Food Inst.).

176. *Id*.

177. FDA SCIENCE BOARD, *supra* note 173, at 44.

178. The Food Safety and Modernization Act requires preventative controls be "consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis." FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885, 3896 (2011).

179. FDA SCIENCE BOARD, *supra* note 173, at 44.

180. *Id.* at 49.

D. Purposivism

Finally, an analysis of the Food Safety and Modernization Act's purpose can further clarify the meaning of the term "science-based."[181] This method of statutory interpretation involves "decid[ing] what purpose ought to be attributed to the statute and to any subordinate provision of it which may be involved" and "interpret[ing] the words of the statute immediately in question so as to carry out the purpose as best it can."[182] Purposivism seeks to advance legislative preferences and goals to carry out the legislature's objective.[183] Discussion of the legislature's purpose differs from an analysis of the legislature's intent in that "intent" refers to the legislature's specific understanding of what it meant in a particular circumstance, whereas purpose reflects what the legislature ultimately sought to accomplish.[184] Examining "science-based" in light of Congress's purpose in passing the Food Safety Modernization Act will provide further clarification of this text.

Over the course of the legislative history of the Food Safety Modernization Act (the "Act"), the nature of the globalized food market arose in discussion. In the Senate Committee on Health, Education, Labor, and Pensions hearing on food safety, Committee Chairman Tom Harkin noted:

> Over the last 100 years, our meals have gotten more complex in this world. They include more varied ingredients, so they're subject to more diverse methods of processing and preparation. Today, raw agricultural products travel thousands of miles, from farms to processors to factories to the table. They're routinely processed and mixed along the way. In addition, we rely more and more on foods imported from abroad.[185]

At the House Subcommittee on Livestock, Dairy, and Poultry hearing, Jill Appell of the National Pork Producers Council further stated, "The U.S. pork industry today provides about 20 billion pounds of safe,

181. *See* Ragsdale v. Wolverine World Wide, Inc., 535 U.S. 81 (2002) (striking down a Labor Department regulation for imposing a penalty that was against the remedial intent of Congress in enacting the controlling legislation).

182. HENRY HART & ALBERT SACKS, THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW 1374 (William N. Eskridge, Jr. & Philip P. Frickey eds., 1994).

183. Michael Herz, *Purposivism and Institutional Competence in Statutory Interpretation*, 2009 MICH. ST. L. REV. 89, 92 (2009).

184. *Id.* at 93.

185. *October 22 Hearing*, *supra* note 171, at 6 (testimony of Sen. Tom Harkin, D-IA, Chairman, S. Comm. on Health, Educ., Labor, & Pensions).

wholesome and nutritious meat protein to consumers worldwide."[186] Given today's globalized food market, the purpose of the Act likely considered food safety in the United States as a part of the international economy.[187] The World Trade Organization (WTO) establishes a range of international food safety standards.[188] Although scarcely mentioned in the legislative history,[189] ignoring WTO standards would undermine the purpose of the Act, as the United States could face a WTO dispute if it violates WTO agreements.

The Sanitary and Phytosanitary Agreement (the "Agreement") of the WTO requires the scientific justification of regulatory measures based on a risk assessment.[190] Article 5, Section 2 of the Agreement states, "In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; [and] relevant inspection, sampling and testing methods."[191] Article 2, Section 2 of the Agreement further emphasizes that sanitary measures are not to be "maintained without sufficient scientific evidence."[192] The purpose of establishing food safety recognizes the United States position on an international level, so "science-based" regulations that reflect the methods established by the Agreement would likely fulfill the legislature's purpose.

IV. CONCLUSION

As the FDA works to promulgate "science-based" regulations, it must ensure that the methods it establishes fall within the meaning of that term in accordance with the Food Safety Modernization Act (the "Act"). As argued in this Comment, this task proves more difficult than it might first appear. Like any broad legislative terminology, the term "science-based" could expose the FDA regulations to challenge in court by disgruntled food production companies or public health advocates.

186. *April 23 Hearing*, *supra* note 149, at 37 (testimony of Jill Appell, former President, Nat'l Pork Prod. Council).

187. *Id.*

188. Committee on Sanitary and Phytosanitary Measures, *Note by the Secretariat: Specific Trade Concerns*, G/SPS/GEN/204/Rev.11/Corr.1 (*adopted* June 1, 2011).

189. The only mention of the WTO in the legislative history occurred in two committee meetings, though neither of these meetings discussed the WTO in detail. *See April 2 Hearing*, *supra* note 147, at 41; *October 22 Hearing*, *supra* note 171, at 74.

190. Agreement of the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, 1867 U.N.T.S. 493 [hereinafter Phytosanitary Measures]; *see also* Jacqueline Peel, *Risk Regulation Under the WTO SPS Agreement: Science as an International Normative Yardstick?*, at 2 (The Jean Monnet Program, Working Paper No. 1087-2221, 2004).

191. Phytosanitary Measures, *supra* note 190, at 70.

192. *Id.* at 71.

While many canons of statutory interpretation and theories of agency deference could factor into scrutiny of such challenges, three commonly used methods of analysis demonstrate varying aspects of the meaning of the text in this instance. The textualist perspective displays the complex nature of the problem posed by a term with such broad meaning.[193] An intentionalist analysis aids in identifying specific factors the legislature considered while discussing the meaning of the text, including HACCP risk assessments, FSIS data analysis mechanisms, and the importance of modern information technology.[194] The purposivist view considers the underlying objectives of the legislature, including the United States' position as an actor in the international food market.[195]

Upon promulgation of the final regulation and subsequent challenge in court, further study of the legislative history and underlying purpose of the Act will present additional insight into the meaning of "science-based" regulations. The analysis can then be tailored specifically to the nature of the challenge. Not all judges give equal weight to these three methods of interpretation. Some, including Justice Scalia, favor one method so strongly that they refuse to use any of the others.[196] However, strong arguments lie in each approach and all help provide a more meaningful connotation to the term "science-based." The varying techniques of textualism, intentionalism, and purposivism each provide a clearer meaning of the term "science-based," presenting important considerations for future analysis.

193. *See supra* Part III.B.
194. *See supra* Part III.C.
195. *See supra* Part III.D.
196. *See* Scalia, *supra* note 129, at 23.