ARE YOU REALLY GOING TO EAT THAT? PRODUCT TRACING, THE FOOD SAFETY MODERNIZATION ACT, AND THE PROMISE OF RFID

*Colin Mieling**

TABLE OF CONTENTS

I. INTRODUCTION

Nearly every day the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) quietly issue notices about hazards posed by a variety of foodstuffs.[1] According to the Center for Disease Control and Prevention's (CDC's) estimates for 2011, roughly 48 million people are sickened by foodborne disease each year.[2] Of these individuals, 128,000 are hospitalized and 3,000 die as a result of the foodborne illnesses.[3] One recent estimate of the total costs of foodborne illness in the United States placed it at roughly $152 billion per year.[4] A study of domestic foodborne illness between 1998 and 2008 found that 51.1% of all outbreaks were attributable to plants as a commodity group, 13.8% were related to dairy products, and 6% were associated with eggs.[5] Over the past few years there has been an increased recognition of the need for a more comprehensive and effective product tracing system.[6] Despite the heightened awareness of the problem, there has traditionally been limited regulatory movement in this area since the enactment of the Food, Drug, and Cosmetic Act (FDCA). However, the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act of 2002)[7] and the more recent FDA Food Safety Modernization Act (FSMA) have fundamentally changed this by mandating the enhanced

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1. *See, e.g.*, *Recalls & Alerts*, FOODSAFETY.GOV, http://www.foodsafety.gov/recalls/index.html (last visited Mar. 8, 2014) (indicating recent recall efforts).

2. *CDC 2011 Estimates: Findings*, CENTER FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html (last updated Jan. 8, 2014).

3. *Id.*

4. ROBERT L. SCHARFF, HEALTH-RELATED COSTS FROM FOODBORNE ILLNESS IN THE UNITED STATES 1 (2010), *available at* http://www.publichealth.lacounty.gov/eh/docs/ReportPublication/HlthRelatedCostsFromFoodborneIllnessUS.pdf.

5. John A. Painter et al., *Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by Using Outbreak Data, United States, 1998–2008*, 19 EMERGING INFECTIOUS DISEASES 407, 410 tbl. 1 (2013).

6. *See Hearing to Review the Legal and Technological Capacity for Full Traceability in Fresh Produce: Hearing Before the Subcomm. on Horticulture and Organic Agriculture of H. Comm. on Agriculture*, 110th Cong. 24 (2008) (statement of Dr. David Acheson, Associate Commissioner for Food Protection of the FDA) ("The ability to trace pathways of any food, including tomatoes and other fresh produce, through every point in the supply chain is crucial for limiting foodborne illness in an outbreak, for preventing future outbreaks, and for reducing the impact on the segments of the industry whose products were not associated with the illnesses. The pathways that fresh produce travels from field to consumer have become increasingly complex, with items sometimes changing hands many times in the supply chain."). *See generally* JENNIFER C. MCENTIRE, INST. FOOD TECHNOLOGISTS, TRACING SYSTEMS: AN EXERCISE EXPLORING DATA NEEDS AND DESIGN 24 (2009) (providing the results of an FDA request to examine trace-back and trace-forward data systems to assist with more rapid tracing and recall efforts).

7. 21 U.S.C. § 350c(b) (2012) (requiring the retention of records of "persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food . . .").

tracing and tracking of foods.[8]

This Note seeks to evaluate the promise and limitations of one of the tracing technologies: the Radiofrequency Identification (RFID) Tag.[9] Although there has been some analysis of the legal aspects of the application of RFID technology in livestock herds,[10] there has been surprisingly little consideration of this technology's application in tracing FDA-regulated foods. In a recent report detailing the results of pilot product tracing projects conducted under section 204(a) of the FSMA,[11] the government contractor—the Institute of Food Technologists (IFT)—acknowledged that it did not test the viability of RFID networks for enhancing product tracing within the pilot projects.[12]

This Note also examines how RFID technology could be applied within the existing national and international food safety regulatory regime to aid in the product tracing of FDA regulated foodstuffs. It begins by examining the national and international regulation of non-meat foods with particular emphasis on the statutes associated with product tracing. It then discusses the current applications of RFID technology and what is required to effectively apply this tool within a supply chain. From there, it explores the challenges and risks in creating a uniform RFID-based tracing regime in the food safety arena. It concludes by setting forth a series of recommendations to establish an effective RFID-based tracing system that would meet the requirements of the FSMA's product tracing mandate while enhancing consumer safety.

Though there is no technological silver bullet to ensure safe and traceable foods throughout the supply chain, technology can play a vital role in mitigating potential harms. RFID technologies represent an increasingly cheap and effective means through which to improve the safety of the global food supply and effectuate the product tracing requirements of the FSMA.

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8. *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 204, 124 Stat. 3885, 3930–37 (2011) (to be codified throughout 21 U.S.C.) (detailing requirements for developing an effective tracing and tracking infrastructure for the FDA).

9. Under the FSMA, the Secretary of Health and Human Services is required to evaluate existing product tracing technologies and assess their overall feasibility to meet the needs of the FDA. FDA Food Safety Modernization Act § 204(b).

10. *See* Margaret Rosso Grossman, *Animal Identification and Traceability Under the US National Animal Identification System*, 2 J. FOOD L. & POL'Y 231, 315 (2006) (indicating that some producers are concerned about the use of RFID technology to assist in the collection of data for the NAIS); Matthew E. Rohrbaugh, Note, *It's Eleven O'Clock, Do You Know Where Your Chicken Is? The Controversy Surrounding the National Animal Identification System and Its Application to Small and Organic Farmers*, 32 VT. L. REV. 407, 422 (2007) (discussing how the draft standards of the National Animal Identification System (NAIS) raise the concerns of some privacy advocates).

11. FDA Food Safety Modernization Act § 204(a).

12. *See* INST. FOOD TECHNOLOGISTS, FREQUENTLY ASKED QUESTIONS ABOUT THE PRODUCT TRACING PILOT 3 (2013), *available at* http://www.ift.org/~/media/ Knowledge%20Center/Focus%20Areas/Traceability/ IFT_FDA_ProductTracingPilotsFAQ.pdf ("IFT is aware that several in the private sector and academic community are exploring RFID, and felt that tests of this nature were better conducted by those operating with more generous timeframes."); *see also* JENNIFER MCENTIRE & TEJAS BHATT, INST. FOOD TECHNOLOGISTS, PILOT PROJECTS FOR IMPROVING PRODUCT TRACING ALONG THE FOOD SUPPLY SYSTEM – FINAL REPORT 48 (2012), *available at* http://www.fda.gov/downloads/Food/ GuidanceRegulation/UCM341810.pdf ("RFID technology was suggested by several (trade associations, technology providers, and consultants) who favored electronic records . . . . The idea that things should be tested to reflect the reality of the industry was common among those open to any kind of record being used.").

Although this technology has not been widely adopted in the food supply chain for a variety of reasons, it has considerable potential to meet the needs of a global supply chain over the long term. This Note argues that RFID technologies can be effectively applied in a manner that benefits both consumers and producers while carrying out the mandates of the FSMA.

II. BACKGROUND

A. A Brief Overview of Food Safety Regulation in America

It is a significant understatement to say that the regulation of foodstuffs in the United States is highly convoluted.[13] At present, fifteen agencies oversee the regulation of food on the federal level.[14] The two primary food safety agencies are the USDA and the FDA.[15] Roughly ten to twenty percent of the nation's food supply is under the USDA's jurisdiction, while the FDA regulates the vast majority of the remainder.[16] Numerous commentators and government officials have discussed the overlapping mandates and fragmented nature of the food safety regulatory regime at length.[17] In order to fully understand the challenges presented in the creation of an effective traceability regime, it is vital to have context for the problem. What follows is a brief overview of the existing state of food safety regulation in the United States.

Unlike many other countries, the United States stubbornly maintains a highly fragmented food safety regime spread out over a variety of agencies.[18] In general, the USDA and the FDA—which is under the aegis of the Department of Health and Human Services (HHS)—are primarily responsible for overseeing the safety of foods in the United States.[19] The fragmentary nature of the U.S. food safety regime is reflected in the seeming lack of

13. A recent Congressional Research Service publication contains one of the most concise and comprehensive overviews of the existing federal food safety regime. *See generally* RENÉE JOHNSON, CONG. RESEARCH SERV., RS 22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER (2012) (providing an overview to the fragmented nature of the food safety regulatory landscape).

14. *Id.* at 1.

15. The GAO has been very critical of the fragmented state of the federal food safety regime and notes that recent changes such as the FSMA have not altered this aspect. *Revamping Federal Oversight of Food Safety*, U.S. GOV'T ACCOUNTABILITY OFFICE, http://www.gao.gov/highrisk/revamping_food_safety/why_did_study (last visited Mar. 8, 2014).

16. JOHNSON, *supra* note 13, at 1.

17. There have been countless discussions of the challenges of consolidating the domestic food safety regime. *See, e.g.*, Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 FOOD & DRUG L.J. 681, 724 (1998) (discussing the proposed Safe Food Act of 1997, which would have consolidated food safety regulation into a single regulatory organization); Richard J. Durbin, *Food Safety Oversight for the 21st Century: The Creation of a Single, Independent Federal Food Safety Agency*, 59 FOOD & DRUG L.J. 383, 385 (2004) (arguing that a single regulatory agency tasked with overseeing food safety would reduce the impact of food-related illnesses); Megan Danko, Note, *Protecting Our Food: A Critical Look at the National Uniformity for Food Act of 2004 and Food Safety in America*, 17 LOY. CONSUMER L. REV. 253, 277 (2005) (discussing how various congressional efforts to consider aspects of the food system are convoluted).

18. *See* JOHNSON, *supra* note 13, at 1–6 (describing each agency's role in food safety).

19. 21 U.S.C. § 393(b)(2) (2012); *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-05-212, FOOD SAFETY: EXPERIENCES OF SEVEN COUNTRIES IN CONSOLIDATING THEIR FOOD SAFETY SYSTEMS 7 (2005) (summarizing the general structure of the domestic food safety infrastructure).

comprehensive food safety regulations.[20] However, Congress finally passed the most sweeping reform to food safety regulation in over seventy years after a series of major outbreaks[21] and increased pressure from consumers.[22] Rather than delve into the minutiae of administrative organizational design and conflicting mandates, this Part aims to provide a general overview of the regulation of FDA-regulated foods with an enhanced emphasis on the product tracing requirements associated therein.

1. The Early History of FDA-Related Food Safety Legislation

The regulation of the overall safety of non-meat foodstuffs in the United States has developed in fits and starts. On May 15, 1862, President Lincoln signed a bill that established the Department of Agriculture (DOA).[23]

In Section Four of the Act, the Secretary was empowered to "employ other persons, for such time as their services may be needed, including *chemists*, botanists, entomologists, and other persons skilled in the natural sciences pertaining to agriculture."[24] The Chemical Division of the USDA was the earliest predecessor to the FDA.[25] Between 1862 and 1905, a handful of specialized food safety statutes[26] were passed, but no comprehensive food safety legislation came forth. After considerable pressure, President Theodore

20. *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-289, FEDERAL FOOD SAFETY OVERSIGHT 1–2 (2011) (noting that the fragmented food safety system leads to inefficient allocation of resources, inconsistent outcomes, and overlapping rulemaking). The inefficiency of the current food safety infrastructure is captured nicely by an interactive Food Integrity Campaign website that highlights some of the overlapping regulatory mandates. *Regulatory Chaos at the Dinner Table*, FOOD INTEGRITY CAMPAIGN, http://www.foodwhistleblower.org/learn-more/regulatory-chaos-at-the-dinner-table (last visited Mar. 8, 2014). This infrastructure problem has been noted by a number of parties to little avail. *See* Brian Naylor, *U.S. Considers Overhaul of Food Safety System*, NPR (Feb. 25, 2009), http://www.npr.org/templates/story/story.php?storyId=100830170 (discussing the overlapping regulatory mandates by highlighting how frozen pizzas are regulated by the FDA or USDA depending on their toppings); *see also* Editorial, *Which Came First, the USDA or FDA?*, L.A. TIMES (Sept. 11, 2010), http://articles.latimes.com/2010/sep/11/opinion/la-ed-eggs-20100911 (discussing regulatory overlap by highlighting how the USDA is responsible for food safety of chicken but the FDA is responsible for the safety of eggs in the shell).

21. In a 2010 salmonella enteritidis outbreak, Wright County Egg recalled over 500 million eggs, which were associated with over 1,500 incidents of illness. Gardiner Harris, *Egg Producer Says His Business Grew Too Quickly*, N.Y. TIMES (Sept. 22, 2010), http://www.nytimes.com/2010/09/23/business/23eggs.html?_r=0. A 2009 outbreak that helped spur federal action on food safety involved peanut products produced by the Peanut Corporation of America that were contaminated with salmonella typhirium. *FDA's Investigation*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Safety/Recalls/MajorProductRecalls/Peanut/FDA%E2%80%99sInvestigation/default.htm (last updated June 6, 2009). The peanut outbreak led to the recall of over 2,100 products manufactured by more than 200 companies that had peanut-based ingredients. *Id.*

22. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (to be codified throughout 21 U.S.C.).

23. Act of May 15, 1862, ch. 72, § 1, 12 Stat. 387, 387 (now codified in 7 U.S.C. §§ 2201 *et seq.* (2012)).

24. *An Act to Establish a Department of Agriculture*, NAT'L AGRIC. LIBR., http://www.nal.usda.gov/act-establish-department-agriculture (last visited Mar. 8, 2014) (emphasis added).

25. *Significant Dates in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm (last updated Nov. 6, 2012).

26. *See, e.g.*, Oleomargarine Act of 1886, ch. 840, 24 Stat. 209, 209 *amended by* Oleomargarine Act of 1902, ch. 784, 32 Stat. 193, 193 (defining "butter" and imposing special taxes on margarine); Tea Act of 1898, Ch. 358, 29 Stat. 604, 604, *repealed by* Pub. L. No. 104-128, 110 Stat. at 1198 (1996) (setting standards for importation of tea).

Roosevelt signed the Food and Drugs Act[27] as well as the Federal Meat Inspection Act (FMIA)[28] into law on June 30, 1906.

2. The Food and Drugs Act

The impact of the Food and Drugs Act on the wholesomeness of foods in interstate commerce was limited due to structural problems with the legislation. Although the statute permitted seizure of adulterated or misbranded foods, federal condemnation of these foods could only occur while the products were in transit or if the goods were contained in unbroken packaging.[29] To make matters worse, mislabeled products could be relabeled prior to their seizure to correct any deficiencies.[30] The impact of the statute was also hindered by the fact that regulations could only be established through joint action by the secretaries of the Treasury, Agriculture, and Commerce.[31] More problematic, however, was the complete lack of uniform standards for food[32] and how the Act did not directly authorize the agencies to develop definitions and standards for food identity.[33]

The Food and Drugs Act's limitations were apparent early on as evidenced by key amendments made shortly after its passage.[34] In 1927, the USDA Bureau of Chemistry was rebranded as the Food, Drug, and Insecticide Administration before being renamed in 1930 as the FDA.[35] After years of criticism of the Food and Drugs Act's limited effectiveness, a group of legislators and academics started drafting proposed revisions in March 1933.[36] The first draft of what would eventually become the FDCA was introduced in the Senate in June 1933.[37] After considerable opposition and numerous revisions to the legislation, the amended bill was signed into law on June 25, 1938.[38]

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27. Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, 768, *repealed by* 21 U.S.C. § 329(a) (1938).

28. Federal Meat Inspection Act of 1906, 34 Stat. 674, 674, *amended by* Pub. L. No. 59-242, 34 Stat. 1260 (1967) (codified at 21 U.S.C. §§ 601 *et seq*. (2006)).

29. 1 JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 3.03 (1976). *See generally* Frederic P. Lee, *The Enforcement Provisions of the Food, Drug, and Cosmetic Act*, 6 LAW & CONTEMP. PROBS. 70 (1939) (describing the enforcement provisions of the Food, Drug, and Cosmetic Act).

30. Lee, *supra* note 29, at 79.

31. Lauffer T. Hayes & Frank J. Ruff, *Administration of the Federal Food and Drugs Act*, 1 LAW & CONTEMP. PROBS. 16, 20 (1939).

32. O'REILLY, *supra* note 29, § 3.03.

33. 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).

34. *See, e.g.*, "Net Weight" Amendment, Pub. L. No. 62-419, 37 Stat. 732 (1913) (requiring disclosure of quantity of packaged foods); Pub. L. No. 66-22, 41 Stat. 234, 271 (1919) (expanding the "Net Weight" Amendment to cover wrapped meats); McNary-Mapes Amendment, Pub. L. No. 71-538, 46 Stat. 1019, 1019–20 (1930) (authorizing the Secretary of Agriculture to standardize regulations for quality and fill of any canned food as well as the labeling requirements for substandard foods).

35. O'REILLY, *supra* note 29, § 3.03.

36. Cavers, *supra* note 33, at 6.

37. O'REILLY, *supra* note 29, § 3.04.

38. Cavers, *supra* note 33, at 6–20.

3. The Food, Drug, and Cosmetic Act of 1938

The FDCA greatly expanded the power of the federal government to regulate the wholesomeness of foods within interstate commerce. Among the changes to earlier legislation, the FDCA empowered the Secretary to: (1) set tolerances for unavoidable poisonous substances in food,[39] (2) establish standards of identity, quality, and fill of container for foods,[40] (3) conduct inspections of manufacturing facilities,[41] (4) use injunctive powers to aid in the seizure of adulterated or misbranded goods,[42] and (5) establish standardized labeling requirements.[43] One key aspect of the passage of the FDCA was that the focus of federal food safety regulation effectively moved from the consumer level to the manufacturing side.[44]

Despite this seeming change in federal food safety regulation, the FDCA still left much to be desired in ensuring the safety of the domestic food supply. One glaring aspect of the FDCA's limitations was the FDA's lack of any form of mandatory recall authority for adulterated or misbranded items.[45] Rather than have the authority to compel recalls of offending products, the FDA's primary judicial remedy under the FDCA was seizure of the adulterated or misbranded products.[46] The finalized version of the 1938 Act limited the overall impact of FDA inspections by adding various caveats such as: (1) the right to inspect methods and processing of food production was removed from the FDA, (2) inspections were limited to *pertinent* items, and (3) inspections were limited to "reasonable times and within reasonable limits . . . ."[47] More problematic, however, was that the FDCA lacked any requirement that foods be traceable throughout the supply chain.

4. Minor Amendments and Adjustments to the FDCA

Over time, numerous amendments were made to the FDCA. In 1954, the Pesticide Chemicals Amendment was passed, which granted the FDA the authority to establish tolerances for various chemical pesticides and restrict the sale of foods that did not comply with these.[48] Similarly, the Food Additives Amendment of 1958 was added to grant the Secretary authority over novel food additives.[49] Later legislation included the Nutrition Labeling and

39. 21 U.S.C. § 346 (2012).
40. *Id.* §§ 341, 343.
41. *Id.* § 374.
42. *Id.* §§ 302, 332; *see also* Lee, *supra* note 29, at 85.
43. 21 U.S.C. § 343.
44. O'REILLY, *supra* note 29, § 9.10.
45. *See Developments in the Law: The Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 683 (1954) ("[T]he basic judicial sanction of the FDA is seizure.").
46. *Id.*
47. 21 U.S.C. § 374; *see also* O'REILLY, *supra* note 29, § 20.02 (describing some of the limitations placed on FDA inspectors).
48. 21 U.S.C. § 346a.
49. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (codified at 21 U.S.C. § 348). In some ways this amendment was unnecessary as the FDA already had authority to regulate *any* deleterious substance within food pursuant to 21 U.S.C. § 342. *See* O'REILLY, *supra* note 29, § 3:6 (discussing how the Food Additives Amendment is largely unnecessary).

Education Act of 1990, which altered the standards for whether a product under the FDA's purview would be considered misbranded.[50]

In 1997, Congress passed the FDA Modernization Act.[51] Despite the impressive-sounding name, the statute was a hodgepodge of legislative tinkering. The elements dealing with food safety matters were rather limited. A large portion of the food-related statutory changes dealt with the regulation of health and nutrient claims associated with various foods.[52] The only sections that directly tied to traditional food safety matters dealt with requirements for disclosing the use of irradiation,[53] a limit on the Secretary's authority to minimize the use of lead and cadmium in the enamel of glass and ceramic ware,[54] and various requirements associated with food contact surfaces.[55] Shortly after the passage of the FDA Modernization Act, there were numerous efforts to implement a more comprehensive update to the federal food safety system; no comprehensive legislation appeared until 2011 with the passage of the FSMA.

5. Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The BT Act of 2002 was the first major piece of legislation to address the issue of product tracing within the foods system.[56] Under Section 306 of the Act, the Secretary of HHS was permitted to establish recordkeeping requirements for "persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food . . . ."[57] The effect of this regulation was to require non-exempt parties to keep records relating to a particular food item both up and down the supply chain for at least one level.[58] Additionally, the BT Act of 2002 amended the FDCA to require "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary."[59]

While this requirement undoubtedly improved food safety to a certain degree, the limitations within the Act were apparent early on. First, the regulations promulgated under this section exempted large swathes of the food

50. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (amending 21 U.S.C. § 343).

51. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (amending 21 U.S.C. §§ 301 *et seq*.).

52. *See id.* §§ 301–05, 111 Stat. at 2350–53 (detailing health and nutrient content claims).

53. *Id.* § 306, 111 Stat. at 2353–56.

54. *Id.* § 308, 111 Stat. at 2353.

55. *Id.* § 309, 111 Stat. at 2354–56.

56. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

57. *Id.* § 306, 116 Stat. at 669.

58. *See* MCENTIRE & BHATT, *supra* note 12, at 232 (describing the "one-up/one-down" requirement of the BT Act of 2002).

59. Public Health Security and Bioterrorism Preparedness and Response Act § 305.

supply chain.[60] Second, by emphasizing the one-up/one-down approach to the supply chain, the Act failed to consider the need for recordkeeping associated with items that undergo numerous transformations or movements within a single entity.[61] Consequently, these oversights limited the overall effectiveness of the product-tracing requirements.

6. Food and Drug Administration Amendments Act of 2007

Among the numerous changes in the Food and Drug Administration Amendments Act of 2007 (FDAAA)[62] there are a series of provisions aimed at improving communication and enhancing product-tracing efforts. Central to this effort is the creation of an FDA-run "reportable food registry,"[63] which would require "responsible part[ies]"[64] to report "an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals."[65] The timeline established for reporting this information is "in no case later than 24 hours after a responsible party determines that an article of food is a reportable food . . . ."[66]

Reports to the reportable food registry require a significant amount of detailed information about the product.[67] This change increased the amount and quality of information consumers and regulators could obtain shortly after an outbreak.[68] Despite this improvement, the FDAAA largely retained the BT Act of 2002's limited one-up/one-down record-keeping requirement to aid in the product tracing of adulterated products.[69] This existing regulatory structure omits numerous elements of the supply chain and is largely incomplete when it comes to addressing the need for improved product tracing.

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60. *See* 21 C.F.R. § 1.327 (2006) (detailing which parties and producers are exempted from the one-up/one-down requirements).

61. Public Health Security and Bioterrorism Preparedness and Response Act § 306.

62. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823.

63. *Id.* § 1005, 121 Stat. at 964 (to be codified at 21 U.S.C. § 350f).

64. *Id.* § 1005(b), 121 Stat. at 965 (to be codified at 21 U.S.C. § 350f(a)(1)).

65. *Id.* (to be codified at 21 U.S.C. § 350f(a)(2)).

66. *Id.* (to be codified at 21 U.S.C. § 350f(b)(1)).

67. This includes—but is not limited to—(1) the registration number of the "responsible party"; (2) notice of when the product was determined to be reportable; (3) a description of the item with accompanying quantity information; (4) the quality and timeline of the suspected adulteration, (5) contact information of the responsible party; (6) identifying information, such as "product codes, use-by dates, and names of manufacturers, packers, or distributors sufficient to identify the article of food"; (7) contact information of related parties in the supply chain; (8) any information of where the product may have ended up; and (9) information about ongoing investigations into the nature of the adulteration. *Id.* § 1005(b), 121 Stat. at 967–68 (to be codified at 21 U.S.C. § 350f(e)). The FSMA broadened some of the reporting requirements of the reportable food registry by mandating that responsible parties submit descriptions of the reportable items in a manner so that consumers are able to identify the product. FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 211, 124 Stat. 3885, 3951–53 (2011) (to be codified at 21 U.S.C. § 350f(f)). However, "raw agricultural commodities" are exempted from this amendment. *Id.*

68. Food and Drug Administration Amendments Act § 1005(b).

69. *See id.* § 1005, 121 Stat. at 966 (to be codified at 21 U.S.C. § 350f(d)(6)(B)) (indicating that a responsible party may be required to submit information to the reportable food registry about the "previous source" of the food and the "immediate subsequent recipient").

7. The FDA Food Safety Modernization Act of 2011

The passage of the FDA Food Safety Modernization Act in 2011 was a watershed moment for consumers and food safety advocates. As the first comprehensive food safety redesign in over seventy years, the FSMA fundamentally changed certain elements of the existing food safety regime.[70] Though focused solely on the materials overseen by FDA,[71] the FSMA established numerous requirements for producers and granted the FDA enhanced authority to take a more proactive approach to food safety issues. One of the most fundamental changes to FDA authority was the power to initiate mandatory recalls of adulterated or misbranded foods.[72]

Broadly speaking, the FSMA has five key elements.[73] First, the FDA has been given a legislative mandate to initiate comprehensive and preventive measures to ensure the safety of domestic[74] and imported foods.[75] Second, the FSMA sets forth the standards associated with how frequently the FDA will inspect various kinds of producers.[76] Third, it empowered the FDA to more effectively regulate imported foodstuffs through various certification efforts.[77] Fourth, the FDA was given the authority to order a mandatory recall of adulterated or misbranded foodstuffs, if necessary.[78] Finally, the FSMA instructed the FDA to train various state and local food safety agencies to reduce the impact of foodborne illness.[79]

Apart from the domestic market, the FSMA fundamentally changed the requirements associated with imported foods. Section 301 of the FSMA details the necessary elements for the verification program for foreign suppliers.[80] Under the statute, importers are required to demonstrate that the foods in question are "produced in compliance with the requirements of section 418 or section 419, as appropriate; and [are] not adulterated under section 402 or misbranded under section 403(w)."[81] In a later section, the statute sets forth the elements for the "Voluntary Qualified Importer Program," which helps

70. It is important to note that the FSMA only impacted elements of the existing food safety regime that are regulated by the FDA. *See* FDA Food Safety Modernization Act, § 403, 124 Stat. at 3972 (codified throughout 21 U.S.C.) (describing the jurisdictional scope of the FSMA).

71. *See id.* (setting forth the jurisdictional limitations of the FSMA's reach).

72. *Id.* § 206, 124 Stat. at 3939–40 (granting the Secretary the power to initiate mandatory recalls).

73. These elements are framed as: (1) "preventive controls," (2) "inspection and compliance," (3) "imported food safety," (4) "response," and (5) "enhanced partnerships." *See Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm (last visited Feb. 27, 2014) (describing the impact of the FSMA and its scope).

74. *E.g.*, FDA Food Safety Modernization Act, § 103, 124 Stat. at 3890 (detailing hazard analysis and risked-based preventive controls (HAACP) requirements for producers, manufacturers, and processors).

75. *E.g.*, *id*. §§ 301–09, 124 Stat. at 3953–67 (creating new obligations such as prior notice, the registration of foreign facilities, and the verified qualified importer program to improve the safety of imported foods).

76. *See id.* § 201(a)(2), 124 Stat. at 3923–24 (setting out minimum standards for FDA inspection).

77. *See id.* §§ 301–04, 124 Stat. at 3953–58 (establishing various requirements for certifying foreign food suppliers).

78. *See id.* § 206, 124 Stat. at 3939–44 (establishing FDA's mandatory recall authority).

79. *Id.* § 209, 124 Stat. at 3945–48.

80. *Id.* § 301, 124 Stat. at 3953.

81. *Id.*

expedite the review of the importation of foodstuffs.[82] The Act also grants the Secretary the authority to require certification that the imported foodstuff in question complies with the requirements of the FSMA.[83] A subsequent section details the statutory requirements for the inspection of foreign facilities and permits the Secretary to refuse the admission of foodstuffs if the owner does not allow the facility to be inspected.[84] To assist with the import inspection regime, the Secretary is empowered to accredit third-party auditors—whether governmental or not—to conduct audits on behalf of the FDA.[85]

a. Product Tracing and the FSMA

The FSMA requires the Secretary of Health and Human Services to "establish . . . a product tracing system to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food that is in the United States or offered for import into the United States."[86] To achieve this, the Secretary was required to conduct one or more pilot projects modeled on recent outbreaks to: (1) demonstrate effective tracking and tracing methods, (2) evaluate existing tracking and tracing technologies, and (3) provide recommendations to aid in the development of effective product tracing requirements.[87] Additionally, per Section 204(b) of the FSMA, the Secretary was charged with assessing "the costs and benefits associated with the adoption and use of several product tracing technologies . . . ."[88]

Importantly, the same section requires that the Secretary use this pilot program to "develop and demonstrate appropriate technologies . . . that enhance the tracking and tracing of food . . . ."[89] Pursuant to the regulations, the Secretary is empowered to establish various recordkeeping requirements for "high-risk foods"[90] but shall "not prescribe specific technologies for the maintenance of records . . . ."[91] Similarly, in the section detailing the requirements for hazard analysis and risk-based preventive controls, the statute notes within the rules of construction that "[n]othing in this subsection shall be construed to provide the Secretary with the authority to prescribe specific technologies, practices, or critical controls for an individual facility."[92]

The FDA contracted with the Institute of Food Technologists (IFT) to

82. *Id.* § 302, 124 Stat. at 3955.
83. *Id.* § 303(b), 124 Stat. at 3956.
84. *Id.* § 306(a), 124 Stat. at 3959.
85. *Id.* § 307, 124 Stat. at 3959–60.
86. *Id.* § 204(c), 124 Stat. at 3931.
87. *Id.* § 204(a)(2), 124 Stat. at 3930 (detailing minimum requirements for the FDA's FSMA product-tracing pilot projects).
88. *Id.* § 204(b)(1)(A), 124 Stat. at 3930.
89. *Id.*
90. The term "high risk" is not defined in the FSMA and will ultimately be determined by the Secretary. A preliminary determination of whether a facility is considered high-risk was set forth in June 2012. *See FSMA Domestic Facility Risk Categorization (FY 2012),* U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm295345.htm (last updated July 23, 2013) (discussing categorization of facilities within the food production system).
91. 21 U.S.C. § 2223(d)(1)(C) (2012).
92. 21 U.S.C. § 350g(n)(4) (2012).

design and conduct the product-tracing pilots described in Section 204(a).[93] One key element of this process was to evaluate the feasibility of various existing product tracing technologies prior to the enactment of rulemaking associated with the requirements of Section 204.[94] On March 12, 2012, the FDA identified the pilot project foods as tomatoes, "frozen Kung Pao-style dishes," and "jarred peanut butter and dry, packaged peanut/spice."[95] In June 2012, the IFT submitted its final report on the tracing pilot studies to Congress, which subsequently approved the report in July.[96] The final report of the pilot tracing projects was released to the public on March 4, 2013.[97] While the report provided a number of recommendations to improve product tracing within the supply chain,[98] the authors acknowledged that their assessment of current technological solutions was limited.[99]

For all of the hoopla surrounding the FSMA, it has provided little guidance with regard to what are or should be the best practices associated with how to effectively maintain records or employ technologies that can increase the efficiency of recall and tracing efforts.[100] Given the myriad of technologies that could be employed to effectuate the requirements of the FSMA, it is difficult to say with any confidence what will emerge as the dominant food safety technology in the near term. However, certain existing technologies—like RFID—could be used more frequently as the demand for effective product tracing increases.

b. International Food Safety

In 1963, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) established the Codex Alimentarius Commission.[101] The Codex Alimentarius Commission was established to set "international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade."[102] The Codex Alimentarius serves as the food code for the global community and provides a means through which countries can harmonize their

93. *Product Tracing*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm270851.htm (last updated Feb. 3, 2014).

94. *Id.*

95. Sherri McGarry, *Rapid Tracing of Food Products Prevents Illness*, FDA TRANSPARENCY BLOG (Mar. 15, 2012), http://fdatransparencyblog.fda.gov/2012/03/15/rapid-tracing-of-food-products-prevents-illness/.

96. *Global Food Traceability Center*, IFT, http://www.ift.org/gftc.aspx (last visited Mar. 8, 2014).

97. *Product Tracing*, *supra* note 93.

98. *See* MCENTIRE & BHATT, *supra* note 12, at 203–14 (presenting ten recommendations to help increase the traceforward and traceback capabilities of the supply chain).

99. *See* INST. FOOD TECHNOLOGISTS, *supra* note 12, at 3 (describing how a number of existent technologies were not suitable for the initial pilot study and only nine providers were utilized).

100. *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 204, 124 Stat. 2885, 3930–31 (2011) (indicating that the Secretary must engage in at least one pilot project to evaluate feasibility of various tracing regimes and to establish within the FDA a product tracing system).

101. *CODEX Alimentarius: Home*, CODEX ALIMENTARIUS, http://www.codexalimentarius.org/codex-home/en/ (last updated Jan. 24, 2014).

102. *Id.*

various food standards.[103] Before standards are adopted, the Commission goes through a multistep process that allows for extensive feedback from member countries and other interested parties.[104] Although the standards by themselves are not binding,[105] countries are increasingly utilizing them to assist with issues of international trade. Pursuant to the World Trade Organization's Sanitary and Phytosantitary agreements, the standards of the Codex are often cited for reference.[106]

Despite the existence of the Codex Alimentarius, there is disturbingly little in the way of meaningful international product tracing. Only recently has the Commission started to set forth the general principles for what product tracing regimes should look like.[107] However, the ability to trace food is becoming increasingly vital to international commerce and an important topic for various governments.[108] Consequently, a number of industry-led initiatives have developed a variety of competing standards for global tracing efforts:[109] none of which have emerged as the definitive solution to the problem. Given that a number of these proposed solutions have been developed fairly recently,[110] it is hard to say with any confidence what will become of the de facto industry standard with time.

III. RFID AND PRODUCT TRACING

A. Defining Product Tracing

The increasing complexity of the domestic and international food system demands that regulators constantly evaluate what the best practices for increasing the safety of the supply chain are and that they enhance consumer confidence in the global food system. The FSMA specifically recognizes the importance of evaluating and implementing a science-based, technological

103. WORLD HEALTH ORG. & FOOD AND AGRIC. ORG. OF THE UNITED NATIONS, UNDERSTANDING THE CODEX ALIMENTARIUS, at v (2006), *available at* ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf.

104. A full consideration of the procedural aspects of the Codex Alimentarius is beyond the scope of this Note. However, the WHO and FAO succinctly parse out the procedural considerations within their respective publications. *See id*. at 16–17 (discussing the Codex's development and purpose).

105. *About Codex*, CODEX ALIMENTARIUS, http://www.codexalimentarius.org/about-codex/en/ (last updated Jan. 24, 2014).

106. *See Work of Other Relevant Organizations: 7.1 The "Three Sister" Organizations*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c7s1p1_e.htm (last visited Mar. 8, 2014) ("Importantly, the SPS Agreement cites Codex standards, guidelines and recommendations as the preferred international measures for facilitating international trade in food.").

107. *See* PRINCIPLES FOR TRACEABILITY/PRODUCT TRACING AS A TOOL WITHIN A FOOD INSPECTION AND CERTIFICATION SYSTEM: CAC/GL 60-2006 (2006), *available at* http://www.codexalimentarius.org/standards/list-of-standards/ (outlining generalized principles for developing a product tracing regime).

108. *See* Ben Bouckley, *Traceability Key to Avoiding Deadly E.coli Crisis Re-run, Expert*, FOODPRODUCTIONDAILY.COM (Sept. 26, 2011), http://www.foodproductiondaily.com/Safety-Regulation/Traceability-key-to-avoiding-deadly-E.coli-crisis-re-run-expert (describing how effective traceability systems are key to avoiding a repeat of the E.coli crisis).

109. *See* MCENTIRE & BHATT, *supra* note 12, at 197–201 (providing an overview of various product tracing global standards).

110. *See id*. (noting that there are competing standards and some of them have been developed more recently).

framework to enhance product tracing.[111] That being said, there is no singular safety technology that can ensure that food is wholesome and unadulterated from farm to fork. As noted above, the FDA has not identified what record-keeping technology—or technologies—will suffice to meet the strictures of the FSMA.[112] Determining how to approach the issue of product tracing is key to addressing the failings of the existing and highly limited product tracing regime.[113]

Currently, the fragmented product-tracing regime represents an extreme form of market failure.[114] The USDA highlighted this fact in a report, which indicated that the product tracing efforts of organizations may be—and often are—less than optimal.[115] More specifically, the USDA indicated that few firms "have an incentive to monitor the health of the Nation's consumers in order to speed the detection of unsafe product."[116] An effective product tracing system requires effective recordkeeping throughout the supply chain.[117] This issue, however, is undermined by the fact that industry has limited incentives to enhance the traceability of foods after they have left their possession.[118]

In its report to the FDA on the results of the FSMA pilot projects, the IFT provided a concise definition for product tracing as "the ability to follow the movement of a food product and its constituents through the stages of production, processing, and distribution, both backward and forward."[119] As a concept, product tracing is a combination of two elements: traceback and traceforward. Traceback deals with the movement from the retail level back to the original sources, and traceforward refers to the ability to follow the components of a food item all the way to the retail level.[120]

Product tracing within the food system relies—at the most fundamental level—on extensive recordkeeping that can be rapidly disseminated to regulators, processors, retailers, distributors, and consumers.[121] Broadly speaking, these records are comprised of series of two kinds of data: "Key Data Elements" (KDE) and "Critical Tracking Events" (CTE).[122] KDEs refer

111. *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 204, 124 Stat. 3885, 3930–31 (2011) (indicating record keeping requirements for high-risk foods must be "science-based" and that the Secretary must evaluate various product tracing technologies).

112. *See Product Tracing*, *supra* note 93 (noting that the FDA "may not prescribe specific technologies to maintain records" for certain high-risk foods).

113. *See* ELISE GOLAN ET AL., USDA, TRACEABILITY IN THE U.S. FOOD SUPPLY: ECONOMIC THEORY AND INDUSTRY STUDIES 35 (2004) (noting extreme variation in the product tracing systems between different food sectors).

114. *Id.* at 37.

115. *Id.* at 35.

116. *Id.* at 39.

117. *See id.* at 19 ("Traceability depends on the recordkeeping standards of the market intermediaries.").

118. *Id.* at 39.

119. MCENTIRE & BHATT, *supra* note 12, at 37. In its report, the IFT acknowledged that product tracing is distinct from traceability. *Id.* Traceability as a term has been used by a number of different parties without any agreed upon definition. *Id.* The IFT's general conceptualization of traceability is the ability to trace an item or items within a single firm. *Id.* In contrast, product tracing refers to the ability to track goods throughout the supply chain be it forward or backward. *Id.*

120. *Id.*

121. *See id.* at 8 (discussing the benefits and recordkeeping costs involved in product tracing).

122. *Id.* at 240–41.

to information that is key to tracking and tracing the product[123] (e.g., address of the immediate previous source of the item, date of receipt, quantity of the package).[124] CTEs refer to points within the supply chain where the item in question is either transformed or transferred in some way.[125] In theory, comprehensive recordkeeping that is readily accessible allows parties to rapidly trace particular items within the supply chain and isolate them accordingly.[126] Given that product tracing relies on the ability to effectively share information with other parties, there is a significant need for increased uniformity within the data collected.[127]

Through conducting the FSMA pilot projects, the IFT synthesized its findings to come up with ten recommendations for the FDA to improve product tracing.[128] The key recommendation from the IFT was that the FDA should "establish a *uniform* set of recordkeeping requirements for *all* FDA-regulated foods and not permit exemptions to recordkeeping requirements based on risk classification."[129] The IFT recommendations encouraged the development of internal product tracing plans,[130] the development of standardized reporting mechanisms for food safety investigations,[131] and the development of more comprehensive product tracing data.[132] Broadly speaking, product tracing relies on the ability of individuals and regulators to access comprehensive supply data in a manner that is easily accessible.[133] Without this essential element, any product tracing system will be seriously compromised and the value to consumers and producers will be significantly diminished. Due to the need for enhanced comprehensive recordkeeping that is increasingly particularized, the role of technology within the product tracing and food safety arena will become more pronounced with time.

B. Properties of RFID Systems

There are a number of existing food safety technologies that could help meet the product tracing requirements of the FSMA. One technology that is likely to play an important role in the product tracing of FDA-regulated foods is the RFID tag. Although a great deal has been written about RFID tags with

123. *Id.* at 15–16, 28 tbl. 2 (detailing best practices and requirements for the effective recordkeeping of CTEs and KDEs).

124. *See, e.g.*, 21 C.F.R. §§ 1.337–.352 (2006) (detailing the recordkeeping requirements for KDEs mandated by the FDA).

125. MCENTIRE & BHATT, *supra* note 12, at 27–28 tbl. 2 (listing various CTEs).

126. *See id.* at 22 (noting that effective recordkeeping allows parties to identify "convergence" of particular items within the supply chain).

127. *See id.* (noting that the lack of uniformity between company data involving CTEs and KDEs can hinder product tracing).

128. *Id.* at 15–16.

129. *Id.* at 15, 26 (emphasis added).

130. *Id.* at 29.

131. *Id.* at 30 (arguing that data relating to specific KDEs and CTEs be communicated via standardized platforms in summary form to assist with investigations).

132. *See id.* at 31 (indicating the benefits of being able to obtain multiple levels of product tracing data from a supply chain partner at a single time).

133. *See id.* at 22 (noting that inconsistencies in data sets can hinder the ability to analyze data).

regard to privacy concerns,[134] there has been little discussion of their application within the food safety infrastructure. This Note considers the practical, technological, and legal challenges to applying RFID technologies within the food safety system. After considering these factors, it recommends specific steps that could be taken to utilize this technology in an efficient manner that protects consumers.

1. What Are They?

Summarizing what RFID systems are and enumerating their potential applications is a daunting task. A highly technical dissection of the technology's component parts is best left to an engineering journal. Rather than focus on these aspects of the technology, this Note addresses RFID technologies and their potential application in the food safety system. Generally, RFID technology is a flow control technology that allows for individuals to obtain information about a particular item throughout an entire supply chain.[135] In essence, it is a technological tool that may enhance the product tracing of items.[136]

2. RFID Architecture

RFID technology is comprised of three key elements: "(1) an RFID tag, which can be directly applied on the displacing good, (2) an interrogator (or antenna), as a device (i.e., the reader) that gathers information from the tag (ID or data stored), and (3) a database system used to store the information gained through the interrogation routines carried out by the antenna."[137]

At a minimum, RFID tags—or transponders—include a microchip, an antenna, and some kind of backing material.[138] The tags can be embedded in various materials depending on their particular use.[139] RFID tags can be designed in read-only, write-once read-many (WORM), electronically erasable read-only memory (EEPROM), and read-write varieties.[140] The decision to choose one form of data access design over the other is largely based on the

134. *See, e.g.*, Reepal S. Dalal, Note, *Chipping Away at the Constitution: The Increasing Use of RFID Chips Could Lead to an Erosion of Privacy Rights*, 86 B.U. L. REV. 485, 514 (2006) (noting that the expansion of novel surveillance technologies like RFID may diminish what can be considered a reasonable expectation of privacy); Katherine Delaney, Note, *RFID: Privacy Year in Review: America's Privacy Laws Fall Short with RFID Regulation*, 1 I/S: J. L. & POL'Y FOR INFO. SOC'Y 543, 570 (2004–2005) (arguing that existing legislation and industry practices do not adequately protect consumer privacy rights); Serena G. Stein, Note, *Where Will Consumers Find Privacy Protection from RFIDs?: A Case for Federal Legislation*, 3 DUKE L. & TECH. REV. 1, 22 (2007) (arguing amendments to federal privacy statutes are the most promising way of protecting individuals' privacy rights).

135. Corrado Costa et al., *A Review of Agri-Food Supply Chain Traceability by Means of RFID Technology*, 6 FOOD & BIOPROCESS TECH. 353, 354 (2012).

136. *Id.*

137. *Id.*

138. *See* P. Kumar et al., *Overview of RFID Technology and Its Applications in the Food Industry*, 74 J. FOOD SCI. R101, R101 (2009) (explaining general structure of RFID tags).

139. Costa et al., *supra* note 135, at 354–55.

140. Kumar et al., *supra* note 138, at R102.

needs of the party employing the technology.[141] In general, the read-write design allows the greatest flexibility as the data on the tag can be manipulated in a manner that provides more information to other parties within the supply chain.[142] WORM tags permit parties to place information on the tag that can be accessed at any point.[143] In contrast, EEPROM tags can be reprogramed and erased at any time.[144] At present, there is no standardized data format for coding RFID tags and their data structure can be designed to fit the particular needs of the party employing the technology.[145]

RFID tags are also segmented into active, passive, and semi-passive tags.[146] Active tags have a battery that powers the microchip as well as a transmitter within the tag.[147] These tags have a "longer range of operation, greater processing power, and higher operating frequency . . . ."[148] Passive tags, by contrast, do not require an independent power source and instead are activated by the reader.[149] These tags have a much more limited range but a longer shelf life.[150] The technique through which the passive tags convert the radio waves from the interrogator into a power source is known as "backscatter."[151] Semipassive—or semiactive—tags use battery power to run the circuit of the RFID microchip.[152] This battery can also be used as a power source for monitors or sensors within the tag that can collect data about external conditions.[153] The tag reader simultaneously serves as a power source for the RFID tags—if passive—and communicates with the tag.[154] RFID tag readers can be either portable or fixed at a specific location depending on the needs of the operation.[155] The reader is used to code and decode data contained within the RFID tag.[156] The precise read range of an RFID is based on its design and whether the tag is active or passive.[157]

141. *Id.* at R102.
142. Costa et al., *supra* note 135, at 355.
143. Kumar et al., *supra* note 138, at R102.
144. *See Glossary of RFID Terms*, RFID J., http://www.rfidjournal.com/glossary/?E (last visited Mar. 8, 2014) (describing the elements of EEPROM tags).
145. *See* Costa et al., *supra* note 135, at 355 (describing the lack of standardized data formats for RFID tags as a potentially positive trait that permits greater flexibility on the part of the end user).
146. Kumar et al., *supra* note 138, at R101–02.
147. Costa et al., *supra* note 135, at 355; Kumar et al., *supra* note 140, at R101.
148. Kumar et al., *supra* note 138, at R101.
149. *Id.*
150. *Id.* at R101–02.
151. Costa et al., *supra* note 135, at 353.
152. Kumar et al., *supra* note 138, at R102.
153. *Id.*
154. *Id.*
155. *See* Costa et al., *supra* note 135, at 356 (indicating that readers can come in a variety of forms to meet the specific needs of the business).
156. Kumar et al., *supra* note 138, at R102.
157. *See RFID Frequently Asked Question*, RFID J., http://www.rfidjournal.com/faq/show?69 (last visited Mar. 8, 2014) (noting that read ranges can be as short as 3 feet and as long as 300 feet depending on the design).

3. Applications and Advantages of RFID Technologies

At present, RFID technology is employed in a myriad of industries.[158] RFID tags are already widespread[159] and are likely to become more common with time.[160] Although the technology has been around in a rudimentary form since World War II, it has only been actively embraced by industry within the past two decades.[161] Increased uniformity and decreased costs have led to an increase in the application of this product.[162]

As a tool, RFID technologies provide an effective means through which to capture supply chain data and share it with the relevant parties in near-real time.[163] There are numerous advantages of RFID technologies over standard barcoding, including the ability to do the following: identify products without physical contact, scan multiple products simultaneously, and improve the tracking of perishable items.[164] Unlike barcodes, RFID tags can be integrated with sensors that can keep a record of conditions or be tracked in real time within the supply chain.[165] Consequently, data from the RFID network can lead to enhanced visibility of information from the supply chain.[166] This enhanced visibility in the supply chain can be leveraged to identify inefficiencies (e.g., excess inventory), provide real-time inventory analysis, and reduce loss associated with spoilage.[167] Additionally, RFID tags have an inherent anti-counterfeiting quality in their ability to authenticate the product in question through the data collected within the supply chain.[168] Through the effective implementation of RFID infrastructures, individuals can obtain more comprehensive information about the vendor's supply chain and additional information about the particular item.

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158. *See generally* Delaney, *supra* note 134, at 544 (discussing the current state of RFID technology).

159. *See* Stein, *supra* note 134, at 5 (noting that RFID technology are in use as means of tracking livestock, pharmaceuticals, and other commercial goods).

160. *See* Jonathan Weinberg, *Tracking RFID*, 3 I/S: J. L. & POL'Y FOR INFO. SOC'Y 777, 835 (2007–2008) (arguing that the application of RFID technology is likely to increase in an increasingly networked world).

161. Paul Violino, *The History of RFID Technology*, RFID J., http://www.rfidjournal.com/articles/view?1338/2 (last visited Mar. 8, 2014).

162. *See* Chi-Fang Huang, *Low-Cost Solution for RFID Tags in Terms of Design and Manufacture*, *in* CURRENT TRENDS AND CHALLENGES IN RFID 113, 114 (Cornel Turcu ed., 2011) (noting how traditional printing technologies may be able to produce low-cost tags in a high-volume manner).

163. *See* T.A. McMeekin et al., *Information Systems in Food Safety Management*, 112 INT'L J. FOOD MICROBIOLOGY 181, 191 (2006) (describing general benefits of RFID systems).

164. Lidong Wang, *RFID-Based Information Technology and Management in Agriculture and Food Supply Chains*, 11 INT'L J. INFO. TECH. & MGMT. 225, 230 (2012).

165. *Id.* at 236.

166. Michael Bourlakis et al., *Conclusions*, *in* INTELLIGENT AGRIFOOD CHAINS AND NETWORKS 281, 285 (Michael Bourlakis et al. eds., 1st ed. 2011).

167. EDMUND W. SCHUSTER ET AL., GLOBAL RFID: THE VALUE OF THE EPCGLOBAL NETWORK FOR SUPPLY CHAIN MANAGEMENT 190 (2007).

168. *Id.* at 15 ("[A]ny object bearing a [RFID] tag can become networked without human intervention or manipulation by automated machines."); *see also* Patrizia Papetti et al., *A RFID Web-Based Infotracing System for the Artisanal Italian Cheese Quality Product Traceability*, FOOD CONTROL, Sept. 2013, at 240 (indicating that RFID data relating to cheese production accessible in a web platform can provide consumers insight into the entire production history).

4. Uniformity

One of the greatest challenges to the effective implementation of a comprehensive RFID network is in ensuring its uniformity. The value of an RFID network comes through its ability to process large volumes of data and communicate that data effectively to concerned parties.[169] At a fundamental level, the network requires well-defined standards to ensure that information can be transmitted effectively across the supply chain.[170] As discussed above, the IFT identified this need for uniform recordkeeping requirements as absolutely central to the development of an effective product-tracing regime.[171] While the need for uniformity has been acknowledged superficially, producers and regulators have not yet developed a comprehensive system.[172]

In the initial adoption of RFID technologies, individual vendors often established their own proprietary standards for RFID networks, which hindered their interoperability.[173] Many organizations have relied on proprietary closed-loop systems; unsurprisingly, they have been reluctant to share information with one another.[174] The lack of a comprehensive set of standards for RFID technologies significantly delayed their adoption by producers and suppliers.[175] This situation changed through the efforts of the Auto-ID Center. The Auto-ID Center is a collaboration of seven academic research labs,[176] which operate with the goal of "build[ing] a business driven, truly global, sustainable, robust, cost efficient, and future-proof EPC Network Infrastructure that is flexible enough to support future technologies, applications and industries."[177] This Center created a numbering scheme and network architecture, which it licensed to EPCglobal, Inc., a non-profit association that sets standards for the global supply chain.[178] EPCglobal is part of the GS1 organization, which is "dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors."[179] GS1 promulgates global standards to enhance the efficiency of the global supply chain for items such as barcodes, network data,

169. SCHUSTER ET AL., *supra* note 167, at 15 ("RFID tags provide the capability for seamless and continuous two-way communication as an object moves through a supply chain.").

170. *See* McMeekin et al., *supra* note 163, at 191 (noting that common identifiers and standards are key to the effective interoperability of the RFID system).

171. *See* MCENTIRE & BHATT, *supra* note 12, at 26 (highlighting the importance of uniform and comprehensive recordkeeping in order to enhance product tracing capacity).

172. *See id.* at 217 ("[P]roduct tracing will remain in a state of perpetual flux until FDA provides clearer definitions for data requirements and begins to share with industry the Agency's vision of an effective product tracing system.").

173. Laura M. Ulatowski, Note, *Recent Developments in RFID Technology: Weighing Utility Against Potential Privacy Concerns*, 3 I/S: J. L. & POL'Y FOR INFO. SOC'Y 623, 637–38 (2008).

174. *See* SCHUSTER ET AL., *supra* note 167, at 188 (noting how certain industries have developed internal proprietary systems).

175. Ulatowski, *supra* note 173, at 637–38.

176. *Advancing the Internet of Things for Global Commerce*, AUTO-ID LABS., http://www.autoidlabs.org/mission/page.html (last visited Mar. 8, 2014).

177. *Mission*, AUTO-ID LABS, http://www.autoidlabs.org/mission/page.html (available through WAYBACK MACHINE, http://web.archive.org/web/20121114074633/http://www.autoidlabs.org/mission/page.html) (last visited Mar. 8, 2014).

178. *Id.*

179. *Overview*, GS1, http://www.gs1.org/about/overview (last visited Mar. 8, 2014).

RFID technologies, and other areas.[180] Although GS1 has attempted to harmonize RFID standards, they have not been adopted uniformly throughout various industries on a global scale.[181]

EPCglobal establishes standards for Electronic Product Codes (EPCs), which can identify items within the stream of commerce by RFID technology.[182] Although EPCglobal has promulgated certain standards for RFID tags, they are not yet universal.[183] The EPCglobal network allows uniquely tagged items to be identifiable by a serial number.[184] The flexibility of the EPCglobal system permits the level of identification (e.g., item, lot, pallet, case) to vary based on the particular needs of the producer.[185]

In 2003, Wal-Mart and the United States Department of Defense formally adopted EPC standards for RFID tagging.[186] As more producers and suppliers become members of GS1 and adopt the EPGglobal standards, RFID technology companies will be incentivized—or pressured—to develop products that work with the ranges set forth by the organization. While the adoption of RFID technology has been slower than expected,[187] it has been gaining greater acceptance over time, particularly in the agrifood supply chain.[188] Considering the history of the adoption of the Universal Product Code (UPC) barcode,[189] it is not too fanciful to speculate that RFID technology will be adopted in a similar manner as the costs and complexity of the systems are reduced.

5. Data Accessibility

The core of an effective RFID infrastructure is a centralized, accessible pool of data that is readily available to parties at all levels of the supply chain. Thus, a product tracing system must include all of the entities throughout the

180. *Products & Solutions*, GS1, http://www.gs1.org/productssolutions (last visited Mar. 8, 2014).

181. *See* Luis Ruiz-Garcia & Loredana Lunadei, *The Role of RFID in Agriculture: Applications, Limitations, and Challenges*, 79 COMPUTERS & ELECTRONICS IN AGRIC. 42, 48 (2011) ("[T]he lack of uniformity in global standards makes RFID implementation more difficult . . . .").

182. SCHUSTER ET AL., *supra* note 167, at 4–5.

183. *See* Ruiz-Garcia & Lunadei, *supra* note 181, at 48 (noting that proprietary RFID systems and different frequencies reduce the universality of RFID standards).

184. SCHUSTER ET AL., *supra* note 167, at 29.

185. *See When Can We Expect to See Item-Level Tagging?*, GS1, http://helpdesk.gs1.org/ArticleDetails.aspx?EPC&id=00d202c9-23d8-e211-8c50-00155d64463e (last updated Sept. 19, 2013) (noting that while item-level tagging is likely far off, pallet and case tracking are viable).

186. FARANAK NEKOOGAR & FARID DOWLA, ULTRA-WIDEBAND RADIOFREQUENCY IDENTIFICATION SYSTEMS 5 (2012).

187. *See* Sue Hutchinson, *Why Hasn't RFID Adoption Taken Off in Retail?*, RETAILCUSTOMEREXPERIENCE.COM (Dec. 10, 2010), http://www.retailcustomerexperience.com/article/178218/Why-hasn-t-RFID-adoption-taken-off-in-retail (noting that there are numerous reasons why uptake of RFID has been slower than anticipated and stressing that standard barcodes took over a decade to gain acceptance).

188. *See* Bourlakis et al., *supra* note 166, at 285 (noting how the agrifood chain is poised to be one of the largest areas where RFID technology is adopted).

189. *See GS1 US: A History*, GS1 US, http://www.gs1us.org/about-gs1-us/corporate/history/gs1-us-a-detailed-history (last visited Mar. 8, 2014) (discussing the history of the barcode from its birth in 1949 to its development into the global GS1 system).

production and distribution chain in order to be effective.[190] An effective product tracing system allows for the effective traceback and traceforward of any particular item.[191] Traceback is key to the initiation of product recalls at the consumer level while traceforward is the reverse.[192] Both require greater integration within the production and distribution supply chains.[193] The integration of information increases the overall transparency of the supply chain while allowing for more timely and direct management of items in the stream of commerce.[194] Despite the clear benefits of integration, many companies have been reluctant to share their supply chain data in toto.[195] Consequently, the data associated with many existing networks does not present a comprehensive picture from the supplier to the consumer.[196]

6. Limitations

As a comprehensive supply chain management technology, RFID technology will only be effective to the extent it is adopted.[197] To be useful, an RFID network requires significant cooperation between parties in the supply chain to ensure that their systems are interoperable.[198] Parties unwilling to share information may hinder the rollout of a comprehensive RFID system.[199] Beyond the need for greater cooperation, another limitation remains due to the fact that different countries still use alternative bandwidths for various RFID applications despite EPCglobal's efforts.[200] The lack of clear standards for international interoperability will hinder establishment of a more comprehensive system.

Apart from the interoperability concerns, RFID systems have other inherent limitations. At the most fundamental level, the more steps a product is involved in within the supply chain increases the difficulty of preserving that

190. Valerie Orsat & Ramesh Murugesan, *Radio Frequency Technology*, *in* HANDBOOK OF FOOD SAFETY ENGINEERING 627, 628 (2011).

191. Bourlakis et al., *supra* note 166, at 117.

192. *Id.*

193. *Id.*

194. *See* Wang, *supra* note 164, at 238 (discussing how RFID technology can create "total visibility across the supply chain").

195. *See* MCENTIRE & BHATT, *supra* note 12, at 49, 108 (noting significant variability with regard to how much product tracing data was shared with downstream customers, and indicating a division between stakeholders in the food system as to whether firms should be required to adhere to any kind of forced collaboration through non-proprietary systems).

196. *See id.* at 94 (indicating that the many product tracing solutions are primarily designed to serve the end user (i.e., manufacturers, retailers) as opposed to regulators).

197. *See id.* at 102 (noting that "[t]echnology and all the analytical tools will only be as good as the underlying data"); *see also* INST. FOOD TECHNOLOGISTS, *supra* note 12, at 4 ("RFID is a data carrier but does not resolve the fundamental issue of determining the appropriate data that need to be captured, stored and shared.").

198. SCHUSTER ET AL., *supra* note 167, at 188–89.

199. *See* Ruiz-Garcia & Lunadei, *supra* note 181, at 48 (noting that information sharing is a substantial challenge to the effective implementation of an RFID system).

200. *See RFID Frequently Asked Question: Do All Countries Use the Same Frequencies?*, RFID J., http://www.rfidjournal.com/faq/show?62 (last visited Mar. 8, 2014) ("[I]t will take years for all governments to agree on a single UHF band for RFID.").

item's unique identification.[201] Items that undergo significant processing may be more difficult to tie to a single source.[202] Also, one of the largest limitations is the sheer cost of implementing an RFID system.[203] While the cost of the hardware and software will likely be reduced over time, it will never be zero.[204] Even if the hardware costs of the RFID systems decrease significantly, this will only reflect a small portion of the system's cost.[205] The more data-intensive the tags are, the more storage and processing costs the supplier will have to incur in order to maintain its product tracing data.[206] While these limitations will hinder the roll out of comprehensive RFID networks in the short term, the potential benefits of the technology will likely overcome this resistance with time as costs come down. The promise of a technology that can provide real-time monitoring of items through the supply chain is probably too much for suppliers to pass up once it is within their price range.

IV. RFID AND FOOD

A. Existing Applications

Despite the limited uptake of RFID tracing technology for the majority of FDA-regulated foods, some producers and manufacturers have started to employ RFID technologies in specific—typically higher-value—foods.[207] Products that have been tracked via RFID technology include ham,[208] cheese,[209] wine,[210] beer,[211] and milk.[212] Additionally, a number of the larger retailers have required their suppliers to utilize RFID technologies in some capacity.[213] This push has helped encourage a wider adoption of the technology than might have occurred otherwise.

RFID tags can be utilized within the food industry in a variety of different

201. *See* Wang, *supra* note 164, at 237 (noting that it is difficult to maintain the identity of an agricultural product which goes through multiple processing steps).

202. *See id.* at 238 (noting that additional processing of agricultural products makes the preservation of unique identifying marks difficult).

203. Weinberg, *supra* note 160, at 790.

204. *Id.*

205. *Id.*

206. *Id.* at 787.

207. *RFID Technology Transforming Food Retailers Like Wal-Mart*, SEEKING ALPHA (Mar. 18, 2010, 5:00 PM), http://seekingalpha.com/article/194466-rfid-technology-transforming-food-retailers-like-wal-mart.

208. Bourlakis et al., *supra* note 166, at 119 (discussing how the Spanish producer Campofrio tracks cured hams with RFID technology).

209. Papetti et al., *supra* note 168, at 240.

210. GS1, AN INEBRIANT JOURNEY: GLOBAL WINE SUPPLY CHAIN VISIBILITY VIA EPCIS NETWORK (2012), *available at* http://www.gs1.org/docs/transportlogistics/2012_05_GS1HKItaly_WinetraceabilityCase.pdf.

211. *RFID Returnable Transit Items (Beer Kegs) Presentation*, GAO RFID INC., http://www.gaorfid.com/index.php?main_page=presentation&ppt=RFID-Returnable-Transit-Items-%28Beer-Kegs%29-Presentation (last visited Mar. 8, 2014) (describing RFID beer keg tracking system).

212. Peggy Coffeen, *Dairy Producers Share Experiences with RFID*, AGRI-VIEW (Mar. 15, 2012, 3:00 PM), http://www.agriview.com/news/dairy/dairy-producers-share-experiences-with-rfid/article_1b1fd0c2-6eb8-11e1-8a5c-001871e3ce6c.html.

213. *See* Bourlakis et al., *supra* note 166, at 116 (noting how Metro group, Wal-Mart, and Tesco now mandate that some of their suppliers track items by RFID tags).

ways since the technology can adapt to meet the needs of the producers, distributors, and retailers. Advances in the durability of tags have allowed them to be employed in a number of circumstances that they were unable to be utilized in just a few years ago.[214] Tags have been developed that can withstand cold temperatures, humidity, acidic conditions, and vibrations during transport.[215] Two advantages of the RFID tag in the context of the food system are the ability to identify individual items and the ability to trace an item through the supply chain.[216] Recent developments in sensor technologies and tag design have the potential to provide significant information about the supply chain.

While the current economics of RFID technologies largely preclude tagging individual items,[217] tagging may become increasingly granular as the costs come down. The level to which a particular food item is identified is likely to be determined by a cost-benefit analysis related to the likelihood of a recall, the administrative cost of utilizing the RFID technology, and the value of the product.[218] Unsurprisingly, producers and suppliers of low-priced commodities have been more reluctant to adopt this technology in any widespread manner absent outside pressure.[219] However, given that roughly ten percent of perishable products are wasted or spoiled before they reach consumers, the retailers and suppliers have *some* incentive to improve the outcomes within the food supply chain.[220]

Although the FDA has proposed a set of rules associated with the safe handling and production of food,[221] it has only just begun to request input and feedback on the results of the IFT's pilot projects and the proposed Section 204 rulemaking.[222] While it is difficult to speculate as to what the proposed

214. *See RFID Tags Prove Durable in Test with Reusable Produce Containers*, SUPERMARKET NEWS (July 10, 2009), http://supermarketnews.com/latest-news/rfid-tags-prove-durable-test-reusable-produce-containers (noting how certain single-use tags could be reused in a variety of environmental conditions if properly situated).

215. Bourlakis et al., *supra* note 166, at 120.

216. *See id.* at 285 (indicating the potential value in RFID technology in identifying particular products and as a means of helping businesses gain more information about their operations).

217. *See* Ruiz-Garcia & Lunadei, *supra* note 181, at 48 (discussing the challenges of implementing an increasingly precise data set within an RFID network).

218. *See* M.F.F. Poças et al., *Smart Packaging Technologies for Fruits and Vegetables*, *in* SMART PACKAGING TECHNOLOGIES FOR FAST MOVING CONSUMER GOODS 152, 164 (Joseph Kerry & Paul Bulter eds., 2008) (noting that high volume and low margin producers may find the use of RFID technologies prohibitively expensive in the near term).

219. *See* Wang, *supra* note 164, at 237 (noting a reluctance to adopt costly product tracing technologies).

220. Mark Roberti, *RFID Will Help Keep Perishables Fresh*, RFID J. (Aug. 3, 2005), http://www.rfidjournal.com/article/view/1775.

221. Proposed Rules to Establish Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption and for Current Good Manufacturing Practice and Hazard Analysis and Risked-Based Preventive Controls for Human Food, 78 Fed. Reg. 10,107 (Feb. 13, 2013) (to be codified throughout 21 C.F.R.); *see also U.S. FDA Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, REGISTRAR CORP., http://www.registrarcorp.com/fda-guidance/produce-safety.jsp (last visited Mar. 3, 2014) ("Section 204 of FSMA now directs us to take a variety of different actions that will enhance our ability to track and trace foods, including to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a foodborne illness outbreak. Further efforts to enhance the tracking and tracing of food are outside of the scope of this proposed rule.").

222. *See* Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA to

product-tracing rule will look like, it is highly unlikely that the FDA would even suggest that any singular technological solution would be required.[223] That being said, the recordkeeping requirements of product tracing regulations could likely be met by a comprehensive RFID system.[224] However, it needs to be emphasized that there is not necessarily a need for item-level tagging, particularly in the case of low value goods; RFID tags can—and have—been applied at a case or lot level to low value goods.[225] While there may be a benefit to item level tagging, depending on the nature of the product, the lot or batch level of identification may be sufficient in light of the potential risks to the consumer.[226]

At present, most RFID networks within the food supply chain only cover a limited portion of it.[227] Most products are tagged when the product is ultimately consolidated or manufactured at a particular location.[228] RFID networks also typically end once the retailer receives the product.[229] Consequently, consumers have little to no interaction with the network and are largely precluded from investigating it in its current form.[230] This pattern is reflected in the larger supply chain where companies may be reluctant to share data with regulators or other industry participants.[231] Despite this reluctance, there needs to be increased integration and uniformity of data throughout the supply chain before the value of RFID technologies can be unlocked.

B. Private Industry

The FTC has taken a decidedly hands-off approach to the regulation of RFID technologies by relying on a self-regulatory model.[232] Presently, there

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Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food, 78 Fed. Reg. 14,309, 14309–11 (2013) (requesting comments and information regarding the results of the IFT's pilot project and the general requirements of Section 204 of the FSMA).

223. *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 204(d)(1)(C), 124 Stat. 3885, 3931 (2011) (prohibiting the FDA from "prescrib[ing] specific technologies for the maintenance of records" for high-risk foods).

224. *See* Kumar et al., *supra* note 138, at R106 (describing the general viability of an RFID network within the supply chain).

225. Tim Dreyer, *RFID Tracks Both a Field's Productivity—and the Field's Produce*, VISIBLE VALUE BLOG (May 24, 2010, 1:45 PM), http://blogs.zebra.com/blog/bid/38288/RFID-Tracks-Both-a-Field-s-Productivity-and-the-Field-s-Produce.

226. *See* P. Barge et al., *Item-Level Radio Frequency Identification for the Traceability of Food Products: Application on a Dairy Product*, 125 J. FOOD ENG'G 119, 119 (2014) (noting that item or batch level allows better control over the production process).

227. *See* JENNIFER C. MCENTIRE, INST. FOOD TECHNOLOGISTS, TRACING SYSTEMS: AN EXERCISE EXPLORING DATA NEEDS AND DESIGN 1, 32 (2009) ("It should also be considered that many industry systems lack inoperability along various points in the supply chain, and do not lend themselves to product tracing for the entire sector.").

228. *See generally* Bourlakis et al., *supra* note 166, at 121–25 (discussing some of the potential benefits to individual companies of RFID networks).

229. *See id.* at 124 (noting how RFID technologies have some promise in improving the checkout process).

230. *See* Ahmed Musa et al., *Product Visibility: Methods, Systems and Impacts*, 41 EXPERT SYS. WITH APPLICATIONS 176, 177 (2014) (discussing the recent push for visibility in food chains).

231. *See* MCENTIRE, *supra* note 227, at 26–27 (noting how the gaps in data collection hindered trace forward and traceback efforts).

232. FED. TRADE COMM'N, RADIO FREQUENCY IDENTIFICATION: APPLICATIONS AND IMPLICATIONS FOR

are no minimum FTC standards of what kind or quality of information is required to be contained in RFID tags on foods.[233] The FDA has not set forth any standard for what kind of information is required within any kind of RFID tag or label.[234]

Although the benefits of an integrated supply chain have been discussed repeatedly, there has been little motivation for producers to develop a comprehensive traceback regime.[235] Without pressure from regulators or consumers, producers and suppliers have limited incentive to invest in RFID technologies or integrate their tracing data with other firms.[236] The existing regulatory framework provides limited incentive for the organizations to work together;[237] unsurprisingly, there has been a great deal of reluctance for producers, suppliers, and retailers to coordinate their product tracing efforts.[238] Convincing producers and suppliers to invest in an expensive nascent technology to address a low-probability event is a rather daunting task. That being said, it is reasonable to assume that many retailers and consumers will start to demand increased transparency and traceability within the supply chain in light of the FSMA's requirements.[239]

C. Privacy

For all of their advantages, RFID systems have several areas of concern

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CONSUMERS 1, 22–23 (2005), *available at* http://www.ftc.gov/os/2005/03/050308rfidrpt.pdf (noting that a self-regulatory approach to RFID technologies should address issues of transparency, consumer education, and data protection).

233. Jonathan Collins, *FTC Asks RFID Users to Self-Regulate*, RFID J. (Mar. 10, 2005) http://www.rfidjournal.com/articles/view?1437 ("Despite calls from the Electronic Privacy Information Center (EPIC) that the FTC issue guidelines for use of RFID devices in the private manufacturing and retail sector, the FTC instead believes that RFID policies and public-education campaigns like those adopted by Marks & Spencer in the U.K. and Wal-Mart in the U.S. can serve as models for how the industry should educate consumers about RFID tags on their purchased items.").

234. *Id.* ("In the FTC report, the agency says it will encourage industry-led initiatives where retailers and manufacturers provide clear notices for consumers whenever RFID tags are being used and outline what data will be collected and what it will be used for. The FTC also states that any industry self-regulatory program should include meaningful accountability provisions to help ensure compliance.")

235. *See* MCENTIRE & BHATT, *supra* note 12, at 128–29 (noting that many of the pilot project participants stated that they were unable to justify the expense of a comprehensive product tracing system); Sandra Hoffmann, USDA, *U.S. Food Safety Policy Enters a New Era*, AMBER WAVES (Dec. 1, 2011), http://www.ers.usda.gov/amber-waves/2011-december/us-food-safety-policy.aspx#.UxUtZvRdX6E ("[M]arkets have not been as effective in encouraging traceability that meets public needs related to food safety.").

236. Those parties that are early adopters of enhanced product tracing systems may—counter-intuitively—place themselves at a great risk of being liable in the event of an outbreak or recall. *See* GOLAN ET AL., *supra* note 113, at 38 ("If traceability systems increase the probability that a firm will be identified in the case of food safety problems and exposed to liability, then the firm may have an incentive to underinvest in traceability: the value of anonymity may reduce the firm's incentives to invest in traceability systems.").

237. *See* MCENTIRE & BHATT, *supra* note 12, at 94 (noting that many of the existing product tracing systems currently being utilized are targeted to serve the needs of a particular user, not provide information in a collaborative format).

238. *Id.*

239. *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (to be codified throughout 21 U.S.C.) (describing the requirements for developing a successful tracing and tracking system).

when tied to food products.[240] The sheer volume of data that is collected is one of the most problematic aspects of a comprehensive product-tracing regime.[241] RFID technologies widely adopted throughout the supply chain could lead to significant privacy concerns in that the collected data would form a complete representation of the consumer's consumption habits.[242] Given that the heart of a product-tracing regime is the ability to quickly access information about a particular item as it passes through the stream of commerce, there is a distinct risk that an individual consumer could be rapidly identified by a quick scan of her grocery bag.[243] While this kind of rapid identification is very useful in the food safety context, it presents risks for consumers.[244]

Although the EPC serial number on an item contains no information that could be used to readily identify an individual, once this information is paired with other data—e.g., credit card, loyalty card, location—it becomes increasingly easy to tie a particular individual to a specific item.[245] While the benefit of RFID technologies to the suppliers of products is abundantly clear, there is considerable debate about the net value to consumers with regard to this loss of privacy.[246] Given that a product-tracing regime needs to be comprehensive in order to be effective, there will be a tension between the need to protect consumer privacy and ensure that all of the KDEs and CTEs are captured by the network.[247] That being said, it is likely that this area will come under increased scrutiny as more retailers utilize RFID data systems. However, there is limited value in speculating about what regulators do to protect consumer data and that topic is beyond the scope of this Note.

V. RECOMMENDATIONS

Enhancing the ability to trace foods throughout the supply chain is absolutely vital to the American economy in the long-term. The benefits of utilizing RFID technologies to carry out the dictates of the FSMA and increase consumer confidence in food products are readily apparent. Although food-related tracing RFID technologies are still nascent, they can—and will—likely

240. *See generally* Polymeros Chrysochou et al., *Traceability Information Carriers. The Technology Backgrounds and Consumers' Perceptions of the Technological Solutions*, 53 APPETITE 322 (2009) (discussing RFID use with food products).

241. *See* Laura Hildner, Note, *Defusing the Threat of RFID: Protecting Consumer Privacy Through Technology-Specific Legislation at the State Level*, 41 HARV. C.R.-C.L. L. REV. 133, 139 (2006) (noting that RFID technology enables "consumer profiling and tracking to an unprecedented degree").

242. *See id.* at 140 (indicating that people can become identified solely through the data associated with the products they have in their possession).

243. *Id.*

244. *See* Chrysochou et al., *supra* note 240, at 329 (noting that the implementation of RFID networks may be hindered due to ethical and privacy issues from the consumer end).

245. *See* Hildner, *supra* note 241, at 140 (discussing how pairing this kind of data creates a condition where parties can be identified by the objects in their possession).

246. *Id.* at 140–41 (noting that RFID technologies may eliminate consumer consent in data collection and retention); *see* Bourlakis et al., *supra* note 166, at 114–15 (noting that there are substantial concerns about the risk posed by collected RFID data to consumers); Chrysochou et al., *supra* note 240, at 325 (noting in multinational focus group survey that consumers expressed concerns about how the collected data from RFID tags would be used).

247. MCENTIRE & BHATT, *supra* note 12, at 15.

play an increasing role within the domestic and international food safety system. In order for this technology to be effectively implemented on a nationwide or global scale, a number of issues need to be taken into consideration.

A. Uniformity

RFID technologies require uniformity in order to be effectively implemented. Uniformity needs to be achieved in terms of what information is contained within the tag at the time of packaging and shipping, what information is collected on the tag during transit, and how the data can be accessed.[248] None of these standards will be easy to achieve. Despite the pioneering efforts of the Auto-ID Center and GS1, there has yet to be a uniform standard set forth that takes into account specific food safety concerns.[249] This problem is only exacerbated by the fact that RFID vendors offer competing proprietary systems that are not readily compatible.[250] Further, most organizations utilize their product tracing technologies for different purposes (e.g., warehousing, metrics) on a narrower range of the supply chain than food safety professionals would prefer.[251]

A good starting place for establishing, codifying, and adopting uniform standards is to build off of those set forth by the Auto-ID Center and GS1 in the EPCglobal network.[252] While this is a baseline for the application of this kind of technology, the bare standards set forth by GS1 are insufficient to ensure that foods are wholesome and unadulterated. Although the numerous GS1 standards add value to the overall traceability of foods, the system is far from being utilized to its fullest capability. A meaningful RFID product tracing system needs to provide more comprehensive information about the product in question and the conditions of its transport and needs to be accessible at all levels within the supply chain.[253] This uniform data requirement should extend to domestic and imported foods; otherwise the vitality of the system will be fundamentally hindered.

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248. *Id.* at 37.

249. *See id.* at 205 (detailing the IFT's suggestions for the recordkeeping of KDEs and CTEs).

250. *See* RF CODE, AN ANALYSIS OF ACTIVE RFID FOR ASSET TRACKING 2 (2010), *available at* http://merfida.com/files/An%20Analysis%20of%20Active%20RFID%20for%20Asset%20Tracking.pdf (explaining the difficulty that companies have when there are over 100 vendors to choose from, each promising that they offer the leading solution).

251. *See* MOTOROLA, IMPROVING THE SAFETY OF THE FOOD SUPPLY CHAIN: THE VALUE OF RFID AND TRACEABILITY ON A GROWING PROBLEM 2–5 (2008), *available at* https://portal.motorolasolutions.com/web/Portal/resources/docs/ngem/pdf/RFIDFS-Whitepaper-0808.pdf (discussing the advantages of extending RFID tracking to all parts of the food supply chain).

252. *See* AUTO-ID CENTER, DRAFT PROTOCOL SPECIFICATION FOR A 900 MHZ CLASS 0 RADIO FREQUENCY IDENTIFICATION TAG 6 (2003), *available at* http://www.gs1.org/docs/epcglobal/standards/specs/900_MHz_Class_0_RFIDTag_Specification.pdf (discussing the mandatory and optional specifications for a low cost item identification tag operating in the ultra high frequency band in accordance with accepted and evolving worldwide standards).

253. *See* EPCGLOBAL, INC., EPC INFORMATION SERVICES (EPCIS) VERSION 1.0.1 SPECIFICATION 22 (2007), *available at* http://www.gs1.org/gsmp/kc/epcglobal/epcis/epcis_1_0_1-standard-20070921.pdf (noting that the Electronic Product Code Information Service (EPCIS) of the EPCglobal Network allows for the ability to add new data on top of the data contained within the original tags).

At a minimum, EPC codes should be able to demonstrate to the lay consumer: (1) the specific location(s) the product came from, (2) where it was transported to, (3) the conditions of the transport that are relevant to the consumer (e.g., temperature, humidity), (4) the date of its production/picking, (5) contact information for all of the parties in the supply chain, (6) any information relating to its "best by" or expiration date, and (7) information about any transformations the item underwent.[254] This would not only improve supply chain visibility but also build confidence by authenticating products.

B. Consumer Awareness

Dovetailing with the previous issue is the need for consumers to have a better understanding of the risks and benefits of a comprehensive RFID regime.[255] To date, producers and suppliers have largely left the consumers out of this dialogue. As RFID technologies become increasingly common in the marketplace, it is vital that producers and suppliers explain the relative benefits of a comprehensive product tracing while ensuring that consumers are informed about the network's existence. While this will—admittedly—be a tough sell, it is essential that consumers come to see themselves as vital components in an effective food safety infrastructure.[256] However, given that consumers routinely use loyalty cards that track all of their purchases within a particular store,[257] utilize credit cards which can readily be tied to specific purchases,[258] and use cellular technologies that create substantial data about their habits,[259] it may be increasingly easy to convince consumers to feel comfortable with the idea that RFID data is tracked and retained.

As certain presumptions of privacy are reduced over time through the increased use of location-based technologies, it is likely that the collection and retention of RFID data at the consumer level will be less objectionable to the average consumer. However, there may still need to be some consumer level protections to ensure that data collected about individuals is not used in

254. These suggestions are presented in a largely consumer-focused manner and are somewhat broader than those suggested by the IFT. The IFT's somewhat similar suggested KDEs and CTEs are in a more industry-centric format and capture little about the specific conditions of the transport or transformation of products. *See* MCENTIRE & BHATT, *supra* note 12, at 205 (detailing the IFT's suggested recordkeeping for KDEs and CTEs).

255. *See* Nancy J. King, *When Mobile Phones Are RFID-Equipped–Finding E.U.-U.S. Solutions to Protect Consumer Privacy and Facilitate Mobile Commerce*, 15 MICH. TELECOMM. & TECH. L. REV. 107, 199 (2008) (noting that the potential privacy risks associated with the application of RFID technologies in a particular context is key to developing some means of privacy safeguards).

256. *See* GOLAN ET AL., *supra* note 113, at 38 (noting that many consumers are reluctant to have a store retain records about their shopping habits).

257. *See* MCENTIRE & BHATT, *supra* note 12, at 120 (noting how shopper card data is stored by retailers and can be tied to specific products).

258. *See* Janet Dean Gertz, Comment, *The Purloined Personality: Consumer Profiling in Financial Services*, 39 SAN DIEGO L. REV. 943, 952–53 (2002) (indicating how financial data can be directly tied to a particular consumer unless encrypted or deleted).

259. *See* David Kravets, *Which Telecoms Store Your Data the Longest? Secret Memo Tells All*, WIRED (Sept. 28, 2011, 6:30 AM), http://www.wired.com/threatlevel/2011/09/cellular-customer-data (detailing data retention timelines for major telecommunication companies).

nefarious ways and is secured by the organizations that collect it. The explicit design of idealized data retention policies and regulations is outside of the scope of this Note as this issue is currently confronting numerous industries.[260]

C. Limited Federal Legislation

Federal legislation of RFID data collection and transmission should be limited to protect consumer privacy and ensure that data that is provided within the EPC benefits all parties who utilize the technology. Federal legislation should be aimed at developing the minimum standards for what kind and amount of data needs to be collected and accessible. While the specific kind of data that is necessary will likely depend on the particular product and the risk it poses to consumers, all products should at least meet the minimums set forth in Part V.A of this Note.

Apart from the minimum standards for data collection, federal legislation could be utilized to protect at least some element of consumer privacy. In a situation where products are tagged at the item level, RFID technology creates the potential to develop an extensive record of each individual's consumption habits.[261] Consumers need to be aware about the collection of such information. Likewise, companies should be restricted from using this data in a manner that will harm the individual consumer or discriminate against him or her at any level.

D. Other Technologies

RFID tracing is only one of a host of technological innovations that will improve food safety in the coming years. Any RFID product-tracing regime should work in concert with other emerging technologies to mitigate risk within the supply chain. Among the emerging technologies that will reduce future outbreaks are various forms of smart packaging,[262] active packaging,[263] and nanotechnology[264] which will lead to better management within the food

260. *See* Lois Beckett, *Everything We Know About What Data Brokers Know About You*, PROPUBLICA (Sept. 13, 2013, 11:21 AM), http://www.propublica.org/article/everything-we-know-about-what-data-brokers-know-about-you (indicating that data brokers obtain information about individual consumers in part through purchasing it from retailers); *see also* Lois Beckett, *Yes, Companies Are Harvesting—and Selling—Your Facebook Profile*, PROPUBLICA (Nov. 9, 2012, 1:09 PM), http://www.propublica.org/article/yes-companies-are-harvesting-and-selling-your-social-media-profiles (discussing data brokers' practices regarding Facebook profiles).

261. *See* Quentin Archer, *RFID: A Threat to Privacy?*, COMPUTERWEEKLY.COM (Apr. 2005), http://www.computerweekly.com/opinion/RFID-a-threat-to-privacy (discussing RFID's application in tracking individual's spending habits).

262. Smart packaging refers to the packaging materials and indicators that can provide information about the quality of the product over time to the consumer directly. These materials can include time-temperature indicators, leak indicators, and spoilage indicators. P.S. Taoukis, *Smart Packaging for Monitoring and Managing Food and Beverage Shelf Life*, *in* FOOD AND BEVERAGE STABILITY AND SHELF LIFE 303, 303–04 (David Kilcast & Persis Subramaniam eds., 2011). RFID tags are often considered to be a form of smart packaging. *See* Poças et al., *supra* note 218, at 162–64 (noting that the monitoring properties of RFID technologies may be considered smart packaging).

263. Active packaging refers to packaging that contains materials or technologies that can help preserve and protect the food item in question as it is exposed to altered conditions. Poças et al., *supra* note 218, at 17.

264. Nanotechnology will likely be increasingly employed to improve food packaging materials. *See*

supply chain and enhance consumer safety in the aggregate. A comprehensive food safety regime requires that the technologies employed throughout the supply chain are mutually beneficial. The successful application of emerging food safety technologies combined with the development of more refined production practices will ultimately reduce the likelihood that foods are adulterated at any point within the supply chain.[265] Regardless of how much the overall safety of food is improved through technological innovation, there still needs to be a means through which products can be rapidly isolated and traced in the event of adulteration. Without the ability to rapidly trace products, consumers and purveyors of similar goods are placed at risk.[266] Consequently, the ability to trace products effectively and efficiently is a cornerstone to any food safety system. An efficient RFID network would capably address this issue.

E. Recapturing Costs

This will likely be the most difficult aspect of any technological approach to the food system.[267] The uncertainty about the ability to recapture the costs of developing a product tracing system is one of the most significant stumbling blocks to the development of an effective traceability regime.[268] This problem is exacerbated by the fact that there is a limited amount of quantitative data about the true costs of implementing a product tracing system and the net benefit to those parties that adopt a system.[269] More problematic is that the primary beneficiary of an effective product tracing system is the general public, not the party that implements the system.[270] Few companies are willing to make this kind of investment if they have no clear vision of the potential benefit.[271]

Aaron Brody et al., *Innovative Food Packaging Solutions*, 73 J. FOOD SCI. 107, 113 (2008) (noting the significant potential for nanotechnology's application in food packaging). One of the more fascinating potential applications for nanotech is in the development of nanosensors that could detect foodborne pathogens, toxins, or other chemicals. *Id.* at 114. Nanotechnologies can be incorporated into packaging materials to (1) improve their general properties, (2) act in an active capacity (e.g., antimicrobial), (3) act in a smart capacity (e.g., monitoring functions), or (4) improve the biodegradability of the packaging material. *See* Qasim Chaudry et al., *Applications and Implications of Nanotechnologies for the Food Sector*, 25 FOOD ADDITIVES & CONTAMINANTS: PART A 241, 245 (2008) (noting potential applications for nanotechnologies in food packaging).

265. *See generally* NAT'L RESEARCH COUNCIL, IMPROVING FOOD SAFETY THROUGH A ONE HEALTH APPROACH: WORKSHOP SUMMARY 15 (Natn'l Academies Press, 2012) (aligning current issues and concerns in food safety with modern approaches to solving them).

266. *See* William Nganje et al., Traceability in the Food Systems: An Economic Analysis of LGMA and the 2006 Spinach Outbreak, Presentation at the 85th Annual Conference of the Agricultural Economics Society (Apr. 18–20, 2011), *available at* http://ageconsearch.umn.edu/handle/108776 (noting how untimely and overbroad recalls cause producers and distributors of unadulterated products to suffer).

267. *Id.* at 6.

268. MCENTIRE & BHATT, *supra* note 12, at 232 (noting the lack of quantitative studies about the cost of product tracing networks' setup costs).

269. *Id.*

270. *Id.* at 125.

271. Companies that participated in the IFT's product tracing study indicated that they were unable to justify the expense of establishing a product tracing system without a clear idea of its potential benefit. *See id.* at 128–29 (noting the general reluctance to be the prime mover where the payoff is uncertain).

Due to this apprehension, parties will have to be incentivized in some manner to develop comprehensive and effective product tracing systems. One clear incentive is the mere existence of Section 204 of the FSMA.[272] Although specific traceability regulations have yet to be issued by the FDA, the statutory language may encourage those parties covered by the legislation to start developing product-tracing plans.[273] In addition to the legislative cudgel, there are numerous readily identifiable benefits that could be emphasized by the FDA and larger retailers to encourage suppliers to develop a traceability system.[274]

For growers, enhanced traceability is a means through which their product can be readily identified and their operations are less likely to be interrupted in the event of an outbreak of a similar product.[275] Processors can benefit through the reduction in recordkeeping labor and data management.[276] Distributors that adopt more transparent product tracing systems may be able to reduce their overall costs and increased sales through more efficient product tracing.[277] Similarly, retailers with enhanced product tracing systems may be able to manage their inventory more effectively.[278]

As more firms develop comprehensive product tracing systems, there will be a larger data pool from which to analyze the net benefits of those systems. Firms that are early adopters of product tracing systems will likely benefit from reduced insurance rates and be less impacted by problems associated with adulterated foodstuffs of similarly situated products.[279] While these benefits will reduce the costs of developing such a system, it is unclear whether they will fully cover them.

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272. *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 204, 124 Stat. 3885, 3930–37 (2011) (to be codified throughout 21 U.S.C.) (enhancing tracking and tracing of food recordkeeping).

273. *Id.*

274. *Id.*

275. *See* MCENTIRE & BHATT, *supra* note 12, at 173.

276. *Id.*

277. *Id.*

278. *Id.*

279. *See Traceability: Why Do You Need It?*, ONTARIO MINISTRY AGRIC. & FOOD, http://www.omafra.gov.on.ca/english/food/foodsafety/traceability/need.htm (last visited Mar. 8, 2014) (noting some of the benefits of enhanced traceability systems).