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Not Sick Yet

FOOD-SAFETY-IMPACT LITIGATION AND BARRIERS TO JUSTICIABILITY

Diana R. H. Winters[†]

INTRODUCTION

The United States food-safety regulatory program is a behemoth. It is overseen by at least five federal agencies administering at least six statutes. Yet almost 17 percent of the American population (approximately forty-eight million people) gets sick from food each year, 128,000 of these people are hospitalized, and three thousand die.¹ Foodborne illness costs the United States over \$150 billion per year.² Food recalls are massive and frequent—like that of cantaloupe in 2011, which, with approximately thirty deaths from listeria, was the deadliest outbreak in almost a century;³ eggs in 2010, where

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¹ *CDC Estimates of Foodborne Illness in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html> (last updated Feb. 7, 2012). This CDC estimate was made public in December 2010. *Id.* The previous estimate was higher—seventy-six million people a year getting sick, with five thousand dying. See William Neuman, *New Estimates of Food Poisoning Cases*, N.Y. TIMES, Dec. 15, 2010, at A1, available at <http://www.nytimes.com/2010/12/16/business/16illness.html?scp=1&sq=cdc%20food%20poisoning&st=cse>. The lowering of the numbers is a result of different calculation methods, not an improvement in food safety. *Id.*

² ROBERT L. SCHARFF, HEALTH-RELATED COSTS FROM FOODBORNE ILLNESS IN THE UNITED STATES 1-2 (Produce Safety Project, Georgetown Univ. 2010), available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Produce_Safety_Project/PSP-Scharff%20v9.pdf?n=1136. This study was based on the Center for Disease Control's (CDC) previous estimates of seventy-six million sick Americans a year, and therefore would be lower based on the new estimates. *Id.* The costs include medical services, deaths, and lost work and disability. *Id.* at 2.

³ Michael Booth, *Cantaloupe Listeria Outbreak Declared Over as One Last Death Reported*, DENVER POST (Dec. 9, 2011, 1:00 AM), http://www.denverpost.com/news/ci_19502146.

more than a thousand people were sickened with salmonellosis;⁴ peanut butter in 2009, with over four hundred hospitalizations, and at least six deaths;⁵ and spinach in 2006, where 131 people were sickened and over sixty hospitalized.⁶ The nation's food regulatory system is inefficient, underenforced, and underfunded.

Although multiple agencies are responsible for food safety, and have overlapping duties, there are wide gaps in oversight and regulation.⁷ The agencies must negotiate the competing goals of protecting the public health, marketing the nation's commodities, and appeasing the interests of regulated entities. Compounding this problem is a severe shortage of resources allocated to food-safety enforcement.⁸ Given the regulatory failures,⁹ and their

⁴ Scott Hensley, *Salmonella Cases Rise as Recall of Contaminated Eggs Grows*, NPR (Aug. 20, 2010, 12:29 p.m.), <http://www.npr.org/blogs/health/2010/08/20/129321965/salmonella-recalled-egg-contamination>. Salmonellosis is an infection caused by the bacteria salmonella.

⁵ *More Peanut Butter Products Recalled*, MSNBC (Jan. 18, 2009, 6:52 PM), http://www.msnbc.msn.com/id/28695782/ns/health-food_safety/.

⁶ Drew Falkenstein, *Spinach Recall Among Huffington Post's Worst Product Recalls of All Time*, FOOD POISON J. (Feb. 24, 2010), <http://www.foodpoisonjournal.com/2010/02/articles/foodborne-illness-outbreaks/spinach-recall-among-huffington-posts-worst-product-recalls-of-all-time/>.

⁷ Broadly conceived, food safety covers three areas: (1) the prevention of foodborne illness; (2) nutrition monitoring; and (3) the prevention of fraud in the marketplace. This article only addresses the first category, although there is overlap amongst the three. For example, I do not discuss cases regarding deceptive claims or fraudulent labeling, such as those brought in recent years by the Center for Science in the Public Interest (CSPI), although they certainly concern food safety. *See, e.g.*, Amended Complaint at 1-2, 29, *Parham v. McDonald's Corp.*, No. CGC-10-506178 (Cal. Super. Ct. Jan. 5, 2011), *available at* http://cspinet.org/new/pdf/mcdonald_scomplaint.pdf (CSPI's McDonald's litigation charges McDonald's with unfair and deceptive marketing for including toys in Happy Meals); Complaint at 2-3, *Ackerman v. Coca-Cola Co.*, No. 09-CV-0395 (E.D.N.Y. May 20, 2009), *available at* http://cspinet.org/new/pdf/vitaminwater_filed_complaint.pdf (CSPI's VitaminWater litigation charges Coca-Cola with fraudulent marketing for including claims of healthfulness on its VitaminWater products).

⁸ *See, e.g.*, William Neuman, *On Food Safety, a Long List but Little Money*, N.Y. TIMES (Aug. 22, 2011), <http://www.nytimes.com/2011/08/23/business/with-a-long-list-and-short-on-money-fda-tackles-food-safety.html?scp=5&sq=%22food%20safety%22%20fund&st=cse>.

⁹ The Food Safety Modernization Act (FSMA), signed by the President on January 4, 2011, addresses some of the problems with the regulatory system. It provides more power, and, theoretically, more funding to the Food and Drug Administration for its food-safety duties, and changes the food-safety focus of the agency from responsive to preventative. *See* Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011). It does not, however, address the inefficiencies or inconsistencies caused by the fact that multiple agencies have authority over food regulation, nor does it alter the fact that the agencies have political imperatives, *see, e.g.*, James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 962-72 (2008), and, in some instances, must balance the competing goals of economic viability of food production with the public health. *See, e.g.*, *Mission Statement*, U.S. DEP'T AGRIC., http://www.usda.gov/wps/portal/usda/usdahome?navid=MISSION_STATEMENT (last modified Oct. 29, 2009).

significant public health consequences, it is imperative to discuss alternatives to regulation as a means to improve the food-safety system in this country.

Advocacy group litigation can complement agency regulation in the field of food safety. And, just as such litigation enhances the enforcement of environmental laws, so too can advocacy group litigation add an element of “attentive monitoring” to food-safety statutes.¹⁰ This paper provides, for the first time, a comprehensive examination of advocacy group litigation, or food-safety-impact litigation,¹¹ in the food-safety context, assessing its viability and utility.

In evaluating the potential efficacy of food-safety-impact litigation, this paper puts particular focus on the barriers to justiciability that such litigation faces,¹² including standing challenges and justiciability issues under the Administrative Procedure Act.¹³ These threshold issues are particularly important here because plaintiffs in advocacy group litigation are not the direct objects of the regulation they target¹⁴ and because the injury to which they point is often an increased risk of future harm.¹⁵ Although the environmental laws contain structural legal elements, such as citizen-suit provisions and consultative arrangements, which food-safety laws do not, the absence of such

¹⁰ William H. Rodgers, Jr., *The Seven Statutory Wonders of U.S. Environmental Law: Origins and Morphology*, 27 LOY. L.A. L. REV. 1009, 1019-21 (1994). Rodgers explains that “attentive monitoring,” which contributes to the success of certain seminal environmental laws, comprises “personal activities such as face-to-face observation, emotions such as shame and pride, and group sanctions such as ostracism and citizen lawsuits.” *Id.* at 1020. He notes that these mechanisms are encouraged by structural legal changes. *Id.*

¹¹ This article defines food-safety-impact litigation as suits brought against food-safety regulatory agencies to improve the regulatory scheme for the purpose of protecting the public health in general and the plaintiff’s own health in particular. Impact litigation may be brought, for example, to contest an allegedly arbitrary and capricious denial of an administrative petition, or to argue that a final agency action was unreasonable.

¹² I confine my discussion here to cases brought by individuals or entities against regulatory agencies for the purpose of forcing the agency to comply with its statutory mandate by either passing regulation, or interpreting existing regulations differently.

¹³ Food-safety litigants suing private parties under state law or suing state government to enforce or strengthen state regulation must also negotiate federal preemption doctrine. Preemption issues, however, do not arise in litigation against the federal government, for obvious reasons, and I therefore leave a discussion of preemption issues to another paper.

¹⁴ See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992).

¹⁵ Impact litigation in the field of food safety is brought before an outbreak of foodborne illness, and seeks stronger regulation to prevent or minimize the chance of such an outbreak. For that reason, such litigation must be based on probabilities—the plaintiffs argue that it is x percent more likely that an outbreak of foodborne illness will take place with the current state of regulation than with the requested regulation.

provisions is not an insurmountable barrier to impact litigation.¹⁶ Thus despite these justiciability challenges, food-safety-impact suits are possible to bring, and possible to win.

Why, then, is there so little food-safety-impact litigation? Essentially, the answer is that there is no culture of citizen food-safety litigation, as there is for environmental-impact litigation. The environmental bar has spent decades learning to litigate around the justiciability barriers discussed in this paper, and courts have adapted many of these doctrines for the environmental context.¹⁷ But there is no food protection community practiced in the art of litigation against agency action and inaction.

For food-safety-impact litigation to be successful it must be modeled after environmental litigation. The doctrines developed by environmental-impact litigation provide an avenue for successful pre-illness food-safety litigation. Both food-safety and environmental-impact litigation depend on probabilities and involve great uncertainty. Governmental regulation of this uncertainty involves a negotiation of risk, cost-benefit analysis, public perception, and political reality. Both the environmental laws and the food-safety laws envision a joint state-federal system of enforcement. Moreover, the injury stemming from environmental or food-safety harms is likely to be widely shared, yet particularized. For this reason, the few courts that have actually dealt with food-safety-impact litigation look to environmental litigation as a backdrop,¹⁸ and mechanisms developed by litigants to maneuver environmental

¹⁶ I have spoken with several lawyers at public interest organizations who confirmed my inclination that food-safety cases can be successful. For example, Allison Zieve, the director of Public Citizen's Litigation Group, told me that these cases were no longer generated by anyone at her organization, and that she would be willing to consider such suits if litigable issues were brought to her attention. Telephone Interview with Allison Zieve, Dir., Pub. Citizen Litig. Grp. (Jan. 28, 2011) (notes on file with the author). I spoke with a former Associate Chief Counsel of the FDA, who asked not to be named, who told me that during his tenure at the FDA, which was during George W. Bush's administration, several of his colleagues and he wished there had been citizen litigation against the FDA. During these years, he explained, the agency was market oriented instead of food-safety oriented, and he felt that citizen litigation could have forced the agency's hand as to certain regulatory issues in the food-safety field.

Indeed the food-safety-impact litigation that does exist has a more than respectable success rate—out of thirteen cases, plaintiffs achieved at least some of their requested relief in three of the cases, and a fourth case was mooted when the agency adopted plaintiff's position during pendency of the suit.

¹⁷ See *Va. State Corp. Comm'n v. Fed. Energy Regulatory Comm'n*, 468 F.3d 845, 847-49 (D.C. Cir. 2006).

¹⁸ See, e.g., *Baur v. Veneman*, 352 F.3d 625, 634 (2d Cir. 2003); *Levine v. Johanns*, No. C 05-04764 MHP, No. C 05-05346 MHP, 2006 U.S. Dist. LEXIS 63667, at *14-31 (N.D. Cal. Sept. 6, 2006).

litigation past justiciability barriers are both necessary and useful for food-safety litigation.

This article begins a discussion of the parameters and implications of food-safety citizen and advocacy group litigation. Moreover, this article provides an added perspective on the need for courts to adapt traditional barriers to justiciability to the realities of litigation that involves injuries based on the possibility of future harm and the increase in risk associated thereof. Food safety involves issues on the frontier of regulation, including the need to address the role of lifestyle choice in conjunction with public health, and the need to regulate a massive system involving minutely local as well as global elements. Moreover, issues about food are increasingly in the forefront of public awareness. The understanding that advocacy-group litigation is possible and can be successful may be a valuable tool for this burgeoning movement.

Any expansion of the regulatory state carries challenges to its scope and authority as a counterpart to its growth. These challenges come both from proponents and opponents of regulation.¹⁹ As noted above, public challenges to the regulatory system will confront obstacles to litigation, as courts attempt to negotiate their role vis-à-vis this public litigation. Justiciability issues will be at the forefront of much public litigation in the coming years.

This article proceeds as follows: Part I summarizes the structure of the United States food regulatory system, and looks at some of the problems with agency enforcement and nonlegal sanctions. Part II discusses the absence of a culture of food-safety-impact litigation, addressing the nature of food and the divergent paths that environmental protection and food-safety regulation have taken in the United States. Part III turns to the justiciability barriers that food-safety-impact plaintiffs will face, and have faced in the few already litigated cases, focusing on constitutional and prudential standing issues, and reviewability challenges under the Administrative Procedure Act. This section concludes with an analysis of how food-safety citizen plaintiffs can successfully navigate the justiciability challenges they are sure to face. Finally, the

¹⁹ See, e.g., *Pub. Citizen Health Research Grp. v. U.S. Dep't of Labor*, 557 F.3d 165, 169 (3d Cir. 2009) (public interest group and union challenge Occupational Safety and Health Administration (OSHA) regulation for its underregulation of hexavalent chromium; industry group challenges the same regulation for its overregulation of same chemical).

article concludes that, under certain circumstances, citizen litigation can be a valuable counterpart to government regulation and spur regulatory agencies to fulfill their statutory mandates. Food-safety regulation, like environmental regulation, is a massive endeavor involving many agencies, statutes, regulated entities, and beneficiaries, and requiring vast resources. As citizen advocacy groups have acted as a counterpart to government regulation in the environmental arena, so could they be useful in the field of food safety.

I. AN OVERVIEW OF THE UNITED STATES FOOD REGULATORY SYSTEM

A. *The Regulatory Structure of Food Safety*

Food safety is mainly overseen by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), although several other agencies play a part as well.²⁰ Government regulation of food has historically had three main purposes: (1) to protect the integrity of the market; (2) to regulate the nutritional content of food; and (3) to protect the safety of the food supply.²¹ Although there is overlap among the three goals, the topic of this paper—impact litigation to minimize the threat of foodborne illness—is mostly contained within the third.²²

The FDA has authority under the Federal Food, Drug, and Cosmetic Act (FFDCA) over most food products except meat, poultry, and processed egg products.²³ The FFDCA, passed in

²⁰ The Environmental Protection Agency regulates drinking water and pesticide residues; the Federal Trade Commission shares jurisdiction over advertising; the Alcohol and Tobacco Tax and Trade Bureau regulates alcohol; the Centers for Disease Control and Prevention tracks foodborne illness; the National Marine Fisheries Service helps regulate fish and seafood products; the Customs Service regulates imported foods; and the Department of Justice prosecutes individuals and companies for violations of food-safety statutes. See NEAL D. FORTIN, *FOOD REGULATION* 24-27 (John Wiley & Sons, Inc. 2009).

²¹ Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 ANN. REV. NUTRITION 1, 2 (1984).

²² Protecting the food supply includes more than the prevention of foodborne illness. It can also involve measures to prevent external security threats, for example, intentional poisoning of the food supply, which I do not discuss in this article. See, e.g., Armen Keteyian, *Latest Terror Threat in U.S. Aimed to Poison Food*, CBS NEWS (Dec. 20, 2010, 11:48 PM), <http://www.cbsnews.com/stories/2010/12/20/eveningnews/main7169266.shtml>. Additionally, steps taken to protect the food supply may also protect the integrity of the market, and vice versa.

²³ 21 U.S.C. §§ 301-2252 (2006). The FDA does have authority, however, over imported wild game. See *Fact Sheets: Meat Preparation*, U.S. DEP'T AGRIC.,

1938, updated the 1906 Pure Food and Drug Act.²⁴ It has been substantially amended since 1938, but still retains its basic structure.²⁵ The 1938 FFDCAs has been described as “a catalogue of definitions elaborating two basic concepts: ‘adulteration’ and ‘misbranding.’”²⁶ The Act specifies when a food (or drug device or cosmetic) is adulterated or misbranded, and prohibits the distribution or sale of any such food.²⁷

To enforce the FFDCAs, the FDA has authority to institute various administrative, civil, or criminal actions. It can issue warning letters, request a voluntary recall of an adulterated product, order recalls under certain circumstances, seize products that violate the Act,²⁸ assess civil penalties,²⁹ and work with the Department of Justice to take court action.³⁰

The FDA Food Safety Modernization Act, signed into law in January 2011, is the biggest reform of the FDA’s food regulatory powers since 1938, and its implementation will reorient the FDA to take a preventative rather than a responsive role regarding food safety.³¹ The Act amends the FFDCAs to, among other things, give the FDA: (a) mandatory recall authority;³² (b) expanded authority to inspect records;³³ and (c) the authority to suspend the registration of a food facility.³⁴ The Act also requires owners and operators of food

http://www.fsis.usda.gov/Factsheets/Farm_Raised_Game/index.asp#4 (last modified May 27, 2011).

²⁴ Hutt, *supra* note 21, at 7.

²⁵ PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW* 14 (Foundation Press, 3d ed. 2007).

²⁶ *Id.* at 13.

²⁷ 21 U.S.C. §§ 331, 342, 343.

²⁸ *Id.* §§ 334, 350a(f)(2); FORTIN, *supra* note 20, at 510; *see also Inspections, Compliance, Enforcement, and Criminal Investigations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> (last updated Feb. 8, 2012).

²⁹ 21 U.S.C. § 335b.

³⁰ *Id.* § 337.

³¹ Certain provisions in the Act, such as the mandatory recall provisions, take effect immediately, while the FDA must write rules to implement other provisions of the Act. *See* Helena Bottemiller, *Q & A with Michael Taylor, Part I: Implementing FSMA*, FOOD SAFETY NEWS (Jan. 23, 2012), <http://www.foodsafetynews.com/2012/01/qa-with-michael-taylor-part-1-implementing-fsma/>. Implementation of the Act’s provisions and the FDA’s expanded powers also rests on whether adequate funding is provided by Congress, an issue that is in question. *See* Lyndsey Layton, *Overhaul of Food Safety Laws May Not Be to GOP’s Taste*, WASH. POST (Dec. 25, 2010), <http://www.washingtonpost.com/wp-dyn/content/article/2010/12/24/AR2010122402795.html>.

³² S. 510, 111th Cong. § 206 (2010) (amending scattered sections of 21 U.S.C.).

³³ *Id.* § 101 (amending 21 U.S.C. § 350c(a)).

³⁴ *Id.* § 102(b) (amending 21 U.S.C. § 350d(a)).

facilities to evaluate the hazards that could affect food,³⁵ and implement and monitor preventative controls.³⁶ Imported food will have to meet the same standards.³⁷ The FDA is also directed to increase inspections of domestic and foreign facilities, directing resources to the riskiest facilities.³⁸

The USDA shares authority over food safety with the FDA. Its Food Safety Inspection Service (FSIS) has authority over meat, poultry, processed egg products, and egg grading,³⁹ and it regulates products related to meat and poultry, including stews, pizzas, and frozen foods. The major food-safety statutes administered by the USDA are the Federal Meat Inspection Act (FMIA), passed in 1906⁴⁰ and amended in 1967 by the Wholesome Meat Act;⁴¹ the Poultry Products Inspection Act (PPIA);⁴² and the Egg Products Inspection Act (EPIA).⁴³ The FSIS, like the FDA, can issue warning letters and seize products under the FMIA and the PPIA.⁴⁴

Unlike food producers under the authority of the FDA,⁴⁵ however, meat-and-poultry producing establishments must have a USDA inspector present whenever they are operating.⁴⁶ Much of the FSIS's power over the food supply for which it is responsible stems from its ability to take a regulatory control action in relation to its inspection authority. Such actions include "the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically-identified product."⁴⁷ FSIS can also withhold a mark of federal inspection (without which a product

³⁵ Facilities will have to implement Hazard Analysis and Critical Control Point (HACCP) protocols, which the USDA has required of meat and poultry facilities since 2003. *See, e.g.*, Control of *Listeria Monocytogenes* in Ready-to-Eat Meat and Poultry Products, 9 C.F.R. § 430.4 (2003).

³⁶ S. 510, 111th Cong. § 103 (2010) (amending scattered sections of 21 U.S.C.).

³⁷ *Id.* §§ 301-309 (amending scattered sections of 21 U.S.C.).

³⁸ *Id.* §§ 201-211 (amending scattered sections of 21 U.S.C.).

³⁹ *About FSIS*, U.S. DEPT AGRIC. FOOD SAFETY & INSPECTION SERV., http://www.fsis.usda.gov/About_FSIS/index.asp (last visited Jan. 20, 2012).

⁴⁰ FORTIN, *supra* note 20, at 6.

⁴¹ 21 U.S.C. §§ 610-611 (2006); FORTIN, *supra* note 20, at 29.

⁴² 21 U.S.C. §§ 451-472.

⁴³ *Id.* §§ 1031-1056.

⁴⁴ *Id.* §§ 673, 467b.

⁴⁵ This may change, in that the FSMA directs the Secretary of the Department of Health and Human Services (HHS) to establish regulations concerning inspections for facilities under its authority. S. 510, 111th Cong. § 201 (2010).

⁴⁶ 9 C.F.R. § 302.3 (2010); FORTIN, *supra* note 20, at 567 ("FSIS inspects meat and poultry under a 'continuous inspection' system, which means that an inspector is assigned to every FSIS-regulated establishment and is required to be present when the establishment is in operation.").

⁴⁷ FORTIN, *supra* note 20, at 568.

cannot be distributed or sold), or suspend inspection at a certain facility.⁴⁸ If inspections are suspended at a facility, the facility must stop operating until the USDA reinstitutes inspections.⁴⁹ If a grant of federal inspection is withdrawn, a facility must cease operations completely.⁵⁰

B. *Enforcement Shortcomings*

Notwithstanding the imposing regulatory structure built to oversee food safety, and the recent enactment of the FSMA, our food regulatory system is falling short for several reasons. First, the bifurcation of major food regulatory duties between the FDA and the USDA results in inefficiencies, inconsistencies, and even some absurdities.⁵¹ For an oft-repeated example, pizza is regulated by the FDA unless it has a topping of more than 2 percent of cooked meat or poultry, in which case the USDA is in charge.⁵² For this reason, pizza production facilities are often regulated by both agencies.⁵³

Redundant oversight is clearly inefficient. But more dangerous to the consuming public is the possibility of inconsistency in the agencies' regulatory regimes. For example, eggs are subject to a baffling array of regulations and regulatory oversight, the result of which leaves gaps in food-safety enforcement.⁵⁴ Eggs were responsible for approximately 75

⁴⁸ 9 C.F.R. § 500.1-2.

⁴⁹ FORTIN, *supra* note 20, at 513.

⁵⁰ *Id.* at 514.

⁵¹ Consolidation of agency responsibilities, an often touted solution, is not only politically inviable at this time, but also may not actually fix the problems. *See, e.g., Note, Reforming the Food Safety System: What if Consolidation Isn't Enough?*, 120 HARV. L. REV. 1345, 1347 (2007) [hereinafter *Reforming the Food Safety System*].

⁵² *See Investigation Operations Manual*, FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/ICECI/Inspections/IOM/ucm127390.pdf> (last visited Jan. 10, 2012).

⁵³ *Reforming the Food Safety System*, *supra* note 51, at 1350 (citing INST. OF MED. NAT'L RESEARCH COUNCIL, ENSURING SAFE FOOD: FROM PRODUCTION TO CONSUMPTION 85 (1998)).

⁵⁴ *See* U.S. GEN. ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL COMMITTEES, FEDERAL FOOD SAFETY OVERSIGHT (2011), available at <http://www.gao.gov/new.items/d11289.pdf> ("FDA is generally responsible for ensuring that eggs in their shells—referred to as shell eggs—including eggs at farms such as those where the outbreak occurred, are safe, wholesome, and properly labeled. FSIS, on the other hand, is responsible for the safety of eggs processed into egg products. In addition, USDA's Agricultural Marketing Service (AMS) sets quality and grade standards for shell eggs, such as Grade A, but does not test the eggs for bacteria such as Salmonella. Further, while USDA's Animal and Plant Health Inspection Service manages the program that helps ensure laying hens are free from Salmonella at birth, FDA oversees the safety of the feed they eat.").

percent of all salmonella outbreaks between 1985 and 1998⁵⁵—although this percentage may be dropping due to a new egg-safety rule promulgated by the FDA in 2009⁵⁶—and the country was reminded of their potential dangerousness during the massive 2010 egg recall. There is also the possibility of inconsistency within one agency’s regulation of different products. For example, in one of the suits discussed below, poultry consumers sued the USDA over what they contended was irrationally inconsistent treatment of meat and poultry.⁵⁷

Funding for food safety is also a problem. The Center for Science in the Public Interest has noted that “[s]ince 1972, inspections conducted by the FDA declined 81 percent. Since 2003, the number of FDA field staff dropped by 12 percent, and between 2003 and 2006 federal inspections dropped by 47 percent.”⁵⁸ Although meat and poultry account for less foodborne illness than do seafood and fresh produce, which are regulated by the FDA, the USDA spends significantly more money on food safety than does the FDA.⁵⁹ Moreover, the FDA will not be able to implement the inspections mandated by the Food Safety Modernization Act if Congress withholds funding, as it has threatened to do.⁶⁰

Finally, there is a perception that both the FDA and the USDA are subject to agency capture, whereby regulated entities exert such an influence over their regulators that they essentially control the agencies, at the expense of the intended beneficiaries of the regulatory system.⁶¹ The prevalence of such

⁵⁵ U.S. GEN. ACCOUNTING OFFICE, GAO/T-RCED-99-184, FOOD SAFETY: U.S. LACKS A CONSISTENT FARM-TO-TABLE APPROACH TO EGG SAFETY 3-4 (1999), available at <http://www.gao.gov/products/RCED-99-184>.

⁵⁶ Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation, 74 Fed. Reg. 33,030 (July 9, 2009).

⁵⁷ See *infra* notes 245-47 and accompanying text.

⁵⁸ *Keep America’s Food Safe: The Case for Increased Funding at the FDA*, CENTER FOR SCI. IN THE PUB. INT., <http://www.cspinet.org/foodsafety/fdafunding.html> (last visited Jan. 12, 2012).

⁵⁹ See Helena Bottemiller, *Obama Boosts FDA Food Safety in FY2011 Budget*, FOOD SAFETY NEWS (Feb. 23, 2010), <http://www.foodsafetynews.com/2010/02/obama-boosts-food-safety-in-fy2011-budget/>.

⁶⁰ See, e.g., Molly Peterson, *Food-Safety Funding Battle Looms as Obama Prepares to Sign Reform Bill*, BLOOMBERG (Jan. 4, 2011, 12:01 AM), <http://www.bloomberg.com/news/2011-01-04/food-safety-funding-battle-looms-as-obama-prepares-to-sign-reform-bill.html>.

⁶¹ See, e.g., Nicholas Bagley, *Agency Hygiene*, 89 TEX. L. REV. SEE ALSO 1, 2, 8 n.32 (2010); William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1590-91 (2007) (“Agencies may be able to secure expanded budgets or even engage in outright favoritism to affected industry in exchange for the usual rewards of regulatory capture—electoral support for the

an industry viewpoint in the FDA and the USDA may produce lax enforcement and a reliance on industry self-regulation, even when it may not be the best approach for the public.⁶² This phenomenon can be explicit, where there is an actual flow of individuals between industry and decision-making regulatory positions, or implicit, which involves more attenuated but no less real connections between decision makers and industry.⁶³ Under some circumstances, citizen-impact litigation can address some of these regulatory shortcomings and be a useful counterpart to government regulation.

administration in power, revolving doors from agencies to industry, and a reduced risk of embarrassment that might result from more adversarial modes of regulatory exchange.”).

⁶² For example, the mission statement of the USDA contains a provision that makes such industry pressure a mandate, rather than an eventuality—the agency is charged both with expanding and protecting agricultural markets, as well as enhancing food safety. *Mission Statement*, U.S. DEP’T AGRIC., *supra* note 9. While in theory prevention of foodborne illness is entirely consistent with improving the economics of agriculture, the USDA’s main priority is split between economic development and public health. For another example, the *New York Times* recently reported that the USDA was assisting in the marketing of cheese, while simultaneously discouraging its consumption in an anti-obesity campaign. Michael Moss, *While Warning About Fat, U.S. Pushes Cheese Sales*, N.Y. TIMES, Nov. 6, 2010, at A1, available at <http://www.nytimes.com/2010/11/07/us/07fat.html?scp=1&sq=domino+cheese&st=nyt>.

As to the FDA, there is much scholarship on the effect that industry pressure has had on the FDA’s nutrition policy. See generally Emily J. Schaffer, *Is the Fox Guarding the Henhouse? Who Makes the Rules in American Nutrition Policy?*, 57 FOOD & DRUG L.J. 371 (2002) (collecting scholarship). And, regarding food safety, until the FSMA was passed, the FDA relied on voluntary recall for adulterated products. Market incentives support such a policy because industry is invested in the public perception of the safety of its products. Nevertheless, voluntary recall power does not remedy industry reluctance to insure the safety of its own food. See, e.g., Miriam Falco, *FDA: Peanut Plant Knew Product Was Tainted with Salmonella*, CNN (Jan. 28, 2009), http://articles.cnn.com/2009-01-28/health/salmonella.outbreak_1_peanut-corporation-salmonella-typhimurium-peanut-plant?_s=PM:HEALTH (Peanut Corporation of America shipped product it knew was tainted with salmonella). The FSMA does give the FDA mandatory recall authority, although recalls are still reactionary rather than precautionary.

⁶³ See Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1285 (2006). The question of whether agency capture is actually a problem, or more a perceived problem, and the effects thereof, has been amply discussed in legal scholarship. See, e.g., Thomas W. Merrill, *Capture Theory and the Courts*, 72 CHI.-KENT L. REV. 1039 (1997); Cass R. Sunstein, *What’s Standing After Lujan? Of Citizen Suits, “Injuries,” and Article III*, 91 MICH. L. REV. 163, 183-84 (1992-93); see also Bagley & Revesz, *supra*, at 1284-92 (arguing that the theory of regulatory capture does not adequately explain the reality of governmental agency processes).

II. THE ABSENCE OF AN IMPACT LITIGATION CULTURE IN THE CONTEXT OF FOOD SAFETY

Food-safety-impact litigation, however, is rare. Over the last forty years, fewer than twenty published cases fall into this category.⁶⁴

⁶⁴ I searched for cases by citizens or organizational plaintiffs against the government seeking to change regulation for the stated purpose of improving public health, as well as state and federal cases brought against the USDA, HHS, or the FDA since 1970 that concerned food safety, and found the following fourteen cases: *Levine v. Vilsack*, 587 F.3d 986 (9th Cir. 2009) (citizens brought suit against Secretary of Agriculture challenging rule excluding poultry from Humane Methods of Slaughter Act; Ninth Circuit dismissed for lack of Article III standing; discussed, *infra* Part III.B.2); *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. USDA*, 499 F.3d 1108 (9th Cir. 2007) (trade organization challenged USDA regulation of the importation of Canadian cattle; court deferred to agency; discussed, *infra* Part III.B.3); *Baur v. Veneman*, 352 F.3d 625 (2d Cir. 2003) (citizen sued USDA to challenge refusal to prohibit downed cattle from entering food supply; Second Circuit found standing; discussed, *infra* Part III.B.1); *Am. Fed'n of Gov't Emps., AFL-CIO v. Veneman*, 284 F.3d 125 (D.C. Cir. 2002) (organizations representing government employees challenged a new provisional inspection system instituted by the USDA of meat and poultry carcasses; court ultimately found that this new, but provisional and temporary system was adequate; standing not discussed); *Kenney v. Glickman*, 96 F.3d 1118 (8th Cir. 1996) (poultry consumers and red meat producers challenged alleged inconsistencies between regulation of meat and poultry; court found case reviewable under APA; discussed in detail, *infra* Part III.C); *Arent v. Shalala*, 70 F.3d 610 (D.C. Cir. 1995) (consumer and public interest groups challenged labeling of raw fish and produce; court found FDA's industry standard to be reasonable); *Simpson v. Young*, 854 F.2d 1429 (D.C. Cir. 1988) (consumer advocacy public interest group challenged FDA conclusion that a certain color additive was safe; court deferred to agency decision); *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987) (public interest groups and consumers sued the FDA for its promulgation of "action levels" instead of formal tolerance levels for aflatoxins, a carcinogen, in corn; after the United States Supreme Court decided tolerance levels were not necessary, Court of Appeals found the action levels nevertheless needed to be promulgated pursuant to notice and comment rulemaking; standing conceded "under the broad grant of standing" found in the FFDCa and the APA); *Nat'l Pork Producers Council v. Bergland*, 631 F.2d 1353 (8th Cir. 1980) (trade organizations representing pork producers and meat packers challenged new USDA regulations allowing certain products not cured with nitrates (such as hot dogs) to be sold under their traditional names; court found regulation valid); *Pub. Citizen v. Foreman*, 631 F.2d 969 (D.C. Cir. 1980) (consumer advocacy public interest group sought declaratory judgment that nitrites were an unsafe food additive; court held that nitrites fell under the prior sanction exception to FDA responsibility; discussed *infra* note 162); *Am. Pub. Health Assoc. v. Butz*, 511 F.2d 331 (D.C. Cir. 1975) (public health advocacy organization sued Secretary of Agriculture for allegedly violating the Wholesome Meat Act and the Wholesome Poultry Products Act by refusing to affix safe handling instructions to raw meat and poultry; court held that labels as currently written were not false and misleading); *Schuck v. Butz*, 500 F.2d 810 (D.C. Cir. 1974) (citizen sued the Secretary of Agriculture seeking repeal of regulations permitting the use of nitrates and nitrites in meat products; court held that appellants had to petition for a rulemaking); *Pub. Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1987) (consumer advocacy public interest group petitioned HHS for rule banning interstate sales of raw milk; court agreed with petitioners; discussed in detail, *infra* Part III.C); *Pub. Citizen v. Dep't of Health and Human Servs.*, 632 F. Supp. 220 (D.D.C. 1986) (consumer advocacy public interest group challenged provisional listing of nine color additives as safe for use; court held the listing to be consistent with

The paucity of citizen suits is not explained by the lack of citizen-suit provisions in the statutes regulating food safety,⁶⁵ nor by the absence of a private right of action under the FFDCFA,⁶⁶ the FMIA,⁶⁷ or the PPIA.⁶⁸ A viable alternative for plaintiffs is to sue under the Administrative Procedure Act (APA), which prescribes procedural safeguards and establishes judicial review over federal regulatory agencies.⁶⁹ And although such litigation will, and does, confront justiciability barriers—including challenges to standing and to the suits' justiciability under the APA—these barriers are surmountable. Food-safety citizen litigation can be brought, and can be won, as demonstrated by prior cases.

This is not to minimize the advantage that a statutory citizen-suit provision provides a plaintiff. Citizen-suit provisions generally permit “any person” to sue certain persons, including government officials, who violate certain legal obligations, or who fail to carry out nondiscretionary duties.⁷⁰ Judicial review over agency decision making is

human health, not unreasonably delayed under the APA, and the Delaney Clause challenge to be unripe). In all probability there are other such cases I could not find, and which most likely were dismissed at an early stage for lack of final agency action, or a similar procedural problem.

I did not include here a citizen suit challenging the FDA's decision to allow the use of certain color additive dyes in external cosmetic use, because cosmetics are not food. Nevertheless this suit involved an interpretation of the Delaney Clause, which prohibits the listing of color additives, ingested or not, if they are found to induce cancer in man or animal, and thus affects food safety. The citizen suit in this case was successful, in that the court determined that the FDA's reading of the Delaney Clause to permit a *de minimis* exception was unreasonable, and that the dyes therefore needed to be delisted. *Pub. Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987). Nor did I include the private litigation that CSPI has been involved in, although this certainly touches on food safety.

⁶⁵ See Poultry and Poultry Products Inspection Act, 21 U.S.C. §§ 451-472 (2006); Federal Meat Inspection Act, Egg Products Inspection Act, 21 U.S.C. §§ 601-695 (2006).

⁶⁶ See, e.g., *Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804, 806-07 (1986).

⁶⁷ See *Mario's Butcher Shop & Food Ctr., Inc. v. Armour & Co.*, 574 F. Supp. 653, 654 (N.D. Ill. 1983).

⁶⁸ See *Rogers v. Tyson Foods, Inc.*, 308 F.3d 785, 790 (7th Cir. 2002) (Poultry Products Inspection Act provides no private right of action).

⁶⁹ Section 702 of the APA provides that “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.” 5 U.S.C. § 702 (2006). Suits under this provision of the APA cannot be brought for money damages, but only for declaratory or injunctive relief, and must challenge “agency action made reviewable by statute and final agency action for which there is no adequate remedy in a court.” *Id.* § 704. Section 701 carves out two exceptions to judicial reviewability: (1) when “statutes preclude judicial review”; or (2) when “agency action is committed to agency discretion by law.” *Id.* § 701. Litigants bringing suit under section 702 of the APA must still meet constitutional and prudential standing requirements, including demonstrating injury in fact and meeting the zone of interests test, both described below.

⁷⁰ See, e.g., Clean Water Act, 33 U.S.C. § 1365 (2006); Clean Air Act, 42 U.S.C. § 7604 (2006); Endangered Species Act, 16 U.S.C. § 1540(g) (2006).

limited,⁷¹ and courts may be reluctant to delve too deeply into an agency's decision-making processes, especially if the decision at issue contains technical or scientific aspects.⁷² Whereas a plaintiff suing under a citizen-suit provision must show a violation of legal obligations under the relevant statute to win, a plaintiff suing pursuant to the APA must show that the agency's action was arbitrary and capricious.⁷³ But, as the presence of a citizen-suit provision does not guarantee a plaintiff's ability to bring suit, in that he or she must still satisfy the constitutional and prudential requirements of Article III, neither does the absence of such a provision foreclose food-safety-impact litigation.

Citizen-suit provisions also provide for attorney's fees to the prevailing party.⁷⁴ Although it may be possible for litigants against the federal government to be awarded fees and costs under other statutory provisions,⁷⁵ it is unrealistic to think that organizations dedicated to food safety and committed to impact litigation would rely on attorney-fee provisions for their survival in any event. Consider environmental organizations dedicated to impact litigation. Although the availability of attorney's fees may assist in perpetuating organizations funding environmental-impact litigation, these fees are not necessary to the survival of these groups, nor are they the focus of litigation. These organizations are instead sustained through private donations and grants.⁷⁶ Notably, environmental-impact litigation began before the passage of environmental legislation containing citizen-suit provisions.⁷⁷

⁷¹ See 5 U.S.C. § 706.

⁷² See Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 734 (2011).

⁷³ 5 U.S.C. § 706.

⁷⁴ See, e.g., 42 U.S.C. § 7604(d) (citizen suit provision of the Clean Air Act).

⁷⁵ See Equal Access to Justice Act, 28 U.S.C. § 2412(d)(1)(A) (2006) (allowing fees against the federal government "unless the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust."); see also *Hanover Potato Prods., Inc. v. Shalala*, 989 F.2d 123 (3d Cir. 1993) (holding that a coalition of fresh potato producers, which was the prevailing party in its litigation against the FDA regarding a regulation, was entitled to fees under the Equal Access to Justice Act).

⁷⁶ William W. Buzbee, *The Story of Laidlaw*, in ENVIRONMENTAL LAW STORIES 231 (Foundation Press 2005).

⁷⁷ See, e.g., *Scenic Hudson Pres. Conference v. Fed. Power Comm'n*, 354 F.2d 608 (2d Cir. 1965). The Natural Resource Defense Council began its environmental litigation work before the environmental laws were passed, sometimes using century-old statutes. See JOHN H. ADAMS & ET AL., A FORCE FOR NATURE 53 (Chronicle Books 2010) (describing NRDC litigation regarding stream channelization, brought pursuant to the 1899 Refuse Act).

Food safety significantly overlaps with environmental protection. Beyond the actual commonalities between the two subjects—i.e., more responsible stewardship of land will lead to a safer food supply; cleaner agriculture and husbanding practices result in cleaner land—both food safety and environmental protection involve compulsory and comprehensive participatory systems. Everyone has to breathe the air, drink the water, live on the earth, and somehow nourish themselves. Beyond that, of course, individual discretion exists as to where, how, and what, although the extent of this individual discretion varies according to numerous demographic factors.

There are certain key differences between food safety and environmental protection, however, which have led to a vigorous impact litigation culture in the context of environmental law, and a virtual absence of one in the context of food safety. These differences include: (a) the nature of food versus that of the environment, and (b) the disparate historical development of (i) the regulatory structures overlaying the food-safety system and the management of the environment, and (ii) the advocacy movements concerned with issues touching on food safety and with issues regarding environmental protection.

A. *The Nature of Food*

Although both food and the environment involve compulsory systems, an individual's relationship with each system is quite different. To begin with, there is no seemingly helpless entity in the food-safety context that needs an advocate on its behalf. Since its proposal in a law review article by Christopher Stone in 1972, and its citation in Justice Douglas's dissent in *Sierra Club v. Morton*, the concept of trees and rocks having standing to sue in American law is a concept that, although repeatedly mocked, has had remarkable resilience and has even been recently revived.⁷⁸ It is argued that, if inanimate objects and spaces cannot protect themselves in court, it stands to reason that advocates are needed to

⁷⁸ Christopher D. Stone, *Should Trees Have Standing? Toward Legal Rights for Natural Objects*, 45 S. CAL. L. REV. 450 (1972); see also *Sierra Club v. Morton*, 405 U.S. 727, 741-42 (1972) (Douglas, J., dissenting). On recent revival of the idea, see Noaki Schwartz, *Effort May Give Birds, Bees, Trees Legal Standing*, SFGATE.COM (Dec. 4, 2010), http://boston.com/news/local/maine/articles/2010/12/04/effort_may_give_birds_bees_trees_legal_standing/ (describing recent community ordinances giving nature legal standing).

represent them. No one, however, has argued that a tomato needs standing. Food itself is not perceived as requiring protection outside of its relationship to the human consumer. A consumer may choose to protect his consumption based on numerous factors—religious, cultural, economic, and health—but the food supply has no independent moral content. An exception to this is the prevention of animal cruelty, which is invested with a moral value beyond the consumption of animals by humans, and there is a vigorous tradition of advocacy surrounding the prevention of animal cruelty. The American Society for Prevention of Cruelty to Animals was founded in 1866, a quarter century before the founding of the Sierra Club. Animal welfare organizations have, in fact, brought a significant amount of the small body of existing food-safety impact cases.

Moreover, environmental protection is about the protection of physical space. Pre-harm environmental litigation is focused on protecting a particular space, whether it is an individual's home, or somewhere imbued with environmental value.⁷⁹ Geographic proximity to the area at issue allows a court a measurable index to assess actual injury.⁸⁰

Real property holds a unique and exalted place in American history and the American psyche, and consequently, in American law. The narrative of development in this country is one of territorial conquest, and the closing of the United States frontier in 1890 was a significant event.⁸¹ Property ownership has long been an American success symbol, fostered by governmental policies supporting homeownership.⁸² The law also

⁷⁹ See, e.g., *Sierra Club*, 405 U.S. at 728 (action by the Sierra Club to prevent recreational development in the Sequoia National Forest); *Forest Voice, LLC v. Town of Forest*, Civ. Action No. 11-CV-100, U.S. Dist. Ct., Western District of Wisconsin, complaint filed Feb. 9, 2011, available at <http://articles.law360.s3.amazonaws.com/0224000/224907/ee.pdf> (citizens sued an energy company over plans to build a wind turbine system in their town). Even pre-harm Endangered Species Act litigation concerns habitat protection. See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562-63 (1992).

⁸⁰ *Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc.*, 528 U.S. 167, 181-82 (2000).

⁸¹ See, e.g., FREDERICK JACKSON TURNER, *HISTORY, FRONTIER, AND SECTION* (University of New Mexico Press 1993). Turner claimed that the frontier was the most important force in American society, culture, and politics, and that its disappearance would gravely affect the national character and mindset.

⁸² See, e.g., 26 U.S.C. § 163 (2006) (provision of the Internal Revenue Code allowing a home mortgage interest deduction). Of course, the emphasis on home buying has come under scrutiny since the housing crisis. Binyamin Appelbaum, *Administration Calls for Cutting Aid to Home Buyers*, N.Y. TIMES, Feb. 11, 2011, at A1, available at <http://www.nytimes.com/2011/02/12/business/12housing.html?scp=2&sq=housing+crisis+>

treats property uniquely, above and beyond necessity. For example, if a court, either state or federal, takes jurisdiction over real property, it may be able to enjoin any other court from continuing adjudication of the same property.⁸³ Although the underlying policy reason behind this—to avoid inconsistent determinations over the same piece of property—is logical, it does not explain the absence of such safeguards over other adjudicatory subjects, such as bank accounts, where inconsistent judgments would carry the same detrimental consequences.⁸⁴

On the other hand, food is largely divorced from its origin—distributed and packaged as uniformly as possible so as to disguise any indication of where it is from. One of the hallmarks of our country's food distribution system is its centralization, and the inability to trace the origins of much of the domestic food supply is one of the obstacles to minimizing the effect of foodborne illness outbreaks.⁸⁵ Acknowledging this, the Food Safety Modernization Act includes a provision that enhances the capacity of the Secretary of Health and Human Services to trace food items for the purpose of improving the capacity of the government to detect and respond to food-safety problems.⁸⁶

The significance of food's ubiquity and non-fixedness is threefold. First, it may be difficult for courts to analogize to environmental law in finding particularized injury to fulfill Article III standing requirements for food-safety impact litigants because there is no analog to the category of geographic proximity. Second, food is seen as more fungible than pieces of land. If a consumer believes that the regulatory scheme overlaying a particular food product is unlawfully inadequate, he may choose another comestible, whereas a homeowner who believes an environmental agency is acting unlawfully may have no recourse but to sell her property. This may lead to decreased incentive to litigate for stronger

home+buying&st=nyt (discussing Obama administration's proposal to make buying homes more difficult for some Americans).

⁸³ See, e.g., *Mitchum v. Foster*, 407 U.S. 225, 235 (1972).

⁸⁴ See ERWIN CHEMERINSKY, *FEDERAL JURISDICTION* 746-47 (Wolters Kluwer, 5th ed. 2007).

⁸⁵ For example, cantaloupe grown on a Colorado farm caused a multi-state outbreak of listeria poisoning in 2011. Authorities had difficulty, however, determining to which states exactly the tainted cantaloupe were shipped, thus complicating the attempt to stem the outbreak. See, e.g., Michael Booth, *More States May Have Received Listeria-Contaminated Cantaloupe*, DENVER POST (Sept. 22, 2011, 3:35 PM), http://www.denverpost.com/breakingnews/ci_18955276.

⁸⁶ 21 U.S.C. § 2223 (2006).

regulation, because if an individual thinks chicken inspection is inadequate, that individual can choose not to buy chicken.⁸⁷

Third, because of the difficulty of knowing where one's food comes from, and the invisibility of the processes that led to its packaging in its current consumable form, citizens have less personal control over determining the source of any foodborne illness. One cannot see the pathogens that spread foodborne illness, nor is the consumer exposed to the production facility where the pathogen originated. By contrast, even if the pollutant itself targeted by environmental litigants is invisible, it is most likely that its origin is not.⁸⁸ This inability to self-trace in the food-safety context leads to the necessity for a reliance on experts and scientific evidence at an early stage of litigation, and is compounded in the case of impact litigation.

B. The Disparate Historical Development of Food Safety and Environmental Protection

Major milestones in American environmentalism, including developments in the governmental management of natural resources, as well as the ferment of citizen activity, coincide roughly with major milestones in the developments of a national food-safety regulatory regime. These milestones generally took place at times of urbanization and technological advancement, which led to actual threats on the country's natural resources and food supply, as well as to national anxiety regarding threats to traditional ways of life, and consequentially, to human health.

However, the regulatory and legislative structures developed very differently in the two fields. In the context of environmental protection, the government organized entities to manage natural resources but major environmental legislation was not passed until the early 1970s, whereas in the context of food-safety regulation, we see the amendment and supplementation of several major statutes that originated at the beginning of the twentieth century. We also see that, in environmental protection, citizen advocacy groups were always an important counterpart to governmental regulation, a situation that did not exist in the context of food safety.

⁸⁷ Of course, consumer choice is constrained by numerous factors, including cultural norms, economic realities, and governmental policy.

⁸⁸ See, e.g., *Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc.*, 528 U.S. 167, 182-83 (2000).

1. A Brief History of Environmental Protection in the United States

The first wave of American environmentalism took place at the turn of the twentieth century in reaction to a massive increase in immigration and urbanization.⁸⁹ From 1860 to 1890 the United States population increased from thirty-one million to seventy-five million people, and between 1860 and 1900 the number of people living in urban areas doubled from 20 percent to 40 percent.⁹⁰ In 1890, the United States Census Bureau declared the United States frontier officially closed, and in 1893, Frederick Jackson Turner articulated his famous thesis as to the effect of the frontier, and its closing, on American history.⁹¹ Urbanization resulted in the need for the American people to refashion their relationship with the natural resources of the country.

A small group of prominent intellectuals and public figures brought the perceived necessity for the conservation of the American wilderness to the nation's attention.⁹² The Sierra Club was founded in 1892, and the National Audubon Society in 1905. Theodore Roosevelt's administration embarked on a concerted campaign to forward the regulated use of resources towards the goal of the fullest use for the present generation.⁹³ Before Roosevelt left office in 1909, he worked with the head of the Forest Service and the secretary of the interior to withdraw over four million acres of the public domain from consideration for private sale.⁹⁴

In the 1930s, a series of natural disasters began to make apparent the consequences that could ensue from the unregulated exploitation of the nation's resources. For

⁸⁹ See MARK DOWIE, *LOSING GROUND: AMERICAN ENVIRONMENTALISM AT THE CLOSE OF THE TWENTIETH CENTURY* 8 (MIT Press 1995).

⁹⁰ ROBERT L. DORMAN, *A WORD FOR NATURE: FOUR PIONEERING ENVIRONMENTAL ADVOCATES, 1845-1913*, at 130 (University of North Carolina Press 1998).

⁹¹ See TURNER, *supra* note 81.

⁹² See STEPHEN FOX, *THE AMERICAN CONSERVATION MOVEMENT: JOHN MUIR AND HIS LEGACY* 110 (University of Wisconsin Press 1981). Historians of the American environmental protection movement divide the early twentieth century environmental movement into two strains, the conservationist—which measured nature's value according to its worth for mankind—and the preservationist—which was ecologic and biocentric. See *id.* at 108; JOSEPH M. PETULLA, *AMERICAN ENVIRONMENTALISM: VALUES, TACTICS, PRIORITIES* 26 (Texas A & M Press 1980).

⁹³ M. NELSON MCGEARY, *GIFFORD PINCHOT: FORESTER-POLITICIAN* 98 (Princeton University Press 1960); MICHAEL L. SMITH, *PACIFIC VISIONS: CALIFORNIA SCIENTISTS AND THE ENVIRONMENT 1850-1915*, at 174-82 (Yale University Press 1987).

⁹⁴ MCGEARY, *supra* note 93, at 116-17.

example, the dust storms of the 1930s, which rendered nine million acres of formerly arable land unusable by 1938, were partly the result of haphazard farming practices.⁹⁵ After World War II, several organizations concerned with conserving the country's natural resources became involved in major, and public, environmental battles,⁹⁶ and these organizations, including the Sierra Club and the Wilderness Society, had over three hundred thousand members by 1960.⁹⁷

It was not until the publication of Rachel Carson's monumentally influential book *Silent Spring* in 1962, however, that the American populace was galvanized to the cause of environmental protection. *Silent Spring* addressed the effects of DDT and other pesticides on human health and the environment.⁹⁸ The book was on the *New York Times* bestseller list for thirty-one weeks and sold over a half million hardcover copies.⁹⁹

The 1960s also saw the advent of strategic environmental litigation brought by public interest groups as administrative law challenges. Beginning with the 1965 case *Scenic Hudson Preservation Conference v. Federal Power Commission*, in which the Second Circuit allowed citizens standing to sue under the Federal Power Act to overturn three orders of the Federal Power Commission based on their "interest in the aesthetic, conservational, and recreational aspects of power development,"¹⁰⁰ newly formed environmental groups aggressively sought judicial review of administrative action.¹⁰¹ The organizations bringing these challenges faced hurdles, especially regarding their standing to sue (although *Scenic Hudson* was a milestone in that regard), but pursued suits nonetheless.¹⁰²

Inspired by this movement, a flood of environmental legislation was passed in the early 1970s.¹⁰³ Congress intended

⁹⁵ DONALD WORSTER, *NATURE'S ECONOMY: A HISTORY OF ECOLOGICAL IDEAS* 221-53 (Cambridge University Press 2d ed. 1994).

⁹⁶ KIRKPATRICK SALE, *THE GREEN REVOLUTION: THE AMERICAN ENVIRONMENTAL MOVEMENT, 1962-1992*, at 5 (Hill & Wang 1993).

⁹⁷ *Id.* at 5-6.

⁹⁸ RACHEL CARSON, *SILENT SPRING* (Houghton Mifflin Co. 1994) (1962).

⁹⁹ SALE, *supra* note 96, at 4.

¹⁰⁰ 354 F.2d 608, 616 (2d Cir. 1965).

¹⁰¹ David Sive, *The Litigation Process in the Development of Environmental Law* (1995 Garrison Lecture), 19 PACE ENVTL. L. REV. 727, 731 & n.20 (2002) (listing pre-NEPA environmental cases).

¹⁰² A. Dan Tarlock, *The Story of Calvert Cliffs*, in ENVIRONMENTAL LAW STORIES 81 (Foundation Press 2005).

¹⁰³ This legislation includes the National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-4370f (2006); the Clean Air Act of 1970, 42 U.S.C. §§ 7401-7671q (2006);

citizens and advocacy groups to have a role in enforcing the new environmental legislation,¹⁰⁴ and these statutes contain citizen-suit provisions, a legal mechanism encouraging citizen actions against polluters. These powerful provisions permit “any person” to sue certain persons, including government officials, who violate certain legal obligations, or who fail to carry out nondiscretionary duties.¹⁰⁵ The remedies available in such suits are injunctive relief, civil penalties—which go to the federal treasury, and the recovery of attorney’s fees and costs.¹⁰⁶ The citizen-suit provisions were written into environmental laws partly to encourage the very litigation that was already taking place.¹⁰⁷

2. A Brief History of Food-Safety Regulation in the United States

The urbanization of the country that took place at the turn of the twentieth century also resulted in massive changes to the relationship between individuals and the food supply. Consolidation of the food supply and the creation of distribution networks became necessary to feed large populations of people who could not grow their own food. The end of the nineteenth century also saw extensive development in food science, especially in the creation of new food additives.¹⁰⁸ At that time, only certain imported foods were subject to federal regulation—all other food regulation was state and local.¹⁰⁹

Public awareness of the need for national regulation was raised during the late nineteenth century by the head of the U.S. Bureau of Chemistry, Harvey W. Wiley, M.D., who campaigned

the Federal Water Pollution Control Act of 1972, 33 U.S.C. §§ 1251-1387 (2006); the Resource Conservation and Recovery Act of 1972, 42 U.S.C. §§ 6901-6992k (2006); and the Endangered Species Act of 1973, 16 U.S.C. §§ 1531-1544 (2006).

¹⁰⁴ Indeed, environmental organizations assisted in the drafting of certain of the new statutes. *See* ADAMS ET AL., *supra* note 77, at 51, 53 (explaining how two members of the Natural Resources Defense Council helped to draft the 1977 amendments to the Clean Air Act); Tarlock, *supra* note 102, at 92 n.51 (recounting the influence of Myron Cherry, an important anti-nuclear lawyer in the 1970s, on the drafting of NEPA and its legislative history).

¹⁰⁵ *See, e.g.*, Clean Water Act, 33 U.S.C. § 1365 (2006); Clean Air Act, 42 U.S.C. § 7604; Endangered Species Act, 16 U.S.C. § 1540(g).

¹⁰⁶ It is important to keep in mind, however, that the existence of a citizen-suit provision does not satisfy Article III standing requirements; a litigant must still show injury-in-fact, causation, and redressability before her suit may proceed. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562, 571-78 (1992).

¹⁰⁷ ADAMS ET AL., *supra* note 77, at 27.

¹⁰⁸ FORTIN, *supra* note 20, at 5.

¹⁰⁹ Hutt, *supra* note 21, at 6.

for a federal food and drug law. The press also began to expose some safety problems with commonly used food preservatives and dyes.¹¹⁰ A series of damaging newspaper articles about the food industry as well as the publication in 1905 of Upton Sinclair's *The Jungle* garnered public support for the national regulation of the food supply, and in 1906, Congress passed the Pure Food and Drug Act and the Meat Inspection Act.¹¹¹ The Food and Drug Act was to be administered by the Bureau of Chemistry within the USDA, and the FMIA by the Bureau of Animal Industry, also within the USDA.¹¹²

The focus of each of the 1906 acts was to prevent the adulteration of food, and the Food and Drugs Act included the prohibition of additives that would be deleterious to human health as well as of substances that would dilute the product for the purpose of making the food cheaper to produce.¹¹³ The Meat Inspection Act prohibited adulterated or misbranded livestock products to be sold as food, and also mandated the improvement of sanitation at slaughtering facilities, in response to Sinclair's book.¹¹⁴

The Bureau of Chemistry was split in 1927, with regulatory functions, including responsibility for the 1906 Act, taken over by the Food, Drug, and Insecticide Administration (which became the FDA in 1930).¹¹⁵ Responsibility for the Meat Inspection Act was not transferred, however, and authority for its enforcement remained within the Department of Agriculture. FDA officials began advocating for the modernization of the 1906 Act in 1933,¹¹⁶ but passage of a new bill was stalled until 1938.¹¹⁷ Precipitating passage of the 1938 Federal Food, Drug, and Cosmetics Act (FFDCA) was the death of over one hundred people in 1937 who had taken an antibiotic that had been mixed with a sweet substance to improve its

¹¹⁰ FORTIN, *supra* note 20, at 5-6. Wiley established a "Poison Squad"—a group of volunteers who consumed food additives, including boric acid and formaldehyde, to assess their effects on the human body. *Id.* at 5; see also *About FDA: Milestones in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/default.htm (last visited Jan. 13, 2012).

¹¹¹ FORTIN, *supra* note 20, at 6.

¹¹² Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 78-79 (2000).

¹¹³ Hutt, *supra* note 21, at 6.

¹¹⁴ FORTIN, *supra* note 20, at 6.

¹¹⁵ *About FDA: 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 visited Jan. 13, 2012).

¹¹⁶ Hutt, *supra* note 21, at 7.

¹¹⁷ HUTT, MERRILL & GROSSMAN, *supra* note 25, at 13.

taste, but had never been tested for safety.¹¹⁸ In 1940, the FDA was transferred from the USDA to the Federal Security Agency, and in 1988, to the Department of Health and Human Services, with a commissioner of food and drugs appointed by the President with the advice and consent of the Senate.¹¹⁹

Since 1938, the FFDCA has been amended hundreds of times.¹²⁰ Significantly, during World War II, food processing technology was developed to preserve and transport food for war, and this massive alteration in the general food supply led to public concern about the addition of synthetic ingredients and potential carcinogens to the food supply.¹²¹ The FDA reacted by passing the 1958 Food Additives Amendment and the 1960 Color Additive Amendment. The 1970s and 1980s saw such food-safety amendments to the FFDCA as the Low-Acid Food Processing Regulations (1973).¹²² The Nutritional Labeling and Education Act was passed in 1990.¹²³

As to meat and poultry, the Poultry Products Inspection Act (PPIA) was passed by Congress in 1957 in response to a rapidly expanding poultry industry, which was also developing poultry processing techniques. In 1967, the FMIA was amended as the Wholesome Meat Act, which requires the inspection of all meat, and the PPIA was amended in 1968. In 1971, the Animal and Plant Health Inspection Service, a division of the USDA, was charged with meat and poultry inspection, and this was assigned to the Food Safety and Quality Service in 1977. The Food Safety and Quality Service became the Food Safety and Inspection Service (FSIS) in 1981.¹²⁴

Food-safety advocates have never embraced impact litigation as a way to achieve food-safety goals. Even food-safety organizations claiming to use litigation as a strategy to achieve their goals use it sparingly. For example, the Center for Food Safety, which was established in 1997, and is a “non-profit public interest and environmental advocacy membership

¹¹⁸ *Id.*; FORTIN, *supra* note 20, at 6.

¹¹⁹ *About FDA: Significant Dates in U.S. Food and Drug Law History*, *supra* note 115.

¹²⁰ See HUTT, MERRILL & GROSSMAN, *supra* note 25, at 14-15.

¹²¹ FORTIN, *supra* note 20, at 7; HUTT, MERRILL & GROSSMAN, *supra* note 25, at 393-94. Concern about carcinogens and pesticides was also, at this time, galvanizing the environmental movement.

¹²² Low Acid Regulations, 21 C.F.R. §§ 108.25, 108.35 (2010).

¹²³ FORTIN, *supra* note 20, at 8.

¹²⁴ *About FSIS: Agency History*, U.S. DEP'T AGRIC. FOOD SAFETY & INSPECTION SERV., http://www.fsis.usda.gov/About_Fsis/Agency_History/index.asp (last modified Nov. 7, 2011).

organization [that] combines multiple tools and strategies in pursuing its goals, including litigation and legal petitions for rulemaking,¹²⁵ is listed as a party in fewer than forty cases since its founding.¹²⁶ The Center for Science in the Public Interest, an influential consumer advocacy organization focused on improving public health, nutrition, and food safety, is listed as a party in under twenty cases since its founding in 1971.¹²⁷ By comparison, since its founding in 1967, the Environmental Defense Fund is listed as a party in approximately 280, and since 1970, the year of its founding, NRDC is listed as a party in over 750 cases. Since 1997, when the Center for Food Safety was founded, the NRDC is listed as a party in over 400 cases.¹²⁸

This comparison of impact litigation in the realms of environmental protection and food safety serves to illustrate how environmental advocates and food-safety advocates have different approaches to advocacy and effective means of change.¹²⁹ It is crucial to emphasize that the difference cannot be explained by the lack of citizen-suit provisions in the food-safety laws. As mentioned above, the passage of environmental legislation in the 1970s was not the beginning of environmental-impact litigation. Although environmental-impact litigation accelerated greatly after the passage of environmental legislation, strategic litigation had been imagined and implemented in the decade prior, as environmental advocacy organizations, both old and new, began to litigate to protect the environment.¹³⁰

¹²⁵ *About Us*, CENTER FOR FOOD SAFETY, <http://www.centerforfoodsafety.org/about> (last visited Apr. 14, 2012).

¹²⁶ Result yielded from a Westlaw search performed on April 14, 2012. See WESTLAW, <http://westlaw.com> (search “ti(‘Center for Food Safety’)” in the “allcases” database “after 1/1/1997”).

¹²⁷ In 2005, CSPI hired Stephen Gardner to direct its food-safety litigation, which is focused on private litigation against companies that refuse to take action to improve food safety. This strategy has been remarkably successful in improving the food safety of market-leading companies, as well as improving relationships between these companies and advocacy organizations, such as CSPI. Telephone Interview with Stephen Gardner (Jan. 5, 2011).

¹²⁸ Results yielded from a Westlaw search performed on April 14, 2012. See WESTLAW, <http://westlaw.com> (search “ti(‘Environmental Defense Fund’)” in the “allcases” database “after 1/1/1967”; “ti(‘Natural Resources Defense Council’)” in the “allcases” database “after 1/1/1970”; and “ti(‘Natural Resources Defense Council’)” in the “allcases” database “after 1/1/1997”).

¹²⁹ See, e.g., Sive, *supra* note 101, at 729 (“In no other political and social movement has litigation played such an important and dominant role [as in the environmental movement].” (citation omitted)).

¹³⁰ ADAMS & ET AL., *supra* note 77, at 53; Tarlock, *supra* note 102, at 82 n.15; Sive, *supra* note 101, at 731.

Nor can the disparity be explained by pointing to the superior funding of the environmental advocacy groups—although the NRDC was founded in part with money from the Ford Foundation, this money was granted after the idea to focus on litigation was formed, not before.¹³¹ It may be impossible to actually identify why food-safety litigation is not a prevalent form of advocacy and activism, but it is important to note that the absence of the development of such a tradition was not dictated by legal constraints, nor prescribed by social circumstances.

III. JUSTICIABILITY BARRIERS TO FOOD-SAFETY-IMPACT LITIGATION

Food-safety-impact litigation faces difficulties getting into court because it involves multiple—including associational—parties, probabilistic harms, widely-shared harms, and requests for prospective relief. The judicial system is still struggling to adapt traditional doctrines of justiciability to such litigation, even though such litigation has been ongoing in various contexts since at least the middle of last century.¹³² Although it is relatively uncontroversial that suits based on uncertain injury *can* be heard by federal courts,¹³³ the questions of who can bring such suits, when they are ready for suit, and where the suits can be brought are still vigorously contested, with the answers changing by jurisdiction, and over time. These questions of who, when, and where must be determined before courts can reach the merits.

The justiciability barriers most likely to be faced by food-safety impact litigants are standing challenges and challenges to justiciability under the APA.¹³⁴

A. *Standing*

Standing determines whether a federal court litigant is the proper party to bring the suit before the court.¹³⁵ The notion

¹³¹ ADAMS & ET AL., *supra* note 77, at 17-24.

¹³² All social justice litigation falls into this model, including litigation in the fields of civil rights and environmental protection.

¹³³ *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967); *Brandt v. Vill. of Winnetka*, 612 F.3d 647 (7th Cir. 2010).

¹³⁴ Although ripeness and mootness challenges in this context are conceivable, indeed likely, I focus here on the actual cases and the barriers with which courts have actually grappled when dealing with this type of litigation.

of standing has both constitutional and prudential dimensions. A court must first determine if the litigant meets the criteria of Article III: (1) whether the litigant has suffered an injury-in-fact, which must be “concrete and particularized,” and “actual or imminent”; (2) whether the alleged injury is fairly traceable to the harm targeted; and (3) whether the remedy sought is likely to redress the alleged injury.¹³⁶ Prudential concerns include prohibitions against the litigation of generalized grievances and litigating the rights of third parties, and determining whether the litigant is within the zone of interests of the statute at issue.¹³⁷

In 1992, the Supreme Court made it more difficult for impact plaintiffs to establish standing, even when they are suing pursuant to a citizen-suit provision. In *Lujan v. Defenders of Wildlife*, the Court denied standing to several environmental organizations challenging a regulation as violating the Endangered Species Act.¹³⁸ The Court found that the organizations did not adequately allege injury in fact.¹³⁹ Justice Scalia, writing for the majority, wrote, “when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily ‘substantially more difficult’ to establish.”¹⁴⁰

Most significantly, the decision prohibited Congress from statutorily creating a legal injury and thereby bestowing standing upon citizens.¹⁴¹ The Court held that a citizen-suit provision did not eliminate the need for a plaintiff to show that she has sustained direct and personal injury.¹⁴² In *Lujan*, the

¹³⁵ For a comprehensive discussion and critique of the separation of powers rationale for the standing doctrine, see Heather Elliott, *The Functions of Standing*, 61 STAN. L. REV. 459 (2008).

¹³⁶ See, e.g., *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Whether these three criteria actually stem directly from Article III, or are themselves judge-made and perhaps misguided, is a matter of discussion among commentators. See, e.g., William A. Fletcher, *The Structure of Standing*, 98 YALE L.J. 221, 229 (1988); Sunstein, *supra* note 63, at 185-86. Nevertheless, used as they have been as Article III criteria for the last four decades, they are, at this point, accepted as constitutional.

¹³⁷ See, e.g., *Allen v. Wright*, 468 U.S. 737, 751 (1984).

¹³⁸ *Lujan*, 504 U.S. at 578.

¹³⁹ A plurality of the Court also found that the plaintiffs had not established redressability. *Id.* at 568-71.

¹⁴⁰ *Id.* at 562 (citation omitted).

¹⁴¹ The Court explained that Congress could still create legally cognizable injuries, i.e., it could “elevat[e] to the status of legally cognizable injuries concrete, *de facto* injuries that were previously inadequate in law.” *Id.* at 578. What Congress could not do was “abandon . . . the requirement that the party seeking review must himself have suffered an injury.” *Id.* (citation omitted).

¹⁴² *Id.* at 573.

Court of Appeals had held that the organizational petitioners had adequately alleged injury in fact because they alleged a procedural injury—that the Secretary of the Interior had failed to consult as required by the ESA—and that this procedural injury was adequate because of the citizen-suit provision, even if the petitioners failed to allege a personal injury.¹⁴³ The *Lujan* Court rejected this view, explaining that

[t]o permit Congress to convert the undifferentiated public interest in executive officers' compliance with the law into an "individual right" vindicable in the courts is to permit Congress to transfer from the president to the courts the Chief Executive's most important constitutional duty, to "take Care that the Laws be faithfully executed."¹⁴⁴

The Court held that a litigant must show that she herself had suffered "injury in fact," and had a tangible and concrete stake, beyond the vindication of a right as a citizen, in the outcome of the case.¹⁴⁵

By requiring a showing of personalized injury-in-fact even when alleging procedural injury, the Court in *Lujan* made it significantly more difficult for the beneficiaries of regulation to protect their interests. Commentators predicted that citizen-suit environmental litigation would be severely restricted, or even eliminated, and the environmental advocacy community began to plan different tactical routes toward the enforcement and strengthening of environmental litigation.¹⁴⁶ The Court reinforced its strict interpretation of Article III standing in *Steel Co. v. Citizens for a Better Environment*, which held that plaintiffs did not have Article III standing based on a lack of redressability when the violations for which the plaintiffs sued had occurred solely in the past.¹⁴⁷

The standing cases of the late 1980s and early 1990s demonstrate a general tightening of standing law and a trend toward the restriction of access to courts for regulatory beneficiaries in public law litigation. This trend did not, however, reflect a unified court, nor consensus among the justices, and in the late 1990s the Court began to relax its approach to standing.

¹⁴³ *Id.* at 571, 572.

¹⁴⁴ *Id.* at 577.

¹⁴⁵ *Id.* at 575-78.

¹⁴⁶ Buzbee, *supra* note 76, at 214-20.

¹⁴⁷ *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 109-10 (1998).

In *Friends of the Earth, Inc. v. Laidlaw Environmental Services*, the Court, with a vigorous dissent by Justice Scalia, the author of the *Lujan* and *Steel Co.* decisions, backed away from the broadest implications of the *Lujan* decision, and granted standing to several environmental organizations that had instituted a citizen suit against a company for alleged Clean Water Act violations.¹⁴⁸ The Court held that the availability of civil penalties against the company was adequate to provide redressability for the citizen plaintiffs because of the potential that such penalties would deter future violations, although injunctive relief against the company was not available because the company had ceased violations since the commencement of the litigation.¹⁴⁹ Distinguishing *Steel Co.*, the Court explained that in *Laidlaw* the violations had not ceased prior to suit as in *Steel Co.*, but had been ongoing at the time suit was commenced.¹⁵⁰ Moreover, the Court found that the absence of evidence of injury to the environment was irrelevant to the injury-in-fact analysis because the plaintiffs were harmed by the lessening of the aesthetic and recreational values of the area.¹⁵¹

After the Court's movement away from its extremely restrictive standing decisions of the early 1990s, it appears that citizen suits were once again viable. *Laidlaw* and other contemporaneous cases¹⁵² signaled the Court's return to deference to legislatively defined injuries, and thereby wedged the doors to the courtroom back open for legislative beneficiaries.¹⁵³

The Court's decision in *Massachusetts v. EPA* further affirmed this trend. In *Massachusetts v. EPA*, the Court found that Massachusetts had standing to challenge the EPA's refusal to regulate greenhouse gas emissions from motor

¹⁴⁸ 528 U.S. 167 (2000).

¹⁴⁹ *Id.* at 173-74.

¹⁵⁰ *Id.* at 187-88.

¹⁵¹ *Id.* at 181.

¹⁵² See *Fed. Election Comm'n v. Akins*, 524 U.S. 11 (1998).

¹⁵³ In *Akins*, a group of voters had challenged a Federal Election Commission's determination that the American Israel Public Affairs Committee (AIPAC) was not a "political committee" as defined by statute, and, consequentially, that AIPAC did not have to disclose certain information. See *id.* at 13-14. The Court held that the petitioners had standing to challenge the FEC's determination because Congress had specifically granted such parties the right to sue; the statute in question contained a provision that "any person who believes a violation of this Act . . . has occurred, may file a Complaint with the Commission." *Id.* at 19 (citing 2 U.S.C. § 437g(a)(1) (1971)). The Court wrote that "[t]he 'injury in fact' that respondents have suffered consists of their inability to obtain information . . . that, on respondents' view of the law, the statute requires that AIPAC make public." *Id.* at 21.

vehicles under the Clean Air Act.¹⁵⁴ The Court provided Massachusetts with “special solicitude in [the] standing analysis” based on its sovereign status,¹⁵⁵ but also found, with a potentially wide reach, that climate-change risks pose a concrete and particularized injury to Massachusetts as a landowner, even though the harm may be widely shared, and that the alleged injury (global warming) would be lessened by the requested remedy (a reduction in motor vehicles emissions), if not eliminated.¹⁵⁶ The full reach of the Court’s standing and redressability analyses remains to be seen.¹⁵⁷

The zone-of-interests test is also significant in any discussion of food-safety-impact litigation. This test is a prudential standing requirement fashioned by the Supreme Court providing that the interest alleged by the plaintiff must arguably be within the zone of interests protected by the statute or constitutional provision at issue.¹⁵⁸ To satisfy this test, congressional intent to benefit the plaintiff is not required.¹⁵⁹ In 1997, the Supreme Court found that the citizen-suit provision of the Endangered Species Act negated the zone-of-interests test in relation to that statute.¹⁶⁰ In the same case, the Court also noted the “generous review provisions” of the APA, and clarified that the zone-of-interests test should be assessed, not in relation to the overall purpose of the statute at issue, but rather in relation to the specific provision relied upon.¹⁶¹

B. *Standing in Food-Safety-Impact Litigation*

Standing is a critical issue in food-safety-impact cases. Three of the six post-1992 decisions in food-safety impact cases

¹⁵⁴ Massachusetts v. E.P.A., 549 U.S. 497 (2007).

¹⁵⁵ For a discussion of the potential implications of the Court’s reliance on Massachusetts’ sovereign status in its standing analysis, see Amy J. Wildermuth, *Why State Standing in Massachusetts v. EPA Matters*, 27 J. LAND RESOURCES & ENVTL. L. 273 (2007).

¹⁵⁶ *Massachusetts*, 549 U.S. at 518-23, 525.

¹⁵⁷ Maxwell L. Stearns argues that the Roberts Court will continue to expand standing doctrine in *Standing at the Crossroads: The Roberts Court in Historical Perspective*, 83 NOTRE DAME L. REV. 875 (2008).

¹⁵⁸ See, e.g., *Allen v. Wright*, 468 U.S. 737, 751 (1984).

¹⁵⁹ *Nat’l Credit Union Admin. v. First Nat’l Bank & Trust Co.*, 522 U.S. 479, 492 (1998).

¹⁶⁰ *Bennett v. Spear*, 520 U.S. 154, 166 (1997). It is unclear whether this holding applies to all statutes with citizen-suit provisions or is confined to the ESA. See, e.g., *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Dep’t of Agric.*, 415 F.3d 1078, 1102 n.17 (9th Cir. 2005).

¹⁶¹ *Bennett*, 520 U.S. at 163 (citation omitted).

that I found involved standing issues.¹⁶² Each of these cases was a challenge to agency action or inaction brought for the ostensible purpose of minimizing the risk of foodborne illness in the United States. One survived a motion to dismiss by demonstrating injury in fact, the second survived an injury in fact challenge only to be dismissed for a lack of redressability, and the third had one of its claims dismissed because the plaintiffs failed to show that they were within the zone of interests protected by the statute.

1. Using Increased Risk of Harm as a Means to Show Injury-in-Fact in Food-Safety-Impact Cases

Plaintiffs in food-safety-impact suits must find a way to show that they have suffered concrete and particularized injury from the challenged regulation although they have not contracted a foodborne illness.¹⁶³ Although they may represent themselves as a consumer of the regulated food, they must show that their grievance is more than a generalized one.¹⁶⁴ Several courts have held that an allegation of increased risk of injury due to a challenged agency action suffices to show such a concrete and particularized injury, but this trend has mainly, although not always, been confined to the environmental context. In *Baur v. Veneman*, however, a 2003 case regarding mad cow disease, the Second Circuit reversed the district court's dismissal of the case for lack of Article III standing, finding that increased risk of harm—based on the increased

¹⁶² See *supra* note 64. I confined my discussion to post-1992 cases because cases involving a standing analysis but decided pre-1992 are less useful in determining whether food-safety-impact litigation is currently viable. For example, in *Public Citizen v. Foreman*, a 1980 case, a public interest organization and several of its members sought a declaratory judgment from both the FDA and the USDA that nitrites were an unsafe food additive, especially in bacon, but faced a standing challenge. The D.C. Circuit found plaintiffs' allegation that nitrite-free bacon was not available at a reasonable price to be an adequate injury-in-fact. 631 F.2d 969, 974 n.12 (D.C. Cir. 1980). Post *Lujan*, the court may have more strictly analyzed plaintiffs' standing. Whether such an injury would be sufficiently concrete or particularized is unclear. Moreover, whether such an injury is the type protected by the relevant statutes is also ambiguous, and the plaintiffs may have failed the prudential zone-of-interests standing test.

¹⁶³ Particularized means that "the injury must affect the plaintiff in a personal and individual way." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 n.1 (1992).

¹⁶⁴ This is not to say that the asserted injury may not be widely shared. A widely shared harm may still be a particularized one. See, e.g., *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 24 (1998) ("[W]here a harm is concrete, though widely shared, the Court has found 'injury in fact.'").

risk of contracting a foodborne disease—satisfied the injury in fact requirement in the context of food and drug safety suits.¹⁶⁵

The plaintiff in this case, Michael Baur, challenged the USDA's and the FDA's allowance of "downed" cattle into the food supply.¹⁶⁶ "Downed" cattle are cattle that are too sick to stand or walk before slaughter, and, at the time, USDA regulations allowed downed cattle to enter the food supply after inspection. Baur alleged that downed cattle were more likely to carry transmissible spongiform encephalopathies (TSEs), which are progressive neurological diseases.¹⁶⁷ The most common of these is bovine spongiform encephalopathy (BSE), which is known as "mad cow disease."¹⁶⁸ Baur claimed that the downed cattle policy violated both the FMIA and the FFDCA.

After Baur's petition to the USDA and the FDA was denied, he brought suit in district court under the APA seeking judicial review of the FSIS's decision.¹⁶⁹ Baur claimed standing

¹⁶⁵ Baur v. Veneman, 352 F.3d 625, 628 (2d Cir. 2003).

¹⁶⁶ In 1998, Michael Baur and Farm Sanctuary, Inc., an animal protection organization, filed a petition with the USDA and the FDA requesting that the agencies "label all downed cattle as adulterated," under the Federal Food, Drug, and Cosmetic Act (FFDCA), Section 342(a)(5). *Baur*, 352 F.3d at 628. This section of the FFDCA provides that any food that is "the product of a diseased animal" is adulterated. 21 U.S.C. § 342 (a)(5) (2006). The FFDCA prohibits the manufacture, delivery, receipt, or introduction of adulterated food "into interstate commerce." *Id.* § 331.

¹⁶⁷ *Baur*, 352 F.3d at 627-28.

¹⁶⁸ *Id.* at 627.

¹⁶⁹ Michael Baur originally brought suit with Farm Sanctuary, Inc., an animal welfare organization. Farm Sanctuary claimed that its members were injured when they observed the treatment of animals at slaughterhouses. The district court dismissed Farm Sanctuary's claims because it had failed to state an interest within the zone of interests of the FMIA. Farm Sanctuary did not appeal its dismissal on standing grounds, and the Second Circuit opinion only discusses Baur. For that reason, I refer only to Baur, although he was joined by Farm Sanctuary at early stages of the litigation. *See* Farm Sanctuary, Inc. v. Veneman, 221 F. Supp. 2d 280, 284-85 (S.D.N.Y. 2002).

Note that there is no requirement in the Article III injury-in-fact standing inquiry that the plaintiff's alleged reason for bringing suit is genuine. The court does not address whether Baur's alleged injury—increased risk of foodborne illness—is genuine, or, in other words, if that is Baur's real motive for being before the court, which in this case, was open to question. Farm Sanctuary is a prominent animal protection organization, founded in 1986 by Gene Baur "to combat the abuses of factory farming and to encourage a new awareness and understanding about 'farm animals.'" *About Us*, FARM SANCTUARY, <http://farmsanctuary.org/about/> (last visited Jan. 13, 2012). The organization opposed what it saw as the unusually cruel practice of dragging a cow that has collapsed on the way to the slaughterhouse to be killed. Robert Terenzi, Jr., *When Cows Fly: Expanding Cognizable Injury-in-Fact and Interest Group Litigation*, 78 FORDHAM L. REV. 1559, 1561 (2009). Many of the members of Farm Sanctuary, however, were vegan. For this reason, Michael Baur, Gene Baur's brother and a Fordham Law professor, joined the case to provide a meat-eating plaintiff. *Id.* A court may delve deeper into a plaintiff's asserted reason for bringing suit if there is a disjunction between an association's stated reason and the main purposes for the association's existence. If the association's purpose for existence does not fall into the zone of interests protected by the statute at issue, the association's suit may be

based on his status as a consumer of meat who was at increased risk of contracting a foodborne illness because of the USDA's policies regarding downed cattle.¹⁷⁰ The district court dismissed Baur's claims for lack of Article III standing, finding that because there was, as yet, no evidence of BSE in the United States, the harm that he alleged was too speculative and not sufficiently particularized to support standing.¹⁷¹

The Second Circuit reversed. First, the court held that Baur's increased risk of harm claim was capable of satisfying the injury in fact requirement.¹⁷² Baur sued under the FMIA and the FFDCFA, and the court recognized that the purpose of these statutes is, in part, to protect the nation's food supply and minimize the risk from dangerous food.¹⁷³ There was a "tight connection" between the injury alleged and the allegedly violated statutes.¹⁷⁴ The court explained that

[a]lthough this type of injury has been most commonly recognized in environmental cases, the reasons for treating enhanced risk as sufficient injury-in-fact in the environmental context extend by analogy to consumer food and drug safety suits. Like threatened environmental harm, the potential harm from exposure to dangerous food products or drugs "is by nature probabilistic," yet an unreasonable exposure to risk may itself cause cognizable injury.¹⁷⁵

The court also found that Baur had shown that he himself faced a credible harm because "the probability of harm which a plaintiff must demonstrate in order to allege a cognizable injury-in-fact logically varies with the severity of the probable harm."¹⁷⁶ Thus because of the severity of contracting

dismissed for lack of standing. See *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Dep't of Agric.*, 415 F.3d 1078, 1103-04 (9th Cir. 2005).

¹⁷⁰ *Baur*, 352 F.3d at 630.

¹⁷¹ *Id.* at 631.

¹⁷² *Id.* at 636.

¹⁷³ *Id.* at 634-35.

¹⁷⁴ See William A. Fletcher, *The Structure of Standing*, 98 YALE L.J. 221 (1988). Fletcher advocates a return to the "legal interest" test for standing, which asks only whether the plaintiff has a legal right bestowed by the legal provision under which he is suing, and if so, does not require an injury in fact. He writes that the APA was meant to provide a flexible standing rule, and that if a litigant bases suit on a statute, the court should look to the relevant statute to determine whether the litigant should have standing, not whether the litigant has suffered an "injury in fact." *Id.* at 255-65. Although not throwing over the injury in fact requirement, the Second Circuit's decision in *Baur* incorporates Fletcher's viewpoint by looking at the degree of connection between the injury alleged and the statutes implicated.

¹⁷⁵ *Baur*, 352 F.3d at 634 (citing *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 160 (4th Cir. 2000)).

¹⁷⁶ *Id.* at 637. The court explained that although the standard was lenient at the pleading stage, the plaintiff could still not rely on conclusory allegations to show standing. *Id.* This analysis may have been different had the case been decided after the

mad cow disease, which is fatal and has no known cure, the court held that the increase in risk may be moderate for standing purposes. The court found the fact that Baur's allegations were supported by government studies supported his claim for standing, as did the fact that his alleged increased risk of harm resulted from an "established governmental policy."¹⁷⁷ Incidentally, after the Second Circuit decision in *Baur* was filed, on December 23, 2003, a cow in Washington State was diagnosed with BSE.¹⁷⁸ Soon thereafter, the USDA passed a regulation banning downed cattle from the food supply,¹⁷⁹ and the case became moot.

While increased risk of harm is a widely recognized basis for injury in fact, it is not entirely uncontroversial.¹⁸⁰ The *Baur* Court commented that "the courts of appeals have generally recognized that threatened harm in the form of an increased risk of future injury may serve as injury-in-fact for Article III standing purposes," and that "[w]ithout questioning standing, the Supreme Court has decided cases in which it appeared to assume that enhanced risk may cause real injury."¹⁸¹ However, as mentioned above, increased risk of harm has rarely been used outside of environmental law cases. Indeed, the Second Circuit refused to sanction the doctrine generally, but instead held only that "[i]n the specific context of

United States Supreme Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), which instructed district courts that a plaintiff needed factual allegations that "raise a right to relief above the speculative level," and must "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 555, 570. Lower courts are now grappling with the implications of applying the "plausibility standard," to determinations regarding challenges to subject matter jurisdiction, including standing challenges. See, e.g., *Coal. for a Sustainable Delta v. Fed. Emergency Mgmt. Agency*, 711 F. Supp. 2d 1152 (E.D. Cal. 2010); *Eugster v. Wash. State Bar Ass'n*, No. CV 09-357-SMM, 2010 WL 2926237 (W.D. Wash. July 23, 2010).

¹⁷⁷ *Baur*, 352 F.3d at 637. The dissent in *Baur* argued that Baur had not shown that he himself faced a credible harm of contracting BSE. The dissenting Judge found the absence of evidence of BSE in the United States to be particularly significant, and wrote that although Baur may be correct in his allegations that the USDA should act differently to prevent an outbreak of BSE in the country, he "cannot properly use this Court as vehicle to advance the claims to proper policy." *Id.* at 652.

¹⁷⁸ *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Dep't of Agric.*, No. 05-35264, 2005 U.S. App. LEXIS 17360, at *18 (9th Cir. Aug. 17, 2005).

¹⁷⁹ 9 C.F.R. § 309.2(b) (2010). For a discussion of the USDA's regulatory response to mad cow disease, and an argument that the agency has acted incompetently and inefficiently, see Jason R. Odesho, *No Brainer? The USDA's Regulatory Response to the Discovery of Mad Cow Disease in the United States*, 16 STAN. L. & POL'Y REV. 277 (2005).

¹⁸⁰ For a discussion of whether risk itself is a harm, see Claire Finkelstein, *Is Risk a Harm?*, 151 U. PA. L. REV. 963 (2003).

¹⁸¹ See *Baur*, 352 F.3d at 633 & n.7 (listing cases).

food and drug safety suits . . . we conclude that such injuries are cognizable for standing purposes, where the plaintiff alleges exposure to potentially harmful products.”¹⁸²

The Second Circuit cited cases from the Fourth Circuit, the Seventh Circuit, the Ninth Circuit, and the D.C. Circuit to show the general acceptance of increased risk of harm as a basis for Article III standing. All of the cited cases, except those in the Seventh Circuit, were in the environmental context.¹⁸³ And although it has recognized that increased risk can be a basis for standing, the D.C. Circuit has taken a strict view of whether increased risk of harm constitutes injury in fact. In *Natural Resources Defense Council v. Environmental Protection Agency*, the court vacated its earlier decision which had dismissed NRDC’s petition for lack of standing.¹⁸⁴ In this case, NRDC sued the EPA, charging that the agency’s issuance of a rule establishing exemptions from an international treaty that mandated the reduction of the use of methyl bromide—a substance that degrades the ozone layer—violated both the treaty and the Clean Air Act.¹⁸⁵ The court initially held that NRDC’s claim that its members faced a greater chance of contracting skin cancer and other illnesses under the EPA rule was too hypothetical to constitute injury-in-fact.¹⁸⁶ NRDC moved for rehearing, and both NRDC and EPA, in its opposition to the petition for rehearing, presented new

¹⁸² *Id.* at 634.

¹⁸³ *Id.* at 633. Courts have occasionally recognized increased risk of harm as a basis for Article III standing in contexts outside of environmental law. For example, in *Sutton v. St. Jude Medical S.C., Inc.*, 419 F.3d 568 (6th Cir. 2005), the Sixth Circuit permitted a plaintiff’s allegation of an increased risk of harm from the implantation of a medical device that required current medical monitoring to constitute injury in fact. The court accepted plaintiff’s analogy to cases where plaintiffs have been exposed to toxins (i.e., nuclear emissions or asbestos) and have an increased risk of disease. *Id.* at 571. Courts in the Second Circuit have also permitted an allegation of increased risk of harm to satisfy the injury in fact requirement when a plaintiff claims an “increased future risk of identity theft,” see *Caudle v. Towers, Perrin, Forster & Crosby, Inc.*, 580 F. Supp. 2d 273, 279 (S.D.N.Y. 2008), an increased risk of being assessed penalties because of reliance on fraudulent tax advice, see *Denney v. Deutsche Bank AG*, 443 F.3d 253, 264-65 (2d Cir. 2006) (“An injury-in-fact may simply be the fear or anxiety of future harm. For example, exposure to toxic or harmful substances has been held sufficient to satisfy the Article III injury-in-fact requirement even without physical symptoms of injury caused by the exposure, and even though exposure alone may not provide sufficient grounds for a claim under state tort law.”), and an increased risk of injury based on the defendant’s failure to secure plaintiff prisoner’s wheelchair properly when he was being transported. *Shariff v. Goord*, 04-CV-6621 CJS(F), 2006 U.S. Dist. LEXIS 49957, at *10, *20 (W.D.N.Y. July 20, 2006).

¹⁸⁴ 464 F.3d 1 (D.C. Cir. 2006), *vacating* 440 F.3d 476 (D.C. Cir. 2006).

¹⁸⁵ *Natural Res. Def. Council v. EPA*, 440 F.3d 476 (D.C. Cir. 2006).

¹⁸⁶ *Id.* at 484.

information regarding the risk to NRDC's members from the EPA's rule.¹⁸⁷ In response to this new information, the D.C. Circuit found that NRDC did have standing.¹⁸⁸ Based on the EPA's own expert estimate, the court calculated that two to four of NRDC's five hundred thousand members would develop cancer as a result of the rule—a risk the court considered sufficient to support standing.¹⁸⁹

In *NRDC*, the court expressly did not decide whether it was appropriate to take a quantitative approach to determining whether an increased risk of injury constituted injury in fact.¹⁹⁰ The court repeated its refusal to decide whether any increase in risk was enough for standing shortly thereafter in *Virginia State Corp. Commission v. Federal Energy Regulatory Commission*, but cabined this open question to environmental disputes, stating that “[o]utside the realm of environmental disputes . . . we have suggested that a claim of increased risk or probability cannot suffice.”¹⁹¹

The D.C. Circuit clarified its position on increased risk in the non-environmental context a year later, in 2007, in *Public Citizen, Inc. v. National Highway Traffic Safety Administration*.¹⁹² In *Public Citizen*, petitioners—including a citizens group, tire makers, and a tire industry association—challenged a federal motor vehicle safety standard requiring cars to contain tire pressure monitors that lit up when the tire pressure fell below a set standard.¹⁹³ The court asked for supplemental briefing on whether the challenged standard “creates a substantial increase in the risk of death, physical injury, or property loss,” over the alternative interpretation, and whether the risk of harm, including the alleged increase, was substantial.¹⁹⁴ The court noted that it had only allowed standing in increased risk of harm cases when both of these factors were present, noting that there were several reasons

¹⁸⁷ *Natural Res. Def. Council*, 464 F.3d at 3.

¹⁸⁸ *Id.* at 7.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 6-7. After deciding NRDC had standing, the court dismissed the case on the merits. *Id.* at 11.

¹⁹¹ *Va. State Corp. Comm'n v. Fed. Energy Regulatory Comm'n*, 468 F.3d 845, 848 (D.C. Cir. 2006). In this case the court found that it “need not face those issues here,” because petitioner, who had argued that its investors faced an increased risk of incorrectly evaluating the company's financial health, made no showing adequate to explain their position. *Id.*

¹⁹² *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279 (D.C. Cir. 2007).

¹⁹³ *Id.* at 1284.

¹⁹⁴ *Id.* at 1297.

why standing should not be allowed lightly in probabilistic cases: (1) allowing injury based on speculative injury would allow judicial review of any agency action because almost all agency action slightly increases risk or, according to citizen preference, insufficiently decreases risk; (2) speculative injury standing would eliminate the requirement that an injury be “actual or imminent” from the standing requirements; and (3) such cases would cause the judiciary to infringe on the Executive’s responsibility to “take care” that the laws were faithfully executed by expanding its role beyond the hearing of actual cases or controversies.¹⁹⁵ Not surprisingly, the court found that Public Citizen did not meet its burden in its supplemental briefing and dismissed its claims.¹⁹⁶

The United States Supreme Court appeared to accept probabilistic harm, characterized as increased risk of injury, as support for standing in the environmental context in *Massachusetts v. EPA*.¹⁹⁷ Although the Court noted that “rising seas have already begun to swallow Massachusetts’ coastal land,” it emphasized that

[t]he severity of that injury will only increase over the course of the next century: If sea levels continue to rise as predicted, one Massachusetts official believes that a significant fraction of coastal property will be “either permanently lost through inundation or temporarily lost through periodic storm surge and flooding events.” Remediation costs alone, petitioners allege, could run well into the hundreds of millions of dollars.¹⁹⁸

¹⁹⁵ *Id.* at 1295.

¹⁹⁶ *Pub. Citizen, Inc. v. Nat’l Highway Traffic Safety Admin.*, 513 F.3d 234, 235-36 (D.C. Cir. 2008). See Amanda Leiter, *Substance or Illusion? The Dangers of Imposing a Standing Threshold*, 97 GEO. L.J. 391 (2009) (arguing that the D.C. Circuit’s imposition of a substantiality-of-risk threshold is unsupported by any theoretical foundation, and is the wrong approach to determining which increased-risk cases should be justiciable).

¹⁹⁷ See Robin Kundis Craig, *Removing “The Cloak of a Standing Inquiry”*: *Pollution Regulation, Public Health, and Private Risk in the Injury-in-Fact Analysis*, 29 CARDOZO L. REV. 149, 194-96 (2007) (discussing the majority’s acceptance of probabilistic harm as a basis for standing); Jonathan Remy Nash, *Standing and the Precautionary Principle*, 108 COLUM. L. REV. 494 (2008) (arguing for “precautionary-based standing,” in which the precautionary principle is applied to the standing analysis and in cases where there is uncertainty about whether irreversible and catastrophic events will occur). *But c.f.* Leiter, *supra* note 196, at 402 (arguing that *Massachusetts v. EPA* does not sanction the use of probabilistic harm as a basis for standing, especially not for individual (versus sovereign) plaintiffs).

¹⁹⁸ *Massachusetts v. EPA*, 549 U.S. 497, 521 (2007) (citation omitted).

The Court's characterization of Massachusetts' standing relies heavily, if not exclusively, on these allegations of future injury.¹⁹⁹

Increased risk of harm as a basis for standing is a critical tool for food-safety-impact litigants, and whether their claims are successful may depend on whether the courts they are before permit increased risk of harm claims in cases outside of environmental disputes, and whether the court views food-safety issues as either a subset of or analogous to environmental disputes. The possibility of reaching the merits of the case in such litigation will also depend on whether the court applies a quantitative assessment to increased risk, or assumes that any increased risk is adequate.²⁰⁰

2. The Necessity of Third-Party Action May Thwart Redressability

In *Levine v. Vilsack*, another food-safety-impact case, the court found that standing failed on redressability grounds rather than injury-in-fact grounds. Here, the district court accepted plaintiffs' allegations of increased injury of harm as a basis for Article III standing, but the Court of Appeals found that plaintiffs did not have standing to challenge a USDA Notice because even if the plaintiffs prevailed in court, the requested relief was only available through a series of speculative steps and the actions of third-parties.²⁰¹ For this reason, plaintiffs failed to satisfy the redressability prong of the standing inquiry.

In 2005, several individual plaintiffs and several associational plaintiffs (the "Levine Plaintiffs") brought suit in federal district court, challenging a USDA Notice ("Notice") issued earlier that year, which stated that the slaughter of poultry is not governed by any federal standard. The Levine Plaintiffs alleged that the Notice was contrary to law, specifically to the APA, and to the Humane Methods of Slaughter Act (HMSA), a 1958 statute that provided that "cattle, calves, horses, mules, sheep, swine, and other livestock"

¹⁹⁹ In this regard, see Justice Roberts' dissent: "[A]ccepting a century-long time horizon and a series of compounded estimates renders requirements of imminence and immediacy utterly toothless. . . . 'Allegations of possible future injury do not satisfy the requirements of Art. III. A threatened injury must be *certainly impending* to constitute injury in fact.'" *Id.* at 542 (Roberts, C.J., dissenting) (citations omitted).

²⁰⁰ Once again, as mentioned *supra* in note 176, it also remains to be seen how courts negotiate the plausibility standard of *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

²⁰¹ *Levine v. Johanns*, 587 F.3d 986, 993-95 (9th Cir. 2009).

must be humanely slaughtered.²⁰² In 1978, parts of the HMSA were incorporated into the Federal Meat Inspection Act (FMIA), which had the effect of prohibiting federal inspection of meat that had not been slaughtered in compliance with the humane slaughter methods dictated by the HMSA.²⁰³ Meat that is not federally inspected cannot enter the marketplace. The 1978 version of the HMSA retained the section of the 1958 HMSA that listed the types of animals that must be humanely slaughtered, which included “other livestock.”²⁰⁴ The Levine Plaintiffs argued that because the 1958 HMSA was still in force, the Notice—which said that no federal standard applied to poultry—was construing “other livestock” to exclude poultry, which was an arbitrary and capricious interpretation. Because of the Notice, argued the Levine plaintiffs, poultry was being slaughtered inhumanely.²⁰⁵

The associational plaintiffs were nonprofit organizations that worked to prevent cruelty to animals, and they brought suit challenging the Notice on behalf of their members, who were also listed as individual plaintiffs, and who were characterized as “regular consumers of poultry meat.” The Levine Plaintiffs alleged that inhumane methods of slaughter increased the possibility that the poultry would be contaminated by bacteria, thereby increasing their risk of illness each time they ate inhumanely slaughtered poultry.²⁰⁶

²⁰² 7 U.S.C. § 1902(a) (2006).

²⁰³ 21 U.S.C. § 610(b) (2006).

²⁰⁴ *Levine v. Johanns*, No. C 05-04764 MHP, No. C 05-05346 MHP, 2006 U.S. Dist. LEXIS 63667, at *3 (N.D. Cal. Sept. 5, 2006). Confusingly, however, the 1978 HMSA, while not repealing the section of the 1958 HMSA applying humane slaughter standards to “other livestock,” also stated that humane slaughter standards only applied to “cattle, sheep, swine, goats, horses, mules, and other equines.” 21 U.S.C. § 610(b).

²⁰⁵ *Levine*, 2006 U.S. Dist. LEXIS 63667, at *4-5.

²⁰⁶ *Id.* at *5. These plaintiffs were joined by several workers in poultry processing plants and two organizations that represented workers. They alleged physical and emotional injuries from working in plants where poultry is slaughtered inhumanely. *Id.* at *6-7.

After this case was filed, the court related it with another case challenging the USDA’s failure to apply humane slaughter requirements to bison and reindeer. Plaintiffs in this case alleged that they regularly ate bison and reindeer meat, and were therefore at increased risk of contracting food poisoning whenever they ate meat that had been inhumanely slaughtered. *Id.* at *9. The court dismissed the Bison plaintiffs’ complaint with prejudice, concluding that the USDA did not have a non-discretionary duty to apply the humane slaughter requirements to bison and reindeer, and the APA challenge therefore failed. *Id.* at *46-50. Section 706(1) of the APA provides for a court to “compel agency action unlawfully withheld or unreasonably delayed,” 5 U.S.C. § 706(1) (2006), and to bring an action under this section, a plaintiff must show that “an agency failed to take a *discrete* agency action that it is *required to take*.” *Levine*, 2006 U.S. Dist. LEXIS 63667, at *46 (quoting *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004)).

The district court found that the individual plaintiffs established the requirements of Article III standing: injury-in-fact, traceability, and redressability.²⁰⁷ The allegation that certain individual plaintiffs were at an increased risk for illness was neither too generalized, nor too speculative to constitute injury-in-fact.²⁰⁸ As long as a harm “is separate from an interest in having the government abide by the law,” it “may be concrete even though it is widely shared,” explained the court.²⁰⁹ Moreover, the court found there to be a “credible” threat that the plaintiffs would suffer concrete harm in the future, which it found sufficient to satisfy the imminence prong of the injury-in-fact inquiry.²¹⁰ Analogizing to *Baur*, the court found the plaintiffs’ claims credible because they relied on the USDA’s own studies showing that bacterial contamination was more likely when inhumane slaughtering methods were used.²¹¹

The court dismissed the claims of the Levine associational plaintiffs with leave to amend because they had failed to satisfy the requirements for associational standing. For an organization to have standing to sue on behalf of its members, it must show that: (1) “its members would otherwise have standing to sue in their own right,” (2) “the interests at stake are germane to the organization’s purpose,” and (3) “neither the claim asserted nor the relief requested requires the participation of individual members’ in the lawsuit.”²¹² The organizations in the lawsuit had asserted the interest of protecting their members’ health, although the actual main purpose of the organization was to prevent animal cruelty.²¹³

²⁰⁷ Although the court dismissed the Bison plaintiffs’ complaint for lack of jurisdiction under the APA, it held that all of the plaintiffs, including the animals, had Article III standing, but that the animals lacked statutory standing as the APA only applied to “person[s].” *Levine*, 2006 U.S. Dist. LEXIS 63667, at *45.

²⁰⁸ *Id.* at *14-31. John Does I and II were found to have Article III standing based on their allegations of physical and emotional injuries. *Id.* at *32.

²⁰⁹ *Id.* at *15 (citing *FEC v. Akins*, 524 U.S. 11, 24-25 (1998)).

²¹⁰ *Id.* at *29.

²¹¹ *Id.* at *20-21.

²¹² See *Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

²¹³ One of the organizational plaintiffs was permitted to continue because it stated that it was dedicated partly to consumer protection and human health. *Levine*, 2006 U.S. Dist. LEXIS 63667, at *37-39. The court also found the challenged Notice to constitute a final agency action which was subject to judicial review. The *Levine* plaintiffs challenged the Notice under APA section 706(2), which provides that a court can “hold unlawful and set aside agency action, findings and conclusions” that are “arbitrary” or “capricious.” 5 U.S.C. § 706(2)(a) (2006). To be set aside under this section, an agency action must be discrete and final, and to be final, an action must “(1) ‘mark the consummation of the agency’s decision making process’ and not be tentative, and (2) have legal consequences.” *Levine*, 2006 U.S. Dist. LEXIS 63667, at *52 (citing

Subsequently, the district court granted summary judgment to defendants, ruling that “Congress intended to exclude poultry from the categorical word ‘livestock.’”²¹⁴ Plaintiffs appealed, and the Ninth Circuit vacated the district court’s decision, remanding the case for the district court to dismiss based on the plaintiffs’ lack of Article III standing. The Ninth Circuit did not question the district court’s injury-in-fact analysis,²¹⁵ but found instead that none of the plaintiffs could show that their alleged injury could be redressed by any ruling of the court. Because the HMSA had no enforcement mechanism, any decision of the court would have to be followed by a series of steps to reach the plaintiffs’ desired result of the use of more humane poultry slaughter methods, all of which steps were speculative. If the court ruled that the Notice was contrary to law and poultry should be included as “other livestock,” the Secretary would have to determine that poultry should fall under the FMIA’s umbrella, and then issue regulations for the humane slaughter of poultry. Furthermore, private processors would then have to follow these regulations. Because of the speculative nature of each of these steps, the court found the likelihood of relief to be too low to satisfy the redressability prong of Article III.²¹⁶

Bennett v. Spear, 520 U.S. 154, 177-78 (1997)). The court determined that the Notice constituted final agency action. *Id.* at *61.

The court also ordered that the *Levine* plaintiffs show cause as to why the claims of the workers, EJC, and WNCWC should not be dismissed for improper venue. *Id.* at *65.

²¹⁴ *Levine v. Conner*, 540 F. Supp. 2d 1113, 1121 (N.D. Cal. 2008). It appears that the *Levine* individual plaintiffs—characterized by the court as “poultry eaters concerned about food-borne illness”—and the organizations representing the workers were the only plaintiffs left. *Id.* at 1113.

²¹⁵ The absence of a discussion regarding injury-in-fact most likely shows that the Ninth Circuit accepts that a “credible” increase in risk suffices as injury-in-fact. In this regard, see also *Central Delta Water Agency v. United States*, 306 F.3d 938, 947 (9th Cir. 2002) (“[T]he possibility of future injury may be sufficient to confer standing on plaintiffs; threatened injury constitutes ‘injury in fact.’”).

²¹⁶ *Levine v. Vilsack*, 587 F.3d 986, 988, 993-95, 997 (9th Cir. 2009). The redressability point was not as clear cut as the Ninth Circuit represented. The court concluded that the chain of events that would have to take place to remedy plaintiffs’ injury (the increased risk of foodborne illness) was too speculative to satisfy the Article III standing requirements, supposing that if the court construed “other livestock” to include poultry, the Secretary of Agriculture would still need to enforce the humane slaughter mechanisms in the FMIA and write regulations to do so. The court also noted that poultry processors would then have to adhere to the regulations. However, if one instead assumes that the Secretary will follow the legislative mechanism, then an inclusion of poultry in the HMSA humane slaughter mandate would lead inevitably to poultry’s inclusion in the FMIA, and the writing of regulations to govern its humane slaughter. Moreover, the inclusion of poultry in the definition of “other livestock” would surely relieve the injury to plaintiffs, which was the failure to include poultry in this definition, even if its ultimate effectiveness in ensuring humane slaughter requirements was delayed. *See, e.g.,*

In *Levine*, the associational plaintiffs failed to satisfy the requirements for associational standing because the interest that they asserted was not germane to the organization's purpose. However, had they asserted an interest in animal welfare, they may have failed to satisfy the prudential zone-of-interests standing test, as did the plaintiffs in the next case.

3. The Zone-of-Interests Standing Requirement

The zone-of-interests standing requirement appears to be a sticking point for the existing food-safety impact cases. This is only, however, because a significant portion of these cases thus far have been instigated by organizations such as animal welfare organizations or trade associations which have as their main purpose something other than food safety or consumer protection. The interests germane to these organizations' purposes are not protected by the food-safety statutes. In *Baur*, Farm Sanctuary, with whom Michael Baur originally brought suit, was dismissed from the case because as an animal welfare organization, it could not assert an interest protected by the Federal Meat Inspection Act or the Federal Food Drug and Cosmetic Act.²¹⁷ The *Levine* associational plaintiffs were dismissed because the interest they asserted in the lawsuit, the protection of their members' health—which presumably they asserted because it fell under the zone of

Massachusetts v. EPA, 549 U.S. 497, 525 (2007) (“[A] plaintiff satisfies the redressability requirement when he shows that a favorable decision will relieve a discrete injury to himself. He need not show that a favorable decision will relieve his every injury” (quoting *Larson v. Valente*, 456 U.S. 228, 244, n.15 (1982))).

The Ninth Circuit also commented that a district court need not take a plaintiff at her word at the motion-to-dismiss stage when determining the redressability prong of Article III standing—that this standard only applies to injury in fact and causation. *Levine*, 587 F.3d at 997 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)).

The court, however, did not discuss whether the standard for taking a plaintiff at her word at the motion-to-dismiss stage had changed since *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). It appears that the Ninth Circuit is now applying the *Iqbal* standard to 12(b)(1) subject matter jurisdiction challenges. See *Coal. for a Sustainable Delta v. Fed. Emergency Mgmt. Agency*, 711 F. Supp. 2d 1152, 1158 (E.D. Cal. 2010).

Here, the Ninth Circuit explained that a plaintiff needed to plead facts showing the likelihood of redressability by pointing to earlier (1990, 1975) Supreme Court decisions, and without addressing *Iqbal* or *Twombly*, thereby implying that this had long been the case. By not discussing the district court's injury-in-fact determination, the Ninth Circuit was therefore able to avoid discussing the possible effect *Iqbal* and *Twombly* would have on such an analysis.

²¹⁷ *Farm Sanctuary, Inc. v. Veneman*, 212 F. Supp. 2d 280, 285 (S.D.N.Y. 2000).

interests of the Federal Meat Inspection Act—was not germane to the purposes of their organization.²¹⁸

And, in 2005, the Ninth Circuit dismissed a claim by the Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (R-CALF), a nonprofit organization representing United States cattle producers “on domestic and international trade and marketing issues [which] . . . is dedicated to ensuring the continued profitability and viability of the U.S. cattle industry”²¹⁹ under NEPA for a failure to satisfy the zone-of-interests prudential standing requirement. R-CALF had sued the USDA seeking to overturn the USDA’s decision to lift a ban on Canadian imports of most bovine meat for human consumption.²²⁰

Until January 4, 2005, the USDA had banned the importation of all ruminants and ruminant products from countries in which BSE had been found, including Canada.²²¹ On that date, the USDA published a Final Rule relaxing the ban on the importation of Canadian ruminants. R-CALF sued to block the implementation of the Rule, arguing that it was arbitrary and capricious under the APA; that it violated NEPA because the agency had failed to make its environmental assessment public before publishing the Rule and had failed to prepare an Environmental Impact Statement; and that it violated the Regulatory Flexibility Act (RFA) by failing to assess whether the Rule’s impact on small businesses could have been mitigated.²²²

The district court agreed with plaintiffs on all counts, writing that the USDA had “preconceived intention, based upon inappropriate considerations, to rush to reopen the border regardless of uncertainties in the agency’s knowledge,” and had “attempted to work backwards to support and justify this

²¹⁸ *Levine v. Johanns*, No. C 05-04764 MHP, No. C 05-05346 MHP, 2006 U.S. Dist. LEXIS 63667, at *38-39 (N.D. Cal. Sept. 5, 2006).

²¹⁹ *About R-Calf USA; Working for the U.S. Cattle Industry*, R-CALF USA, <http://www.r-calfusa.com/about/about.htm> (last updated Feb. 11, 2011).

²²⁰ *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Dep’t of Agric.*, 415 F.3d 1078, 1084 (9th Cir. 2005).

²²¹ As the Ninth Circuit explained, “[r]uminants are hoofed mammals generally defined by their four-chambered stomachs and their practice of chewing a cud consisting of regurgitated, partially digested food,” and “include cattle, sheep, goats, deer, giraffes, camels, llamas, and okapi.” *Id.* at 1084 n.1.

²²² The RFA dates from 1980, and was passed “to ‘encourage administrative agencies to consider the potential impact of nascent federal regulations on small businesses.’” *Id.* at 1100 (quoting *Assoc. Fisheries of Maine, Inc. v. Daley*, 127 F.3d 104, 111 (1st Cir. 1997)).

goal,”²²³ but the Ninth Circuit reversed. First, the court found that the district court had improperly substituted its judgment for that of the agency and had failed to defer properly to the agency’s determinations. The court found the USDA’s determination that the risks inherent in the Rule were both small and acceptable to be supported by an adequate administrative record.²²⁴ As to the RFA, the Ninth Circuit held that the USDA met RFA’s purely procedural requirements, by “conduct[ing] a detailed economic assessment of its proposed rule on small businesses.”²²⁵

Regarding NEPA, the Ninth Circuit held that R-CALF did not have standing to pursue its claim under this statute.²²⁶ NEPA, which prescribes the steps an agency must take before taking an action that will affect the environment, contains no private right of action or citizen-suit provision. A plaintiff suing for a NEPA violation must bring suit under the APA and must fall under the zone of interests protected by NEPA. Under Ninth Circuit law, a party seeking to sue for a NEPA violation must assert an environmental injury.²²⁷ R-CALF, however, exists to protect the economic interests of its members, and the injuries it asserted in its complaint were economic.²²⁸ Economic interests are not protected by NEPA, and R-CALF therefore lacked standing to bring its NEPA challenge. The Ninth Circuit remanded the case, and the district court granted summary judgment to the USDA.²²⁹

4. Conclusion

These cases, both in the abstract and as tools for future food-safety-impact litigation, teach three lessons. First, the

²²³ *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Dep’t of Agric.*, 359 F. Supp. 2d 1058, 1066, 1074 (D. Mont. 2005).

²²⁴ *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am.*, 415 F.3d at 1100.

²²⁵ *Id.* at 1101.

²²⁶ *Id.* at 1103-04.

²²⁷ *Id.* at 1103 (citing *Stratford v. FAA*, 285 F.3d 84, 88 (D.C. Cir. 2002)).

²²⁸ R-CALF also asserted that “R-CALF USA members will also be adversely affected by the increased risk of disease they face when Canadian beef enters the U.S. meat supply.” *Id.* (internal quotation marks omitted).

²²⁹ *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Dep’t of Agric.*, 359 F. Supp. 2d 1058, 1062 (D. Mont. 2005). The Ninth Circuit affirmed, reminding R-CALF that it could not use post-decision evidence to show that the USDA had “relied] on faulty assumptions,” but that it could use this new evidence to petition the USDA to reopen rulemaking under the APA. *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Dep’t of Agric.*, 499 F.3d 1108, 1111, 1117-18 (9th Cir. 2007).

standing challenges are navigable. At least the Ninth Circuit and the Second Circuit have shown themselves amenable to the allegation of an increased risk of contracting foodborne illness as a basis for injury in fact. Such a claim matches the purpose of the statutes that protect the safety of our food supply.

Second, these cases illustrate the absence of a food-safety-impact litigation culture. Two of these three cases were brought by animal welfare organizations, and one by a trade organization. Not one of the organizations spearheading this litigation had as its primary purpose the prevention, or minimization of foodborne illness, although they all alleged the increased risk of such as a basis for standing. Food-safety litigants, especially organizational litigants, must better negotiate the zone-of-interests test.

And finally, in two of the three cases, the court found the plaintiffs' use of the government's own studies to show that the agency action would result in the alleged harm to be strong support for standing. The agency's refusal to act in the face of its own studies lends support to the possibility that the agency's final action was arbitrary and capricious, and allows a court to remain deferential to the agency, while ruling against it.

C. *Challenges to Judicial Review of Agency Action*

As described above, food-safety-impact litigation must be brought under the APA because the major food-safety statutes have neither citizen-suit provisions nor provide for private rights of action. Each case discussed above in the section on standing involved a challenge to agency action under the APA, for these very reasons, and in two, defendants challenged whether the agency action was reviewable under the APA. In *Levine*, the defendants argued that the plaintiffs had not challenged a final agency action, as is necessary for review under the APA, but the court disagreed.²³⁰ And in the *R-CALF* case, the Ninth Circuit ultimately determined that the district court had erred under the APA in its failure to defer to the agency's expertise, and that the agency action was not, therefore, arbitrary and capricious.²³¹

²³⁰ *Levine v. Johanns*, No. C 05-04764 MHP, No. C 05-05346 MHP, 2006 U.S. Dist. LEXIS 63667, at *10, *58-61 (N.D. Cal. Sept. 5, 2006).

²³¹ *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am.*, 415 F.3d at 1100.

Another common²³² challenge to the judicial reviewability of agency action in the food-safety context is the claim that the agency action at issue has been committed to agency discretion by law, and is therefore unreviewable under section 701(a)(2) of the APA.²³³ There are several categories of actions that the Supreme Court have found to fall under section 701(a)(2), and thus to be unreviewable, including “an agency’s decision not to institute enforcement proceedings,” “an agency’s refusal to grant reconsideration of an action because of material error,” and “the allocation of funds from a lump-sum appropriation.”²³⁴ In the following two cases, defendants claimed that the challenged agency action was an enforcement decision, and therefore unreviewable under the APA. In each of these cases, the court disagreed. Furthermore, both of these cases were actually successful in achieving their requested relief.

Public Citizen v. Heckler was the impetus behind the federal government’s ban on the interstate sale of raw milk.²³⁵ Public Citizen, a citizen advocacy organization, filed a citizen petition with the FDA in April of 1984, requesting that the agency prohibit the sale of unpasteurized milk.²³⁶ After no ruling was made, and the FDA refused to provide a schedule for a ruling, Public Citizen filed suit in September 1984 seeking a response to its petition. HHS held an informal hearing in October 1984 to solicit information on whether raw milk was a

²³² “Common” insofar as this challenge was made in two of the fourteen cases found.

²³³ 5 U.S.C. § 701(a)(2) (2006).

²³⁴ *Lincoln v. Vigil*, 508 U.S. 182, 191-92 (1993) (citing *Heckler v. Chaney*, 470 U.S. 821, 831 (1985); *ICC v. Locomotive Eng’rs*, 482 U.S. 270, 282 (1987)) (internal quotation marks omitted).

²³⁵ *Pub. Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1987). Raw milk is milk that has not been pasteurized or homogenized. Before 1987, the federal government did not regulate the sale of raw milk, although many local and state governments did in some manner. The city of Chicago passed a mandatory milk pasteurization law in 1908, and in 1947, Michigan was the first state to do so.

²³⁶ *Id.* at 1231-33. In 1973, the Food and Drug Administration had promulgated a regulation prohibiting the sale of all unpasteurized milk products in interstate commerce, but, in 1974, this was stayed as to certified raw milk until the FDA could hold a hearing as to its safety. *In re* Revising Existing Standards and Establishing New Identity Standards for Milk and Cream, 38 Fed. Reg. 27,924 (Oct. 10, 1973) (stayed in 39 Fed. Reg. 42,351 (Dec. 5, 1984)). “[C]ertified raw milk” satisfies standards established by the American Association of Medical Milk Commissions. *Pub. Citizen*, 653 F. Supp. at 1232.

The FDA collected information from 1974 to 1982, and in 1982, wrote a proposed regulation banning the interstate sale of all raw milk, based on the evidence that the consumption of raw milk was linked to bacterial disease. High-level officials at HHS and the CDC supported this regulation, and statistical support was provided by the Chief of the Bureau of Foods Epidemiology and Clinical Toxicology Division in 1984. *Id.* at 1232-33.

public health concern and, if so, whether requiring pasteurization was the best solution. The evidence collected by the FDA, and the evidence introduced at the informal hearing “conclusively show[ed] . . . [that] raw milk is unsafe.”²³⁷

After the district court ruled that the Department of Health and Human Services’ “justifications for delay were ‘lame at best and irresponsible at worst,’” and ordered the Department to respond,²³⁸ the Department responded by denying Public Citizen’s petition for several reasons, including the following: (1) most raw milk was sold intrastate, (2) illnesses from raw milk stemmed mainly from intrastate commerce, and (3) banning interstate sales of raw milk would therefore have little effect on the public health.²³⁹ Public Citizen returned to district court to challenge the rule as arbitrary and capricious.²⁴⁰

Defendant HHS challenged the reviewability of the petition’s denial, claiming that it was an enforcement decision, and thus fell under the section 701(a)(2) exception to reviewability. The court rejected this contention, explaining that “[h]ere the action at issue is not an individual enforcement action, but an agency’s refusal to engage in rulemaking.”²⁴¹ Furthermore, in *Heckler v. Chaney*, the case establishing the discretionary enforcement exception, the agency chose not to take an enforcement action against an entity, and there were no clear statutory guidelines for the court to interpret on when such actions should be taken. Here, on the other hand, HHS’s action could be reviewed with the clear statutory guidelines of the FFDCAs and the Public Health Act as a guide.²⁴²

The court then determined that the denial of Public Citizen’s petition was arbitrary and capricious. It found the explanation offered to be inconsistent with the evidence in front of the agency; that the documents before the court showed

²³⁷ *Pub. Citizen*, 653 F. Supp. at 1241.

²³⁸ *Id.* at 1234-35 (citing *Pub. Citizen v. Heckler*, 602 F. Supp. 611, 613 (D.D.C. 1985)).

²³⁹ *Id.* at 1235. The FDA’s other reasons were that milk sold interstate did not pose a greater risk than milk sold intrastate, that the FDA did not have the authority to prohibit intrastate sales, and that the problem was better dealt with by state and local governments anyway. *Id.*

²⁴⁰ *Id.* at 1231.

²⁴¹ *Id.* at 1236 (citing *Heckler v. Chaney*, 470 U.S. 821, 825 n.2 (1985)). This issue was settled in *Massachusetts v. EPA*, 549 U.S. 497, 527 (2007) (“Refusals to promulgate rules are thus susceptible to judicial review, though such review is ‘extremely limited’ and ‘highly deferential’” (quoting *Nat’l Customs Brokers & Forwarders Ass’n of Am., Inc. v. United States*, 883 F.2d 93, 96 (D.C. Cir. 1989))).

²⁴² *Public Citizen*, 602 F. Supp. at 1236.

that high level officials at the FDA and the CDC thought a ban on raw milk sales was a good idea, and indicated “a lack of rationality on the part of HHS in the decisionmaking process”; and that the reason given for the decision had “no rational connection to the undisputed facts in the record.”²⁴³ Pursuant to the court’s order, the FDA published a Final Rule banning the interstate sale of all raw milk and all raw milk products.²⁴⁴

In *Kenney v. Glickman*, a number of individual plaintiffs,²⁴⁵ calling themselves “poultry consumers,” sued the USDA for discrepancies in the way that the USDA regulated poultry and meat.²⁴⁶ Plaintiffs argued that the USDA should either issue the same regulations for poultry and meat, or provide a “legally sufficient reason for treating meat and poultry differently.”²⁴⁷

The Eighth Circuit rejected the USDA’s contention that the discrepancies between the meat and poultry inspection standards reflected an enforcement decision—that the agency had merely chosen to use agency resources to enforce meat inspections more rigorously. The standards at issue involved neither a decision about whether there had been a violation nor a refusal to institute proceeding, but were, instead, general

²⁴³ *Id.* at 1237, 1241.

²⁴⁴ 21 C.F.R. § 1240.61 (2010); Memoranda from Milk Safety Branch on Sale/Consumption of Raw Milk to All Regional Food and Drug Directors (Mar. 19, 2003), available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/CodedMemoranda/MemorandaofInformation/ucm079103.htm>.

²⁴⁵ *Kenney v. Glickman*, 96 F.3d 1118, 1118 (8th Cir. 1996). The original plaintiffs included red meat producers, who brought the case to remedy a perceived inequity in the USDA’s treatment of poultry and of beef, but the district court dismissed these plaintiffs for lack of standing. See Joe Roybal, *Fighting for Fairness*, BEEF MAG. (Nov. 1, 2000, 1:00 PM), http://beefmagazine.com/mag/beef_fighting_fairness/. The red meat producers did not appeal. See *id.*

²⁴⁶ Both the PPIA, which regulates poultry products, and the FMIA, which regulates meat, require that carcasses be inspected for the presence of certain contaminants that may cause the carcasses to be termed “adulterated,” and hence not allowed into the food supply. *Kenney*, 96 F.3d at 1121. Individual carcasses are inspected, and any contaminants are removed. *Id.* No contaminants are allowed to remain; there is a “zero tolerance” policy as to these contaminants on individual carcasses. *Id.* The contaminated parts must be removed from meat, while they may be washed off of poultry. *Id.* After the individual carcasses are inspected, an inspector then inspects sample carcasses from a particular lot to determine if there may be any process defects on that lot. *Id.* Until 1993, both the PPIA and the FMIA allowed a tolerance level of slightly more than zero for process defects, but in March 1993, the USDA lowered the tolerance level to zero for meat, but not for poultry. *Id.*

²⁴⁷ *Id.*

policies.²⁴⁸ The case did not, therefore, fall into the *Heckler v. Chaney* category of presumptively unreviewable cases.²⁴⁹

The Court of Appeals also found that the prohibition against allowing adulterated products to enter the food supply provided a “sufficient standard” for the court to evaluate whether the USDA’s policies made sense.²⁵⁰ In addition, the court looked to the legislative history of the PPIA and the FMIA to determine that Congress intended for the two to be construed consistently. For this reason, there was sufficient law to apply to determine whether the USDA acted arbitrarily and capriciously in implementing differing inspection standards for meat and poultry.²⁵¹

After remand, the district court found the discrepancy between meat and poultry regulation to be arbitrary and capricious,²⁵² and in direct response to this decision—indeed, noting the decision in the background to the Final Rule—the FSIS harmonized the regulations.²⁵³

Kenney and *Public Citizen* have three main implications. First, *Heckler v. Chaney*’s presumption of unreviewability does not apply to arbitrary and capricious challenges to the refusal to promulgate rules, which, in any event, was settled definitively by *Massachusetts v. EPA*.²⁵⁴ Second, if a petitioner presents evidence to support its allegations, the statutes governing food safety (including the FMIA, the PPIA, and the FFDCA) provide sufficient guidelines for a court to determine whether the relevant agency has acted reasonably. Third, a court is more likely to permit a case to go forward if petitioner’s evidence was produced by the relevant agency.²⁵⁵

²⁴⁸ *Id.* at 1123.

²⁴⁹ *Id.* One judge dissented in part, finding that the USDA’s regulations regarding tolerance standards for process defects and regarding the methods used to cleanse contaminants were enforcement actions, and were therefore presumptively unreviewable under *Chaney*. *Id.* at 1126 (McMillian, J., dissenting in part).

²⁵⁰ *Id.* at 1124 (majority opinion).

²⁵¹ *Id.*

²⁵² Roybal, *supra* note 245. The district court decision is unavailable.

²⁵³ See Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements, 66 Fed. Reg. 1750, 1751-52 (Jan. 9, 2001), available at <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-054F.html>.

²⁵⁴ *Massachusetts v. EPA*, 549 U.S. 497, 527 (2007) (“Refusals to promulgate rules are thus susceptible to judicial review, though such review is ‘extremely limited’ and ‘highly deferential’” (quoting Nat’l Customs Brokers & Forwarders Ass’n of Am., Inc. v. United States, 883 F.2d 93, 96 (D.C. Cir. 1989))).

²⁵⁵ This has been a theme throughout the food-safety cases. The court relied on the government’s own documents to find standing in *Baur*, and in *Levine* as well, although that decision was overturned on other grounds.

D. *Paths to Success in Food-Safety-Impact Litigation*

The upshot of the food-safety cases described above is that suits brought by food consumers or public health organizations alleging an increased risk of contracting foodborne illness because of an established governmental policy, and relying on the agency's own documents, are likely to get into court. Specifically, these cases have four main implications for justiciability.

First, courts seem to generally accept that the increase in risk of foodborne illness satisfies the Article III injury in fact standing requirement. This is noted with several caveats. One is that not every court is likely to accept such a claim. As discussed above, the D.C. Circuit would most likely look for a quantifiable increase in risk, and may even prohibit this category of claimant from litigating outside of the environmental context. The second caveat is that the cases discussed above were, for the most part, decided before the Court's decisions in *Ashcroft v. Iqbal* and *Bell Atlantic Corp. v. Twombly*,²⁵⁶ which instructed district courts that a plaintiff needed factual allegations that "raise a right to relief above the speculative level," and must "state a claim to relief that is plausible on its face."²⁵⁷ Lower courts are now grappling with the implications of applying this "plausibility standard" to determinations regarding challenges to subject matter jurisdiction, including standing challenges.²⁵⁸ This standard may make it more difficult for impact plaintiffs to progress beyond the motion-to-dismiss stage, although many will have been through the administrative petitioning process before filing a complaint, thus allowing them to gather information and evidence towards their complaint. Those plaintiffs who can accumulate more information before filing a complaint will fare better.

The second lesson learned from the above discussion of justiciability relates to a plaintiff's use of the relevant agency's own documents and evidence to show that the potential harm from the agency action was significant. The *Levine, Baur, Kenney*, and *Public Citizen* courts found the fact that the agency's own documents supported plaintiffs' contentions (i.e., inhumanly slaughtered poultry are more likely to be carriers of

²⁵⁶ *Ashcroft v. Iqbal*, 556 U.S. 662 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

²⁵⁷ *Twombly*, 550 U.S. at 555, 570.

²⁵⁸ See, e.g., *Coal. for a Sustainable Delta v. Fed. Emergency Mgmt. Agency*, 711 F. Supp. 2d 1152 (E.D. Cal. 2010); *Eugster v. Wash. State Bar Ass'n*, No. CV 09-357-SMM, 2010 WL 2926237 (W.D. Wash. July 23, 2010).

communicable illness; downed cattle are more likely to have mad cow disease; the PPIA and the FMIA were meant to be construed similarly; FDA officials themselves acknowledged the danger of drinking raw milk) to be a compelling factor in allowing the case into court, and in the case of *Public Citizen*, to rule in favor of the plaintiff.

Is this not a question for the merits? Yes, such documents ultimately go to whether the plaintiff has managed to show that the agency's action was arbitrary and capricious. But the presence of such documents indicates to the court that the suit is neither futile nor frivolous; it speaks to an implicit likelihood of success inquiry. A court is required to defer to an agency's reasonable construction of its regulations,²⁵⁹ and may not substitute its judgment for that of the agency. This is even more important when a high level of technical expertise is implicated.²⁶⁰ Because judicial deference to agency decision making is so strong, a court must see a role for itself in the dispute, and a way to remain within its institutional competence before it allows plaintiffs into court. Documentary evidence of the relevant harm indicates that, whether through corruption, inefficiency, or sheer irrationality, the agency has acted against its own evidence and, in certain cases, its own directives. Moreover, such documents show that the agency was not acting pursuant to internal management considerations or other factors that a court should have no hand in administering.²⁶¹

The use of an agency's own documents by petitioners does not, however, guarantee success on the merits. For example, in the *R-CALF* case, the Ninth Circuit reversed the district court's grant of a preliminary injunction to plaintiffs,

²⁵⁹ *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984).

²⁶⁰ *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Dep't of Agric.*, No. 05-35264, 2005 U.S. App. LEXIS 17360, at *32 (9th Cir. Aug. 17, 2005). Similarly, in *Simpson v. Young*, 854 F.2d 1429 (D.C. Cir. 1988), the D.C. Circuit dismissed a citizen-suit challenge to the FDA's decision to list a color additive, Blue No. 2 dye, as safe for human consumption. *Public Citizen*, the Center for Science in the Public Interest, and a private citizen alleged that the FDA's studies on the dye had been improperly done. The court explained that it was compelled to "uphold the FDA's decision if it reveals that significant evidence on both sides of the question has been considered and that the agency has explained its conclusions in light of significant objections." *Id.* at 1434. Deference to the agency's judgment was particularly important in cases involving "sophisticated scientific judgment," as was this one. *Id.* And in *Public Citizen v. Foreman*, 631 F.2d 969, 977 (D.C. Cir. 1980), discussed *supra* note 162, the D.C. Circuit dismissed *Public Citizen's* challenge to the FDA's determination that nitrites were sanctioned as a preservative prior to 1958, and therefore qualified for an exemption from the FFDCA, finding that it must defer to the agency's technical expertise.

²⁶¹ *Kenney v. Glickman*, 96 F.3d 1118, 1122-23 (8th Cir. 1996).

explaining that the district court had failed to sufficiently defer to the agency's interpretation of the statute.²⁶² The appeals court noted that the district court had erred by "analyzing each protective component of the regulatory system in isolation," instead of "evaluat[ing] the cumulative effects of the multiple, interlocking safeguards."²⁶³

Third, an organizational plaintiff must be able to show that the interests at stake in the lawsuit are germane to the organization's purpose and that the interests asserted fall under the zone of interests protected by the statute. This was an issue with the animal welfare organizations in *Levine*, which could not show that that an interest in consumer health, as put forward in this lawsuit, was germane to their purposes;²⁶⁴ with R-CALF, which could not show environmental injury so as to have standing under NEPA;²⁶⁵ in *Baur*, when Farm Sanctuary was dismissed from the case;²⁶⁶ and in *Kenney*, where the red-meat producers did not survive a motion to dismiss.²⁶⁷

This barrier is less likely to stand in the way of environmental plaintiffs. In the first place, the citizen-suit provisions arguably negate the zone-of-interests test altogether.²⁶⁸ Moreover, as discussed earlier, there is a well-organized environmental impact plaintiff movement. Nothing similar exists in the food-safety world. The inclusion of citizen-suit provisions in the environmental laws was partially a function of the existence of the environmental protection movement. Legislators, with the help of individuals from these organizations, recognized a beneficial symbiosis between the fledgling EPA and the efforts of these organizations to enforce and strengthen regulation. In a sense, several of these organizations, through a push and pull, became extra eyes, ears, and arms of the government in enforcing environmental protection.²⁶⁹

Because there are fewer litigating public health organizations, food-safety litigation may be brought ostensibly for public health, but actually for other purposes, such as the

²⁶² *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am.*, 2005 U.S. App. LEXIS 17360, at *32.

²⁶³ *Id.* at *37.

²⁶⁴ *Levine v. Johanns*, No. C 05-04764 MHP, No. C 05-05346 MHP, 2006 U.S. Dist. LEXIS 63667, at *37-39 (N.D. Cal. Sept. 6, 2006).

²⁶⁵ *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am.*, 415 F.3d at 1100.

²⁶⁶ *Farm Sanctuary, Inc. v. Veneman*, 221 F. Supp. 2d 280, 284-85 (S.D.N.Y. 2002).

²⁶⁷ See Roybal, *supra* note 245.

²⁶⁸ See *supra* note 176.

²⁶⁹ ADAMS & ET AL., *supra* note 77, at 27; SALE, *supra* note 96, at 34-35.

humane treatment of animals, or the economic interests of cattle producers—hence the associational standing and zone-of-interests problem commonly faced by food-safety-impact litigants. Of course, if an organization brings suit alongside a consumer or two, the consumer may have standing even if the organizational plaintiff does not. The suit can therefore go forward, and the stated goal of the organization in the suit may still be reached. Other goals, however, such as publicity for the issue, and for the organization, may not be forthcoming in such a suit. And in certain cases, increased public awareness is more important than achievement of the suit's sought relief. Moreover, it is publicity that raises the profile of the organization bringing the suit, lends legitimacy to its enterprise, and teaches the public that this is an issue worthy of donating money.

Fourth, and finally, courts are more likely to grant access if the stated injury stems from a present governmental policy—for example, the policy of allowing “downed” cattle to enter the food supply.²⁷⁰ This element speaks to the injury-in-fact prong of the Article III standing analysis as well as the redressability prong—no third party has to act for the injury to take place, nor would a third party need to act for the requested relief to take place.²⁷¹

CONCLUSION

Food-safety-impact cases are few and far between, but there is no compelling reason for this to remain the case. The absence of citizen-suit provisions in the food-safety statutes does not foreclose citizen suits. Food-safety-impact litigation brought by individuals or groups able to show that they or their members are at increased risk of contracting foodborne illness as a result of a final agency action, ideally by pointing to evidence in the relevant agency's own documents, is likely to make it past constitutional and prudential standing challenges. Moreover, it is entirely within the competence of the judiciary

²⁷⁰ *Baur v. Veneman*, 352 F.3d 625, 637 (2d Cir. 2003).

²⁷¹ The *Baur* Court distinguished the harm alleged by plaintiff—increased risk of foodborne illness—from “alleged future injury [that] rested on the independent actions of third-parties not before the court.” *Id.* at 640. And the appeals court in *Levine* found the need for actions by third parties—the poultry producers—to make the possibility of redress for the plaintiffs too attenuated and consequently too speculative to satisfy the Article III requirement. *Levine v. Vilsack*, 587 F.3d 986, 994-95 (9th Cir. 2009).

to assess whether there has been arbitrary and capricious action taken in the food-safety context.

Overseeing food safety in this country is an enormous job, and agency oversight of food safety is, and will likely continue to be, severely underfunded. There are numerous food-safety areas where agency decision making has stalled, either from a lack of resources or from industry pressure. Such inertia is detrimental to the public health. Citizen litigation can act as a counterpart to governmental regulation, pushing agencies to fulfill their statutory mandates, and making judicial review of agency decision making regarding food-safety regulation a valuable tool in reducing the incidence of foodborne illness.