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Pitfalls of the Food Safety Modernization Act: Enhanced Regulation, Minimal Consumer Benefit, and Zero Tolerance Levels for Naturally-Occurring Trace Pathogens

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Pitfalls of the Food Safety Modernization Act: Enhanced Regulation, Minimal Consumer Benefit, and Zero Tolerance Levels for Naturally-Occurring Trace Pathogens

Lindsey Lazopoulos Friedman*
Wesley Van Camp**

Congress enacted the Food Safety Modernization Act (“FSMA”), to regulate the fresh produce industry in the United States and increase consumer safety when handling and consuming raw produce. But FSMA risks imposing a zero tolerance policy on raw produce, even where a naturally occurring low-level pathogen, such as listeria, is found in negligible amounts. A zero tolerance policy for all naturally-occurring pathogens does not increase consumer safety, and only serves to increase the cost of raw produce for consumers. This article begins with a summary of the

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modern history of FSMA, including a brief overview of how the law has been used in the past to impose liability on producers. The article also includes an explanation of a common naturally occurring pathogen—listeria. Although other countries impose a tolerance level for listeria, the FDA relies on FSMA to enforce an unreasonable zero tolerance policy. Next, this article analyzes the term “adulterated” for purposes of United States food safety, and the article reviews support in U.S. case law for not deeming products with low-levels of pathogen “adulterated.” Lastly, this article examines the unintended repercussions of the “real-world,” absurd effects of the FDA’s zero-tolerance policy. This article discusses regulations that apply to all food industries, but focuses specifically on the fresh, unprocessed produce industry. Accordingly, this article concludes that the FDA should promulgate risk and science-based tolerance levels for listeria in minimally processed produce.

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The Food Safety Modernization Act’s (“Act”) fourth birthday has come and gone, but there is little basis for celebrating. Rather than cultivate improved safety in the produce industry, the Act drains considerable resources that could otherwise achieve the Act’s intended goals.

Consumers are aware of what they are eating and interested in fresher, less processed food. Still, convenience and price remain critical factors guiding consumption.¹ For example, fresh-cut produce sales grew from \$2.6 billion in 1994 to over \$8 billion in 2003 and to more than \$11 billion in 2013 in the United States alone.²

But meanwhile, the Act burdens the fresh produce market (“Industry”). The Industry operates on narrow profit margins; the Act narrows these margins even further without increasing consumer safety. Overall, the Act presents a number of frustrations without creating clear overriding benefits.

Most problematic, the FDA relies on enhanced power in the Act to enforce a zero-tolerance policy for minimal traces of low-level pathogens on raw agricultural commodities. The FDA relies on the Act to determine that a product is “adulterated,” but that determination is flawed because the mere existence of certain low-level pathogens, such as *listeria monocytogenes*, does not render a product adulterated. The produce is not adulterated because *listeria* is naturally occurring—it is not a foreign substance; it could be “reasonably expected” by the consumer to exist on the produce; and it does not render minimally processed fresh produce unfit or defective. More importantly, imposing a zero tolerance policy even where a naturally occurring low-level pathogen, such as *listeria*, is found

¹ David Bell, Natalie Kindred & Mary Shelman, *Taylor Fresh Foods*, HARVARD BUSINESS REVIEW, Dec. 15, 2008, at 11.

² Mitchell Clute, *Packaged Produce Sales Soar*, NEW HOPE NETWORK (Apr. 24, 2008), <http://www.newhope.com/news/packaged-produce-sales-soar>; AC Nielsen 52 weeks ending July 13 2013; Roberta Cook, *Trends in the Marketing of Fresh Value Produce and Fresh-Cut/Value-added Produce* (2012), available at https://arefiles.ucdavis.edu/uploads/filer_public/2014/10/08/freshcut20140926finalnewmarycook.pdf.

does not increase consumer safety. Consumers in other parts of the world eat products rejected by the FDA's zero tolerance policy without incident. Accordingly, this article concludes that the FDA should promulgate section 346 risk and science-based tolerance levels for *listeria* in minimally processed produce.

SUMMARY

This article begins with a summary of the modern history of the Act, including a brief overview of how the law has been used in the past to impose liability on producers. The article also includes an explanation of a common pathogen—*listeria*. Although other countries impose a tolerance level for *listeria*, the FDA relies on the Act to enforce an unreasonable zero tolerance policy. Next, this article analyzes the term “adulterated” for purposes of United States food safety, and the article reviews support in U.S. case law for not deeming products with low-levels of pathogen “adulterated.”

Lastly, this article examines the unintended repercussions of the “real-world,” absurd effects of the FDA's zero-tolerance policy. This article discusses regulations that apply to all food industries, but focuses specifically on the fresh, unprocessed produce industry.

I. FDCA AND FSMA: A BRIEF OVERVIEW AND HISTORY

In effect, the Act is a facelift on the Food, Drug and Cosmetic Act, it nipped, tucked, and filled out the original legislation. The Act now affects every aspect of the United States food system, from farmers to manufacturers to importers.³ The Act is a shift from reacting to adulteration and contamination, to preventive techniques that place the burden on farmers and food processors.⁴

The implementation of the Act is similar to most major pieces of legislation. Depending on the type of product and congressional legislation involved, the Act authorizes certain federal agencies to

³ Lyndsey Layton, *House Approves Food-Safety Bill; Law Would Expand FDA's Power*, THE WASHINGTON POST (July 31, 2009), <http://www.washingtonpost.com/wp-dyn/content/article/2009/07/30/AR2009073003271.html>.

⁴ *Id.*

enact regulations and policies for implementing the legislation.⁵ Responsibility for food safety is “divided among fifteen federal agencies,” most notably the Food and Drug Administration (“FDA”) and the United States Department of Agriculture’s Food Safety and Inspection Service (“FSIS”).⁶ In broad terms, FSIS is responsible for meat and poultry and the FDA is responsible for everything else.⁷ Yet, many complicated exceptions abound, which create enduring headaches for private enterprise (e.g., FDA also regulates fish, but not catfish).⁸ The absurdity is best characterized by a sausage—the skin of the sausage link is regulated by the FDA but the meat inside is FSIS’s purview.⁹

But for purposes of raw fruits and vegetables—the focus of this article—the FDA is solely responsible for developing regulations concerning the fresh produce industry. Some commentators argue that the FDA has routinely gone beyond its legislated role and “creatively relies on implied authority”¹⁰ when enforcing the Food Safety Regulations. With Act’s advent, it “has evolved to provide a variety of standards for regulating food safety.”¹¹ The FDA has developed a two-prong approach to address the “new regulation of food safety.”¹² One prong focuses on assuring the safety of intended components of food, i.e., ingredients, and the other prong centers on how best to deal with unintended components of food, what the agency calls contaminants.¹³ The agency has repeatedly relied on the “adulteration provisions” of the act (discussed in greater detail *infra*) to regulate the first prong, and on rulemaking authorities of the act to develop efforts like good manufacturing practices, hazard

⁵ *Selected Federal Agencies with a Role in Food Safety*, FOODSAFETY.GOV, <http://www.foodsafety.gov/about/federal/> (last visited Sept. 18, 2016).

⁶ Wil S. Hylton, *A Bug in the System: Why Last Night’s Chicken Made You Sick*, THE NEW YORKER (Feb. 2, 2015), <http://www.newyorker.com/magazine/2015/02/02/bug-system>.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ Frederick Degnan, *Introduction to THE FOOD SAFETY MODERNIZATION ACT: A COMPREHENSIVE, PRACTICAL GUIDE TO THE LANDMARK LEGISLATION*, 1 (James William Woodlee ed., Food and Drug Law Institute 2012), *available at* http://www.fdpi.org/docs/default-document-library/fsma_preview.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

identifications and the “voluntary” recall with respect to the second prong. It is not clear where pathogens that are naturally occurring micro-organisms fit in this scheme.

A. The backdrop to the Act

Fanfare focused on the Act describes it as the “most sweeping changes in food safety since President Franklin Roosevelt signed the Food, Drug and Cosmetic Act (“FDCA”) as part of the New Deal” in the 1930s.¹⁴ During the New Deal era, Congress gave the FDA the authority to oversee food, drugs, and cosmetics safety.¹⁵ Since the FDCA was first enacted, few changes were made to Federal fresh produce regulation. Food safety wedged its way to the forefront of the American public’s conscious over the last fifteen years after several highly publicized outbreaks of *E. coli* caught the attention of super attorneys.¹⁶

The most notorious outbreaks generally centered on the meat and poultry industry—the first outbreak to really hit the United States news syndicate was the 1993 *E. coli* outbreak traced to hamburger meat from fast food restaurant Jack in the Box.¹⁷ Then in 2006, the fresh produce industry faced an outbreak of *E. coli* traced to fresh spinach.¹⁸ And in 2011, an outbreak of *listeria monocytogenes* was linked to contaminated cantaloupes from Jensen Farms in

¹⁴ Carol Lumpkin & Shawn Hogue, *Food Safety Overhaul Gives FDA Expanded Powers*, FLORIDA BUSINESS REVIEW (Oct. 30, 2014), available at <http://www.dailybusinessreview.com/id=1202675067591/Food-Safety-Overhaul-Gives-FDA-Expanded-Powers#ixzz3HwrxnBGz>.

¹⁵ *Id.*

¹⁶ An illness outbreak is defined by the FDA as two or more cases of food-borne illness during a limited period of time, ostensibly from the same organism (other than botulism) and associated with either the same food product or the same food service operation. *What you Should Know About Government Response to Foodborne Illness Outbreaks*, U.S. FOOD AND DRUG ADMINISTRATION, www.fda.gov/Food/ResourcesForYou/Consumers/ucm180323.htm (last updated Sept. 2, 2015); see *Food Safety: A Year in Review 2012 Issues, Challenges, and Forward Momentum*, DELOITTE, 3 (2013), http://deloitte.wsj.com/riskandcompliance/files/2013/08/Food_safety_Review_2012.pdf.

¹⁷ Hylton, *supra* note 6.

¹⁸ *Multistate Outbreak of E. coli O157:H7 Infections Linked to Fresh Spinach*, CENTER FOR DISEASE CONTROL & PREVENTION (Oct. 6, 2006), <http://www.cdc.gov/ecoli/2006/spinach-10-2006.html>; see also Bell et al., *supra* note 3, at 5.

Colorado.¹⁹ In response, food product recalls have increased during the last decade.²⁰

In 1998, the FDA published voluntary “good agricultural practices,” or GAPs, aimed at reducing the possibility of contamination.²¹ Although the FDA agricultural practices were voluntary, “most U.S. retailers and foodservice companies required suppliers to comply with the FDA recommendations.”²² Some retailers that were particularly concerned about risk to their “brand,” added numerous additional requirements on their own initiative.²³ Specific industries also found ways to self-regulate; for example, the Leafy Green Handler Marketing Agreement (“LGMA”) started after the 2006 spinach outbreak.²⁴ The LGMA was an agreement by spinach and lettuce producers to source only from growers adhering to specific best practices.²⁵ In addition to GAPs, the FDA also mapped out GMPs—Good Manufacturing Processes—and Hazard Analysis and Critical Control Points (“HACCP”).²⁶ HACCPs are management systems, typically organized by industry—seafood, produce, poultry, etc.—that address food safety through the analysis and control of biological, chemical, and physical hazards that arise from raw product handling, manufacturing, distribution, and preparation for consumption.²⁷

Concern for intentional contamination of food also affected regulation because the lingering anxieties from the terrorist attacks of

¹⁹ U.S. Food & Drug Admin., *Information on the Recalled Jensen Farms Whole Cantaloupes*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm272372.htm#final> (last updated July 21, 2014).

²⁰ DELOITTE, *supra* note 16, at 4.

²¹ Bell et al., *supra* note 1, at 5.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ Bell et al., *supra* note 1, at 5. Recently, a panel of food safety experts endorsed the science behind the LGMA’s guidelines and consider the guidelines “more rigorous than the FDA’s food safety regulations.” Tom Karst, *Independent Report Supports LGMA Guidelines*, THE PACKER (May 20, 2016), <http://www.thepacker.com/news/independent-report-supports-lgma-guidelines>.

²⁶ Degnan, *supra* note 13, at 5-12.

²⁷ *Hazard Analysis Critical Control Point*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/HACCP/> (last updated Sept. 3, 2015).

September 11, 2001, “perpetuated fear that the security of our nation’s food from terrorist or other deliberate attacks was also possible.”²⁸ Congress passed a Public Health Security and Bioterrorism Preparedness Response Act, which granted the FDA administrative detention authority over food items if there is credible evidence that indicates the food, may present a threat of serious adverse health consequences or death to humans or animals.²⁹

B. Unintended consequences of Food Safety Alerts

The FDA issues Food Safety Alerts that impact sales for all producers of implicated commodities.³⁰ The FDA issues Food Safety Alerts after reported illnesses have been traced to a produce commodity.³¹ After an Alert, companies often must institute a recall.³² Recalls often significantly effect whether the public chooses to purchase a product, even from producers not associated with implicated product.³³ One year after the 2006 spinach outbreak, spinach still sold at 20–25% below pre-crisis volume levels.³⁴ In 2008, salmonella was found in jalapeño peppers used in common products like salsa.³⁵ Initially, it “was widely publicized that tomatoes were to blame before jalapeños were identified as the real cause, leading to an estimated loss of \$200 million in revenues for the Florida tomato industry.”³⁶

²⁸ See Rhona S. Applebaun, *Protecting the Nation’s Food Supply from Bioterrorism*, FOOD SAFETY MAGAZINE (Feb./Mar. 2004), <http://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2004/protecting-the-nations-food-supply-from-bioterrorism/>.

²⁹ *Id.*

³⁰ *Recall: The Food Industry’s Biggest Threat to Profitability*, TYCO INTEGRATED SECURITY, 2-3, https://www.tycois.com/wps/wcm/connect/ab4fd1f4-4aa2-45a3-a4f1-b91b36539e0f/LT1000-02FoodDefenseWP_Part2_hireresDigital.pdf?MOD=AJPERES (last visited Sept. 22, 2016).

³¹ *Id.* at 4.

³² *Id.*

³³ *See id.*

³⁴ Bell et al., *supra* note 1, at 5.

³⁵ *Id.*

³⁶ *Id.*

C. The Act takes shape

The swell of national concern over food safety—whether from naturally occurring or introduced causes—coincided with the drafting of the Act. The initial version of the law was titled the Food Safety Enhancement Act and passed the United States House of Representatives on July 30, 2009.³⁷ The Senate made additions and edits to what was deemed a “popular” bill and the final result that emerged was the Food Safety and Modernization Act, which the Senate passed—by a 73-25 margin—in November 2010.³⁸ But that vote was voided because the Senate had added a tax provision to the bill.³⁹ Eventually, the 111th U.S. Congress approved the bill and President Barack Obama signed the bill into law on January 4, 2011.⁴⁰

The Act passed with relatively little controversy, except for two amendments, which removed small and local food growers and processors from federal oversight.⁴¹ The Tester-Hagan Amendments—named for the Senators that sponsored the two amendments—offer protections for qualified facilities.⁴² The qualified facilities are operations that sell most of their products directly to consumers in the same state within a 400-mile radius and make less than \$500,000 per year.⁴³

³⁷ *H.R. 2749 (111th): Food Safety Enhancement Act of 2009*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/111/hr2749> (last visited Sept. 21, 2016).

³⁸ *S.510 - FDA Food Safety Modernization Act*, CONGRESS.GOV, <https://www.congress.gov/bill/111th-congress/senate-bill/510> (last visited Sept. 21, 2016); see also Meredith Shiner, *Senate OKs Food Measure*, POLITICO (Dec. 19, 2010), <http://www.politico.com/news/stories/1210/46598.html>.

³⁹ A tax provision must begin in the House in accordance with the US Constitution, a requirement that has garnered recent media coverage after the mandate in the Affordable Care Act was declared a tax—despite the ACA starting in the House. Shiner, *supra* note 38.

⁴⁰ *President Obama Signs Food Safety Modernization Act*, INSIDE UNITED FRESH (Jan. 6, 2010), <http://iuf.unitedfresh.org/newsletters/2011/01/06.php#1>.

⁴¹ Bill Marler, *The Tester-Hagan Amendment to S. 510 Protects Food Safety and Small Farmers*, MARLER BLOG (Oct. 1, 2010), <http://www.marlerblog.com/la-wyer-oped/the-tester-hagen-amendment-to-s-510-protects-food-safety-and-small-farmers/#.Vf9YumRViko>.

⁴² *Id.*

⁴³ *Id.*

The Tester-Hagan Amendments also exempt small-scale producers or “very small business” from the Act’s regulations.⁴⁴ Small-scale producers are producers that sell their goods at farmers’ markets or roadside stands; they are regulated by local and state entities and are not expected to meet the requirements contained in the Act.⁴⁵ But a new proposed rule may qualify the definitions to mean produce sales, not generally food sales.⁴⁶

1. Key elements of the Act and regulations

Although the FDA “historically has had little involvement in raw produce safety,” the Act “directs the FDA to work with the USDA to propose ‘science-based minimum standards for the safe production and harvesting of fruits and vegetables that are raw agricultural commodities for which the FDA has determined such standards will minimize the risk of ‘serious adverse health consequences.’”⁴⁷

The Act includes legislative mandates that require “comprehensive, science-based preventive controls”⁴⁸ for growers and producers. In other words, the FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables.⁴⁹ The standards consider naturally occurring hazards, as well as hazards that are introduced either intentionally or unintentionally.⁵⁰ As a result, the Act includes regulations for hygiene of workers, animals near the growing area and water, packaging requirements, temperature controls, and soil amendments.⁵¹

⁴⁴ *FDA issues first major rule under Food Safety Modernization Act*, FARM & RANCH FREEDOM ALLIANCE (Sept. 17, 2015), <http://farmandranchfreedom.org/first-fsma-rule/>.

⁴⁵ *Id.*

⁴⁶ *FSMA Proposed Rule for Produce Safety*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm> (last updated Sept. 16, 2016).

⁴⁷ J. Glenn Morris, Jr. and Morris E. Potter, eds. *Foodborne Infections and Intoxications*, (4th Ed. 2013) 505.

⁴⁸ DELOITTE, *supra* note 16, at 5.

⁴⁹ *Id.*

⁵⁰ U.S. Food & Drug Admin., *Background on the FDA Food Safety Modernization Act (FSMA)*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm> (last updated July 13, 2015).

⁵¹ 21 U.S.C. § 350h (2011).

The Act also provides the FDA with new authority to conduct inspections and ensure compliance.⁵² Thereunder, the FDA has access to growers' and producers' records, such as their written preventive control plans and food safety information.⁵³

In response to concerns about intentionally contaminated product, the Act broadens the detention authority of the Bioterrorism Act, and allows for administrative detention based on a "reason to believe" that the food item has been misbranded or adulterated and thus violates a legal standard for the product.⁵⁴

In addition to the detention capabilities, the Act also vests the FDA with mandatory recall power.⁵⁵ The Act gives the FDA the authority to recall food in the case of contamination or illness.⁵⁶ Food producers are also required to track their food and implement plans to deal with recalls or outbreaks of disease—the records kept by the producers are of course reviewable by the FDA under FSMA.⁵⁷

The Act adds a new section—section 419—that establishes science-based minimum standards for the safe production and harvesting of fruits and vegetables that are raw agricultural commodities, which the FDA has determined minimize the risk of serious adverse health consequences or death.⁵⁸ The list includes most fruits and vegetables consumers eat each day, such as almonds, apples, apricots, avocados, bamboo shoots, banana, blackberries and blueberries, broccoli, cabbage, cantaloupe, carrots, cauliflower, celery, cherries, citrus (clementine, grapefruit, limes, lemons, mandarin, oranges, tangerines), cucumbers, endive, garlic, grapes, green beans, herbs, mushrooms, nectarine, onions, peaches, pears, peas, peppers, pineapple, plums, radish, scallions, spinach, sprouts, strawberries,

⁵² 21 U.S.C. § 350j (2011).

⁵³ *Id.*

⁵⁴ 21 U.S.C. § 334g (2011).

⁵⁵ 21 U.S.C. § 350l (2011).

⁵⁶ *Id.*

⁵⁷ 21 U.S.C. § 350c (2011).

⁵⁸ Linda Calvin, *The Food Safety Modernization Act and the Produce Rule*, U.S. DEP'T OF AGRIC., 1 (Mar. 29, 2013), <http://www.ers.usda.gov/media/1225180/vgs353sa2.pdf>.

squashes, tomatoes, walnuts, watercress, watermelon and other fruits and vegetables.⁵⁹

Many commentators take issue with the produce safety standards' failure to recognize the nuances and differences inherent in growing varied fresh fruits and vegetables, mushrooms, sprouts, peanuts and tree nuts.⁶⁰ The concern is that the items covered—particularly tree nuts—differ greatly from one another and are grown, harvested, used, and consumed in multitudinous ways. Thus, the products should not be so easily lumped together for regulation purposes. Indeed, some of the regulations paint with too broad a brush. Imposing superfluous restrictions on all types of product does not result in increased consumer protection.

2. Hurdles to implementation

The law's journey from farm to table does not end with the Act's passage. Since President Obama signed the Act into law in 2011, the FDA issued a number of rules—regulations drafted by the Agency and with the force of law—to guide implementation of the Act.⁶¹ As required by the Administrative Procedure Act, the FDA followed a process of issuing proposed regulations and sought comment from the public before a final rule was issued.⁶² The FDA's

⁵⁹ Subpart A – General Provisions, 78 Fed. Reg. 3629-3630 (proposed Jan. 16, 2013) (to be codified at 11 C.F.R. pt. 112.2), *available at* <https://www.gpo.gov/fdsys/pkg/FR-2013-01-16/pdf/2013-00123.pdf> (Produce that is not covered by Section 419 includes produce that is purportedly rarely consumed raw, for example, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, collard greens, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, sweet corn, sweet potatoes, turnips, winter squash (acorn and butternut squash), yams, and other fruits and vegetables. Although trends in the culinary world have certainly seen the advent of more of these foods being consumed raw. Produce produced by an individual for personal consumption and produce that is not a raw agricultural commodity are also exempted).

⁶⁰ *See generally* Degnan, *supra* note 10, at 5-6.

⁶¹ U.S. Food & Drug Admin., *FDA Food Safety Modernization Act (FSMA)*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/> (last updated Sept. 19, 2016).

⁶² U.S. Food & Drug Admin., *The Food Safety Law and the Rulemaking Process: Putting FSMA to Work*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm277706.htm> (last updated July 13, 2015).

proposed rules were published on the Federal Register.⁶³ Industry organizations, leaders, and general members of the public were given between 30 and 90 days to submit comments.⁶⁴ In some instances, the FDA also held a public meeting where commentators were able to provide oral feedback or seek guidance on certain regulations.⁶⁵ When a final rule is issued and published on www.regulations.gov, it is also assigned an effective date, although the amount of time before a rule may go into effect varies.⁶⁶

Although several regulations have been implemented, the process has not been seamless. For example, a consumer interest group, the Center for Food Safety, initiated a lawsuit against the FDA styled *Center for Food Safety and Center for Environmental Health v. Margaret Hamburg, M.D., Commissioner of U.S. Food and Drug Administration, et al*, No. 12-cv-4529 in the United States District Court for the Northern District of California (filed August 29, 2012).⁶⁷ The Plaintiffs sought declaratory and injunctive relief to enforce the Act after the FDA missed seven deadlines for promulgating food safety rules.⁶⁸

The District Court found that the FDA had violated the Act and the Administrative Procedure Act by “failing to promulgate the rules by their statutory deadlines.”⁶⁹ The FDA sought reconsideration, which was denied, and appealed to the United States Court of Appeal for the Ninth Circuit.⁷⁰ While the appeal was pending the parties settled the case, stipulated to vacating the court’s order and stipulated to a consent decree.⁷¹ The consent decree set out a schedule for FDA action on pending FSMA regulations and processes should the FDA need additional time to develop and finalize regulations.⁷²

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Center for Food Safety v. Margaret Hamburg, M.D.*, 2013 WL 5718339, at *1 (N.D. Cal. Oct. 21, 2013).

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ Consent Decree, *Center for Food Safety v. Margaret Hamburg, M.D.*, (No. 4:12CV04529), 2013 WL 5718339.

⁷² *Id.*

Another hurdle to full implementation is the need to introduce supplemental rules and revise prior rules. The FDA has sought several supplemental comments for already-implemented rules in order to reshape the monolithic requirements. The FDA is currently seeking comments for supplemental rules for Produce Safety, Preventive Controls for Human Food and Preventive Controls for Animal Food, and the Foreign Supplier Verification Programs.⁷³ The supplemental rules, though an established method of implementing legislation, nonetheless create difficulty for the produce industry, which must conduct business without clear direction.⁷⁴

A third hurdle to the Act's implementation has been appropriating sufficient funds for FDA's expanded role. The Act requires food producers and importers to pay an annual registration fee, which is used to fund the enhanced FDA inspections, enforcements, and related activities such as food-safety research.⁷⁵ Although more than 360,000 facilities in the United States and abroad are subject to the fees, the Congressional Budget Office reported that the fees would not cover the cost of the new system, leaving the FDA to incur a net cost of \$2.2 billion over five years.⁷⁶

D. The fresh produce industry

Four hundred and twenty-five million hundred pounds of fresh produce from over 1.65 million acres are harvested in the United States each year.⁷⁷ Due to growing consumer trends toward fresh and healthy foods, demand for fresh produce has increased and production of fresh vegetables has grown.⁷⁸ But fresh produce is susceptible to contamination from animal byproducts, water-borne microbes, and cross-contamination with meat.⁷⁹ Insufficient refrigeration during transportation, poor handling practices at restaurants, food retailers, or in the home can also present risks.⁸⁰ Raw product is usually cut by hand, visually inspected and packed directly in the

⁷³ U.S. Food & Drug Admin., *supra* note 62.

⁷⁴ *Id.*

⁷⁵ Layton, *supra* note 3.

⁷⁶ *Id.*

⁷⁷ Bell et. al., *supra* note 1, at 4.

⁷⁸ *Id.* at 5.

⁷⁹ *Id.* at 4.

⁸⁰ *Id.*

field, or in some cases placed in large bins to be packed in a warehouse.⁸¹ Packaging in such a manner is both efficient and minimizes bruising and damage to product from multiple handlings.⁸²

Large food companies are grappling with “a shift in Americans’ tastes towards fresh foods and away from processed foods.”⁸³ The fresh-cut produce industry has grown from “practically zero dollars” in the early 1990s to over \$3 billion in 2007 (about \$1.5 billion of which is realized at the grower/shipper level).⁸⁴ Much of the produce bought in the United States is raw, agricultural product that is often field-packed.⁸⁵ This means that the product is harvested, packaged, and packed for shipment directly in the field.⁸⁶ Field-packing produce can help prevent damage to delicate produce and reduce the number of people that handle the produce, but it also means that the produce is packaged raw without cleaning or processing.⁸⁷ Thus, the product comes directly from the field where it was exposed to the elements, pests, and field-workers, among other factors.⁸⁸

In addition to an increased focus on eating healthy, many consumers seek goods that they consider “local and sustainable.”⁸⁹ Essentially, consumers are concerned with safer and more environmentally friendly rather than “factory farmed” vegetables.⁹⁰ Moreover, locally grown food is viewed as a status symbol—an August 2008 New York Times article called local food “a powerful symbol

⁸¹ *Id.* at 7.

⁸² Bell et. al., *supra* note 1, at 4.

⁸³ Annie Baxter, *Activist Investor May Trim Fat at Oreo Maker*, MARKETPLACE BUSINESS (Aug. 6, 2015), <http://www.marketplace.org/topics/business/activist-investor-may-trim-fat-oreo-maker>.

⁸⁴ Bell et. al., *supra* note 1, at 4.

⁸⁵ See U.S. Food & Drug Admin., *Guide to Produce Farm Investigations (11/05)*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm272372.htm#final> (last updated Nov. 25, 2014).

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ Maggie Hennessey, *Consumers seek out ‘natural,’ ‘locally grown,’ on product label: survey*, FOOD NAVIGATOR-USA (June 25, 2014), <http://www.foodnavigator-usa.com/Markets/Consumers-seek-out-natural-locally-grown-on-product-labels-survey>.

⁹⁰ Bell et. al., *supra* note 1, at 33.

of high quality and goodness.”⁹¹ Although large-scale produce companies have bought from small local farmers for years in order to meet customer demands or fill orders, a wave of demand for local and sustainable ways to eat has increased the pressure on large-scale companies to meet consumer demand.⁹² When these companies buy from small producers, they have to ensure that the quality and food safety requirements are met.⁹³

II. THE “MONSTER” UNDER THE LETTUCE LEAF: *LISTERIA MONOCYTOGENES*

Pathogens and micro-organisms⁹⁴ are an inescapable part of our world’s ecosystem. Naturally occurring pathogens can be harmless or virulent depending on the strain, the amount of pathogen present, the immune system and health of the individual consuming the pathogen, and a host of other factors.⁹⁵ Some of the most common pathogens found on fresh produce include *Salmonella enterica*, *Escherichia coli* 0157:H7 (E. coli), and *listeria monocytogenes*.⁹⁶ Pathogen production and proliferation can depend on environmental stress, pathogen population size, incubation time, type of environment, competition with other leaf microbiota and sample mass.⁹⁷

⁹¹ *Id.*

⁹² *Id.* at 13.

⁹³ *Id.*

⁹⁴ A pathogen is an infection biological agent that causes disease or illness to its host. SCIENCE DAILY, *Pathogen*, available at <http://www.sciencedaily.com/terms/pathogen.htm> (last visited June 25, 2015); The term is used throughout this article interchangeably with micro-organism. Micro-organisms are organisms that are so small that they are invisible to the naked eye. SCIENCE DAILY, *Micro-organism*, available at <http://www.sciencedaily.com/terms/microorganism.htm> (last visited June 25, 2015).

⁹⁵ *Listeria Food Poisoning*, ABOUT LISTERIA, <http://www.about-listeria.com> (last visited Sept. 21, 2016).

⁹⁶ See U.S. Food & Drug Admin., *Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce: Chapter IV. Outbreaks Associated with Fresh and Fresh-Cut Produce. Incidence, Growth, and Survival of Pathogens in Fresh and Fresh-Cut Produce*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm091265.htm> (last updated Aug. 10, 2015).

⁹⁷ Trevor Suslow, *California Leafy Green Research Program 2011-2012 Report: Validation of rapid pathogen detection methods for leafy green production*,

Listeria monocytogenes is the major human pathogen in the listeria family⁹⁸ and *is illustrative*. *It often appears on food items in negligible numbers and with minimal consequences*. Listeria can grow in the presence or absence of air.⁹⁹ And unlike many other germs, listeria can grow even in the cold temperature of the refrigerator.¹⁰⁰ Listeria is the typical cause of the relatively rare bacterial disease, listeriosis, a serious infection caused by eating food contaminated with the bacteria. The disease affects primarily pregnant women, newborns, adults with weakened immune systems, and the elderly.¹⁰¹ Listeriosis is a serious disease for humans—its mortality rate is about 20 percent. The two main clinical manifestations of listeriosis are sepsis and meningitis. Meningitis is often complicated by encephalitis, an inflammation of the brain that is unusual for bacterial infections.¹⁰²

Listeria is present in soil and water, and some animals, including poultry and cattle.¹⁰³ *Listeria* is killed by cooking and pasteurization.¹⁰⁴ In 2011, *Listeria* made headlines when cantaloupes sold by Colorado based Jensen Farms resulted in over 147 confirmed cases of *listeria monocytogenes* and 33 deaths.¹⁰⁵ Most food-related *listeria* cases are caused by deli meats, hot dogs, and soft cheeses made

at 2, available at http://calgreens.org/control/uploads/Food_Safety_-_Pathogen_Detection_Kits1.pdf.

⁹⁸ *Listeria Food Poisoning*, *supra* note 95.

⁹⁹ Anaerobic Bacterial Strains, GLOBALRPH, <http://www.globalrph.com/bacterial-strains-anaerobic.htm> (last visited June 26, 2015).

¹⁰⁰ *Listeria*, FOODSAFETY.GOV, <https://www.foodsafety.gov/poisoning/causes/bacteriaviruses/listeria/> (last visited Sept. 18, 2016).

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/120811/index.html> (last updated Aug. 27, 2012 at 10:30 AM); “An outbreak of Listeria in cantaloupe melons in the U.S. may cause more illness and death in coming weeks.” *Listeria outbreak expected to cause more deaths across U.S. in coming weeks*, THE GUARDIAN (Sept. 29, 2011) available at <http://www.theguardian.com/world/2011/sep/29/listeria-outbreak-us-cantaloupe-melons>; Southwick, F. S.; D. L. Pritch, *More About Listeria*, University of Florida Medical School (last visited Mar. 17, 2015); Todar’s Online Textbook of Bacteriology, *Listeria monocytogenes and*

with unpasteurized milk.¹⁰⁶ Produce is not typically identified as a *listeria* source, but in addition to the Jensen Farms outbreak, *listeria* caused a 2009 sprouts-related outbreak and a 2010 celery-related outbreak.¹⁰⁷

III. LOW-LEVEL PATHOGENS, SUCH AS *LISTERIA MONOCYTOGENES*, DO NOT CONSTITUTE ADULTERATION FOR FSMA PURPOSES

Certainly, Good Manufacturing and Good Agricultural Practices used to produce minimally processed fresh produce cannot be one-hundred percent effective in eliminating potential pathogens. Contamination and sickness can occur even where the grower has implemented—and adheres to—approved practices.

Mistakes happen. Accordingly, state law exists to adjudicate liability and administer relief. For example, certain states use strict liability to hold growers accountable.¹⁰⁸ This article argues that the mere existence of low-level pathogens, such as *listeria monocytogenes*, does not render a product adulterated. The produce is not adulterated because *listeria* is naturally occurring—it is not a foreign substance; it could be reasonably expected by the consumer to exist on the produce; and it does not render minimally processed fresh produce unfit or defective.

A. Naturally occurring, low-level, trace amounts of *listeria* do not meet the statutory definitions of adulteration

The only express reference in the Act to the contamination of food by micro-organisms is found in section 404 (title 344), “Emergency Permit Control.”¹⁰⁹ This section provides the FDA with the extraordinary power of issuing permits for the manufacturers, processors, or packers of the food—permits “to which shall be attached

Listeriosis, Kenneth Todar University of Wisconsin-Madison Department of Biology (2003) (last visited Mar. 17, 2015).

¹⁰⁶ *Multistate Outbreak of Listeriosis*, *supra* at note 105.

¹⁰⁷ *Id.*

¹⁰⁸ *Liability for Foodborne Illness & Injury*, PUBLIC HEALTH LAW CENTER, http://publichealthlawcenter.org/sites/default/files/resources/f.s.food_borne_illnesses.WEB_.pdf (last updated July 2015).

¹⁰⁹ 21 U.S.C. §344 (2011).

such conditions governing the manufacture, processing, or packing of such class of food,” to protect “public health.”¹¹⁰ In order to implement section 404, the FDA must make a finding that “the contaminated and injurious nature of the food cannot be determined adequately until after the food has entered into commerce.”¹¹¹ Adulterated food is defined in the Act at 21 U.S.C. § 402, referred to as section 342:

(a) A food shall be deemed to be adulterated—

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

¹¹⁰ *Id.*

¹¹¹ Degnan, *supra* note 10, at 2-4 (“The FDA’s regulation of food safety has revolved around the legal concept of ‘adulteration.’”).

- (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or
- (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or
- (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
- (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.¹¹²

The FDA relies on this section of the Act to render product found with naturally occurring microorganisms adulterated. Subsection (1) is the only subsection applicable to naturally occurring *listeria* found in minimal trace levels on raw agricultural product.

Subsection (1) renders a product adulterated if it contains any “poisonous or deleterious substance which may render it injurious to health.”¹¹³ Subsection (1) also specifies that where the substance is not “an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.”¹¹⁴ Thus, the mere presence of a poisonous or deleterious substance is not sufficient to result in “adulterating” a product, the substance must be present in such an amount as to be reasonably expected to injure the health of a consumer before the strictures of the section can be imposed.¹¹⁵ The “may render injurious” component of section 402(a)(1) was not original to the 1938 act and, it is a crucial addition because it provided the cornerstone for the FDA’s food adulteration

¹¹² 21 U.S.C. § 342 (2011).

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ Degnan, *supra* note 10, at 2.

authority and control over naturally occurring microbiological contaminants.¹¹⁶

The first time the FDA began using “adulterant” to describe a micro-organism, as opposed to a “toxic industrial chemical,” was in 1994 after the Jack-in-the-Box hamburger *E. coli* outbreak.¹¹⁷ At that time, the USDA’s Food Safety and Inspection Service adopted “a zero-tolerance policy” toward *E. coli* in ground beef.¹¹⁸ Several strains have since been officially classified as “adulterants” for purposes of meat and poultry products.¹¹⁹ As to fruits and vegetables, the FDA has adopted a zero tolerance for *Salmonella* and *E. coli* 0157:H7 in raw sprouts.¹²⁰ Otherwise, the FDA website describes produce as “contaminated,” not adulterated,¹²¹ and does not include a tolerance level for *listeria monocytogenes* or *Salmonella* and *E. coli* 0157:H7 on other products.

B. Case law supports a nuanced application of “adulterated” to produce with trace amounts of pathogen.

Imposition of a zero tolerance policy by the FDA is not a new concept, courts in the past have found that the mere presence of a pathogen does not signify adulteration. In 1974, the Court of Appeals for the District of Columbia considered whether the USDA labeling procedures were adequate to protect consumers.¹²² The court held that official Department of Agriculture inspection labels placed on raw meat and poultry products were not insufficient be-

¹¹⁶ 21 U.S.C. § 342 (2011).

¹¹⁷ Hylton, *supra* note 6.

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ Food and Drug Administration, *Growing Sprouts in Retail Food Establishment - CFP Issues 02-III-01 and 04-III-012*, (Dec. 2004), <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ucm078758.htm>.

¹²¹ U.S. Food & Drug Admin., *Produce: Selecting and Serving it Safely*, DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://www.fda.gov/Food/FoodborneIllnessContaminants/BuyStoreServeSafeFood/ucm114299.htm> (last updated Apr. 06, 2016).

¹²² *See generally Am. Public Health Ass’n v. Butz*, 511 F.2d 331 (D.C. Cir. 1974).

cause they failed to warn of the dangers of salmonella and other bacteria.¹²³ Moreover, the court found that within the meaning of the Wholesome Meat Act, “the presence of Salmonella in meat does not constitute adulteration.”¹²⁴

In a later case, *Seabrook International Foods, Inc. v. Harris*, the Court of Appeals for the Washington, D.C. Circuit considered the language in the *Butz* decision to be “plainly dictum which did not reflect consideration of any factual basis or legal analysis of the adulteration provision of that Act.”¹²⁵ In *Seabrook*, plaintiff, importers of raw, frozen shrimp, sued the FDA and sought injunctive and declaratory relief from an FDA decision to refuse to admit plaintiffs’ product into the United States.¹²⁶ In the late 1970s the FDA analyzed salmonella presence on shrimp imported from India and found that 28% of the sampled shrimp contained salmonella.¹²⁷ The FDA began a practice to automatically detain all raw, frozen shrimp from India.¹²⁸

The court considered whether the FDA’s application of law to the facts of the case was arbitrary, capricious, or an abuse of discretion.¹²⁹ The *Seabrook* court analyzed the meaning of “adulterated” within the FDCA and concluded that the FDA’s actions—refusal to admit *salmonella*-tainted shrimp into the United States—were lawful under the FDA’s definition of “added.”¹³⁰ The court noted that, although “salmonella may occur in nature . . . salmonella contamination may result from human intervention” and the record was clear that the salmonella in the shrimp at issue was “attributable to insanitary processing procedures.”¹³¹

The *Seabrook* court emphasized that the section 342 standard for adulterants is broken into two classes: (1) when a good contains an “added” substance it is adulterated if the substance “may render it injurious to health;” but (2) when a food contains a substance that is

¹²³ *Id.* at 5.

¹²⁴ *Id.* at 4.

¹²⁵ *Seabrook Int’l Foods, Inc. v. Harris*, 501 F. Supp. 1086, 1092 (D.C. Cir. 1980).

¹²⁶ *Id.* at 1087.

¹²⁷ *Id.* at 1088.

¹²⁸ *Id.*

¹²⁹ *Id.* at 1090.

¹³⁰ *Seabrook Int’l Foods, Inc.*, 501 F. Supp. at 1091.

¹³¹ *Id.*

not added, the food is adulterated only if the substance would “ordinarily render it injurious to health.”¹³²

The *Seabrook* court relied on a Fifth Circuit case, *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir. 1980).¹³³ The *Anderson Seafoods* court examined whether mercury in the tissues of swordfish was an “added substance” within the meaning of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 342(a)(1).¹³⁴ The court noted that the Act “did not contemplate, [], the perhaps rare problem of a toxin, part of which occurs “naturally,” and part of which results from human acts.”¹³⁵ The FDA proposed that all the mercury in the swordfish was an added substance, because it resulted not from the creature’s bodily processes but from mercury in the environment, whether natural or introduced by man.¹³⁶ The Plaintiff, Anderson, put forward a second theory—that a substance is not an added substance unless it is proved to be present as a result of the direct agency of man.¹³⁷ Further, only the amount of a substance that could be traced to human intervention is “added.”¹³⁸ In other words, if some mercury in swordfish occurs naturally, and some is the result of man-made pollution, only that percentage of the mercury in fish proved to result directly from man-made pollution is an added substance.¹³⁹ The district court adopted a third theory (which the Fifth Circuit also adopted).¹⁴⁰ Under the court’s theory, if a *de minimis* amount of the mercury in swordfish is shown to result from industrial pollution, then all of the metal in the fish is treated as an added substance and may be regulated under the statute’s “may render injurious” standard.¹⁴¹ The Fifth Circuit ultimately held that: “however, we agree [] that the term “added” as used in section

¹³² *Id.*

¹³³ *See id.*

¹³⁴ *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157, 158 (5th Cir. 1980).

¹³⁵ *Id.* at 160–161.

¹³⁶ *Id.* at 159.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Anderson Seafoods, Inc.*, 622 F.2d at 159.

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

342(a)(1) means artificially introduced, or attributable in some degree to the acts of man.”¹⁴²

The *Anderson Seafoods* court held that “[s]ince the purpose of the ‘may render injurious’ standard was to facilitate regulation of food adulterated by acts of man, we think it should apply to all of a toxic substance present in a food when any of that substance is shown to have been introduced by man.”¹⁴³ Relying on that language to apply to the *salomenlla*-tainted shrimp, the *Seabrook* court concluded that the FDA’s observations of insanitary landing areas and packing procedures, combined with the “general scientific observations on the nature of salmonella contamination in shrimp,” provided an ample basis to conclude that the presence of salmonella in the shrimp appeared to be attributable to human intervention.¹⁴⁴ That conclusion was within the FDA’s discretion and, the FDA did not carry the burden of proving the intervention of man; rather the plaintiffs had the burden of proving the contrary in order to overcome the conclusion that the shrimp appeared to be contaminated.¹⁴⁵

The Supreme Court addressed adulteration, tolerance levels, and section 342 in *Young v. Community Nutrition Institute*.¹⁴⁶ In *Community Nutrition*, two public-interest groups and a consumer brought an action against the FDA alleging that the Act required the FDA to set a tolerance level for aflatoxin before allowing shipment of food that contained the naturally occurring fungus.¹⁴⁷ The District Court granted summary judgment in favor of the FDA, and after the Court of Appeals reversed in part and remanded, the Supreme Court granted certiorari.¹⁴⁸ Ultimately, the Supreme Court, in an opinion authored by Justice Sandra Day O’Connor, held that the FDA had the discretion to promulgate or not promulgate tolerance levels for added, but unavoidable, harmful substances.¹⁴⁹

¹⁴² *Id.* at 160.

¹⁴³ *Id.* at 161.

¹⁴⁴ *Seabrook*, 501 F. Supp. at 1092.

¹⁴⁵ *Id.*

¹⁴⁶ *See generally Young v. Cmty. Nutrition Inst.*, 476 U.S. 974 (1986).

¹⁴⁷ *Id.* at 978.

¹⁴⁸ *Id.* at 975.

¹⁴⁹ *Id.* at 984.

Justice O'Connor reasoned that although "the Act does provide that when a tolerance level has been set and a food contains an added harmful substance in a quantity below the tolerance level, the food is legally not **adulterated**. But one cannot logically draw from this premise, or from the Act, the [] conclusion that food containing substances *not* subject to a tolerance level *must be* deemed **adulterated**."¹⁵⁰ The Supreme Court further reasoned that section 346 gives the FDA authority to "choose whatever tolerance level is deemed 'necessary for the protection of public health,' and food containing a substance less than the tolerance level "shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated."¹⁵¹ As discussed above, section 342 considers a substance adulterated if it is ordinarily injurious to human health. But section 346 states:

"Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect . . . food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated . . ."¹⁵²

The Court held that section 346, therefore, creates a "specific exception to section 342(a)'s general definition of adulterated food as that containing a quantity of a substance that renders the food

¹⁵⁰ *Id.* at 982 (emphasis in original).

¹⁵¹ *Young*, 476 U.S. at 984.

¹⁵² 21 U.S.C. § 346 (2011).

‘ordinarily . . . injurious to health.’”¹⁵³ The Court noted that “simply because the FDA is given the choice between employing the standard of section 346 and the standard of section 342(a), does not render section 346 superfluous.”¹⁵⁴

In other words, the Supreme Court succinctly reasoned that an added amount of a substance does not as a rule render the product adulterated.¹⁵⁵ Clearly, well-reasoned precedent does not support imposing a zero tolerance level for naturally occurring, low-level pathogens. The mere presence of an added, but unavoidable, pathogen in trace amounts does not render a product adulterated and thus subject to Food Safety Alerts, detention, and recalls.

The second standard in section 342 for adulterants should apply in cases where a naturally occurring pathogen is at issue—in other words, the *listeria* should be treated as a substance that is not added by man and thus the food is adulterated only if the substance would “ordinarily render it injurious to health.”¹⁵⁶ Whether it becomes clear that the *listeria* was present at the grower’s farm or whether an investigation fails to show the root cause, unless there is clear evidence that the *listeria* was “attributable to insanitary and improper processing procedures” the food should be considered adulterated only if the amount of *listeria* would “ordinarily render it injurious to health.”¹⁵⁷

C. Imposing a zero tolerance policy for low-levels of *listeria* creates absurd, inconsistent global results.

There is a high potential for major disruptions to business without added benefit to the consumer if minimal trace amounts of a pathogen render the product adulterated. For example, in 2014, trace amounts of *listeria* were found on stone fruit that was being imported into Australia from Wawona Packing Company’s California location.¹⁵⁸ Australian tests found minimal amounts of *listeria*

¹⁵³ *Young*, 476 U.S. at 984.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Seabrook*, 501 F. Supp. at 1091 (emphasis added).

¹⁵⁷ *Id.*

¹⁵⁸ Warwick Long, *Australians Eat Peaches and Nectarines Recalled Due to Listeria Outbreak in the United States*, ABC RURAL (Aug. 5, 2014), <http://www.abc.net.au/news/2014-08-06/nrn-peach-recall/5651690>.

but deemed the product safe for consumption and sale.¹⁵⁹ The product sold and was eaten in Australia.¹⁶⁰ However, in the United States, after sharing the Australian test results with the FDA, Wawona was forced to issue a voluntary recall of its stone fruits, and US media referred to the event as an “outbreak.”¹⁶¹

Although the trace amounts were within the tolerance levels in Australia and New Zealand, the FDA used a zero-tolerance policy for *listeria* and Wawona was forced to recall.¹⁶² After the recall, Wawona ordered additional testing of its product, which came back negative for *listeria*.¹⁶³ The Wawona recall is an example of the extreme results of the FDA’s zero-tolerance policy towards low-level pathogens like *listeria*. The trace amounts found by Australian authorities did not necessitate a costly, unnecessary recall and most importantly, did not sicken or even prevent Australians from consuming the stone fruit.¹⁶⁴ And later testing showed no further traces of *listeria*.¹⁶⁵ In order to avoid the unnecessary expense, waste and distrust created by a recall, the FDA and United States should adopt tolerance levels for low-level pathogens, such as *listeria*.

IV. CONCLUSION

The Act seeks to protect consumer health, but the FDA’s zero tolerance policy is overly broad. GAPs/GMPs, industry self-regulation, and reasonable, science-based standards suffice to ensure safe produce without increasing costs to consumers. With that balance in mind, the FDA should not evaluate low-levels of *listeria* un-

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² Dan Flynn, *Aussie Listeria Tests Lead to Recall of Already-Consumed California Fruit*, FOOD SAFETY NEWS (July 23, 2014), <http://www.foodsafetynews.com/2014/07/aussie-tests-of-california-fruit-lead-to-recall-of-mostly-consumed-fruit/#.VflnXWTBzGc>.

¹⁶³ *Id.*

¹⁶⁴ Long, *supra* note 158.

¹⁶⁵ Coral Beach, *Wawona Stonefruit Recall Spurred by Australian Tests*, THE PACKER (July 22, 2014), <http://www.thepacker.com/fruit-vegetable-news/Wawona-recalls-6-weeks-of-stone-fruit-shipments-267948991.html>.

der the section 342 “may render [] injurious to health” standard because, based on substantive judicial analysis, naturally occurring low-levels of *listeria* are not an added substance under the Act.¹⁶⁶

Moreover, low-levels of *listeria* do not “ordinarily render” the produce “injurious to health,” as evidence by the Wawona Packing example.¹⁶⁷ Based on the Act’s history, reasoned case law, and practical reality, the FDA should promulgate section 346 risk and science-based tolerance levels for *listeria* in minimally processed produce. Section 346 risk and science-based tolerance levels would best fulfill the goal of protecting public health without unduly burdening the Industry.

¹⁶⁶ 21 U.S.C. § 342 (2011).

¹⁶⁷ See Long, *supra* note 158.