KNOWN UNKNOWNS: UNMEASURABLE HAZARDS AND THE LIMITS OF RISK REGULATION

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Abstract

Known unknowns are identifiable hazards that pose an unquantifiable risk of harm. The inability to characterize known unknowns in terms of measurable risk poses a dilemma for regulators. When known unknowns cause harm, public pressure often leads Congress to mandate that agencies establish specific, science-based thresholds for acceptable risk. In response, regulators, who lack scientific evidence to justify such rules, face a choice: they can either delay the rulemaking process or fabricate a scientific justification. If they adopt the first option, they expose themselves to potential litigation by public interest groups demanding that they comply with the law. If they adopt the second option, they expose themselves to potential litigation by regulated entities challenging the new rules as arbitrary and capricious. What's an agency to do?

This Article develops general principles for addressing known unknowns using a case study of efforts to regulate agricultural water quality. Contaminated water used to cultivate fresh produce is a well-known cause of recurrent foodborne illness outbreaks. Unfortunately, it has, so far, proven impossible to reliably quantify the risk of human illness from any given source of agricultural water. A detailed analysis of the challenges that have frustrated successful regulation of agricultural water quality provides the basis for specific, feasible recommendations to help regulators cope with known unknowns in a variety of contexts, such as climate change, environmental toxins, and pandemic response.

When confronting known unknowns, regulators should prioritize harm reduction strategies that generate new policy-relevant information. Additionally, they should rely on localized private governance efforts

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endorsed by a broad representation of stakeholders. Finally, regulators should be more transparent about the limits of risk regulation.

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Introduction

Agricultural production follows a cycle. Each season, farmers prepare the soil, sow seeds, grow crops, and harvest produce. Leafy greens producers in California and Arizona have become accustomed to another cycle, one that threatens the future of their industry—periodic foodborne illness outbreaks, consequent financial losses, subsequent revision of food safety standards and, eventually, another outbreak. More than one hundred such outbreaks have occurred since the early 1980s.[1] Serious illness caused

1. *Foodborne Illness Outbreak Database*, OUTBREAK DATABASE, https://perma.cc/5PTH-PHW6 (last visited Mar. 11, 2024). See *infra* notes 28-41 and accompanying text for more detailed data regarding foodborne illness outbreaks attributable to contaminated leafy greens.

by tainted romaine lettuce, spinach, and bagged salad mixes has become routine and, in some cases, resulted in permanent disability or death.[2] Regulators know that the next growing season will bring more outbreaks. However, because they cannot quantify the risk, they struggle to manage it effectively. These recurrent foodborne illness outbreaks exemplify the problem of known unknowns.

The term known unknowns is used in management science to mean "things you're aware of but don't understand."[3] In this Article, the term specifically denotes identifiable hazards that pose an unquantifiable risk of harm. This Article analyzes the challenges of regulating known unknowns and develops recommendations for helping regulators cope.

Uncertainty is, by definition, inherent in all risk regulation.[4] Even so, known unknows are a species of what scholars call deep uncertainty,[5] and

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2. *See infra* notes 31-42 and accompanying text.

3. Andrea Mantovani, *Known Knowns, Known Unknowns, Unknown Unknowns & Leadership*, MEDIUM (Apr. 28, 2020), https://perma.cc/943F-PB7J.

4. The concept of risk quantifies uncertain outcomes in terms of their probability and magnitude. Giandomenico Majone, *Strategic Issues in Risk Regulation and Risk Management*, *in* ORG. FOR ECON. CO-OP. & DEV., RISK AND REGULATORY POLICY: IMPROVING THE GOVERNANCE OF RISK 93, 102 (2010) [hereinafter RISK AND REGULATORY POLICY] ("Risk is defined as the probability of an unfavourable event multiplied by the severity of harm, if the event occurs.").

5. *E.g.,* Warren E. Walker et al., *Deep Uncertainty*, *in* ENCYCLOPEDIA OF OPERATIONS RESEARCH AND MANAGEMENT SCIENCE 395, 397 (Saul I. Gass & Michael C. Fu eds., 3d ed. 2013) (distinguishing various levels of uncertainty and defining deep uncertainty as a situation where "one is able to enumerate multiple plausible alternatives without being able to rank the alternatives in terms of perceived likelihood"); Daniel Farber, *Catastrophic Uncertainty and Regulatory Impact Analysis* 1 (Legal Priorities Project Working Paper Series No. 2-2022, 2022) (defining deep uncertainty as occurring when the probability of possible outcomes "cannot be quantified").

Instead of distinguishing uncertainty that can be expressed in terms of risk from deep uncertainty, which cannot, some accounts instead categorically distinguish uncertainty from risk. According to these accounts, uncertainty denotes the inability to determine the probability of potential outcomes, making it impossible to quantify them in terms of risk. *See* JOHN ADAMS, RISK 25 (1995), http://www.john-adams.co.uk/wp-content/uploads/2017/01/RISK-BOOK.pdf (paraphrasing economist Frank Knight) (distinguishing risk, "if you don't know [whether an occurrence] will happen, but you know the odds," from uncertainty, where the odds are not known); Stephen Dovers et al., *Uncertainty, Complexity and the Environment*, *in* UNCERTAINTY AND RISK: MULTIDISCIPLINARY PERSPECTIVES 245, 249 (Gabriele Bammer & Michael Smithson eds., 2008) (distinguishing risk, where "believable probability distributions can be assigned to possible outcomes," from uncertainty, "where the direction of change is believed to be known, but precision in predicting the scale or probability of impacts is not possible and believable probability distributions cannot be assigned"); Roger E. Kasperson, *Coping with Deep Uncertainty: Challenges for Environmental Assessment and Decision-*

they present heightened challenges to risk regulators. The inability to characterize known unknowns in terms of measurable risk hinders efforts to regulate them rationally. Because the risks they pose are unquantifiable, known unknowns frustrate cost-benefit analysis.[6] Known unknowns also prompt public anxiety that can fuel demand for increasingly stringent and detailed regulation despite a lack of scientific evidence, on the questionable theory that doing something is better than doing nothing.[7] Since the uncertainty of known unknowns is just as problematic for industry experts as it is for agency officials, policies that rely on private governance yield limited regulatory benefits.[8]

Known unknowns often place regulatory agencies in a bind. The inability of policymakers to characterize these identifiable hazards in terms of measurable risk makes it impossible to establish scientifically justifiable thresholds for acceptable risk, leading agencies to promulgate vague admonitions that lack sufficient specificity to be enforceable. Nevertheless, when these hazards do cause harm, public pressure often leads Congress to mandate that agencies produce specific, enforceable, science-based rules to prevent future harm.[9] In response, regulators, who lack the required scientific evidence to justify such rules, face a choice: they can either delay rulemaking until the science necessary to justify detailed and binding regulations emerges, or they can publish such regulations without adequate scientific justification. If they adopt the first option, they expose themselves to potential litigation by public interest groups demanding that they promulgate new regulations, as required by Congress. If they adopt the second option, they expose themselves to potential litigation by regulated entities challenging the new regulations as arbitrary and capricious. Faced with this dilemma, regulatory agencies sometimes choose a third option.

Making, *in* UNCERTAINTY AND RISK: MULTIDISCIPLINARY PERSPECTIVES, *supra*, at 337, 338 (distinguishing between the concepts of hazards, risk, uncertainty, and ignorance); Cass R. Sunstein, *The Catastrophic Harm Precautionary Principle*, 6 ISSUES LEGAL SCHOLARSHIP, no. 3, article 3, 2007, at 11, https://perma.cc/4EQ9-MCU8 (distinguishing risk, "where outcomes can be identified and probabilities assigned" from uncertainty, "where outcomes can be identified but no probabilities can be assigned"); *cf. id.* at 17-20 (discussing the view of some economists that uncertainty does not exist).

6. *See infra* Section II.B.
7. *See infra* Section II.C.
8. *See infra* Section II.D.
9. *See infra* Section I.B.

They pretend to possess the necessary scientific evidence to justify new regulations. This is known as the "science charade."[10]

This Article analyzes the problem of known unknowns through a detailed case study of efforts to regulate agricultural water quality. For more than a quarter century, fecal contamination of water used to grow fresh produce has been identified as a cause of routine foodborne-illness outbreaks in the United States.[11] Unfortunately, despite the concerted efforts of government officials, industry experts, and academic researchers, it has, so far, proven impossible to reliably quantify the risk of human illness from any given source of agricultural water. Agricultural water is a paradigm case of a known hazard with an unknown risk of causing harm. In addressing the challenge of regulating agricultural water quality, government agency officials have faced the untenable choice between disobeying legal mandates to produce enforceable science-based rules and promulgating rules unjustified by science, so they have engaged in the science charade.[12]

The Article develops five guiding principles for regulating known unknowns. First, regulators should resist the temptation to respond reflexively to public anxiety about known unknowns with stringent and specified risk management rules unsupported by scientific evidence.[13] Second, regulators should prioritize verifiable harm-reduction measures that generate new policy-relevant information or that offer ancillary benefits.[14] Third, regulatory efforts should rely on state-of-the-art risk-management standards developed with broad stakeholder participation.[15] Fourth, regulators should aim to strengthen the integrity of regulatory science by being transparent about its limitations and acknowledging the impossibility of completely eliminating risk.[16] Fifth, regulators should

10. Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1617 (1995) [hereinafter Wagner, *The Science Charade*]. The "science charade" is discussed *infra* Section II.E.

11. Christina K. Carstens et al., *Multistate Outbreaks of Foodborne Illness in the United States Associated with Fresh Produce from 2010 to 2017*, 10 FRONTIERS IN MICROBIOLOGY, article no. 2667, Nov. 2019, at 2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6883221/pdf/fmicb-10-02667.pdf.

12. *See infra* Section II.E.

13. *See infra* Section III.A.

14. *See infra* Section III.B.

15. *See infra* Section III.C.

16. *See infra* Section III.D.

maintain a broad perspective on the hazard to identify emerging opportunities for low-cost, verifiable hazard prevention or mitigation.[17]

Beyond food safety, known unknowns present some of today's most intractable regulatory challenges. For example, it is now well established that carbon pollution causes climate change, but climate science cannot prescribe precise emissions standards that will achieve predictable outcomes.[18] Similarly, regulators have long struggled to reduce environmental toxins in the absence of precise risk information.[19] Likewise, a great deal is known about infectious disease transmission, but science alone cannot justify precise social distancing and masking requirements.[20]

The question of how to regulate uncertain risks has been the subject of fierce debate between proponents of risk-based regulation, who insist on using some form of cost-benefit analysis, and advocates of the precautionary principle, who favor harm reduction.[21] This Article recognizes the merits of both approaches. It recommends that, where known unknowns currently preclude reliable cost-benefit analysis, regulators should adopt a precautionary approach informed by hazard control principles that reduce harm while generating policy-relevant information likely to improve the prospects for reliable cost-benefit analysis in the future. Additionally, this Article presents a novel perspective on regulatory reform. Amid increasingly polarized public discourse about regulatory policy characterized by a contest between two seemingly incompatible ideals of government regulation and unregulated markets, this Article asserts that the most effective way to bolster the integrity of public regulation is through greater reliance on private governance.[22]

The Article proceeds in four parts. Part I introduces the problem of known unknowns. It illustrates this problem through a case study that analyzes why scientists have been unable to assess and, therefore, manage

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17. *See infra* Section III.E.

18. *See* Farber, *supra* note 5, at 1, 7-11; Sunstein, *supra* note 5.

19. *See* Wagner, *The Science Charade*, *supra* note 10, at 1617, 1622.

20. *See* Emily Anthes, *Three Feet or Six? Distancing Guideline for Schools Stirs Debate*, N.Y. TIMES (Mar. 16, 2021), https://perma.cc/36ZN-4QR5 (quoting an expert on viral transmission at Virginia Tech University opining that the CDC's six-foot social distancing recommendation was "almost like it was pulled out of thin air"); Graham Martin & Esmee Hanna, *Science and Society During Covid-19: An Increasingly Fractious Relationship?*, LONDON SCH. OF ECONS. & POL. SCI. (Oct. 8, 2020), https://perma.cc/4HEN-XDMB (warning that "scientists will be the ones who suffer if they overstep their knowledge or understate their uncertainty").

21. *See infra* Section IV.A.

22. *See infra* Section IV.B.

the risk that contaminated agricultural water poses to human health. The discussion traces efforts by regulators to impose specific quantitative agricultural water quality standards despite a lack of scientific evidence to justify them. Part II argues that leading approaches to risk regulation have incentivized regulators to perpetrate a science charade. Part III presents the five guiding principles for coping with known unknowns. It explains how these general principles can inform regulatory design in food safety and beyond. Part IV discusses the implications of these recommendations for regulatory theory more generally.

I. The Problem

The concept of a known unknown rests on the distinction between hazard and risk. A hazard is a potential source of harm.[23] Risk is a metric for measuring hazards in terms of the magnitude of expected harm and the probability of its occurrence.[24] Risk regulation entails risk assessment and risk management.[25] Risk assessment generates information about risks, and risk management implements actions to influence risks.[26] Because known unknowns cannot be characterized in terms of measurable risk, they are not amenable to risk analysis and they frustrate risk management. This feature of known unknowns is aptly illustrated by efforts to regulate agricultural water quality.

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23. Elizabeth Fisher, *Risk Regulatory Concepts and the Law*, *in* RISK AND REGULATORY POLICY, *supra* note 4, at 45, 53 (defining a hazard as "a property or situation that in particular circumstances could lead to harm"); Anna M. Lammerding & Aamir Fazil, *Hazard Identification and Exposure Assessment for Microbial Food Safety Risk Assessment*, 58 INT'L J. FOOD MICROBIOLOGY 147, 148 (2000) (defining a food safety hazard as a microorganism or toxin "that has the potential to cause an adverse health effect").

24. Majone, *supra* note 4, at 102; *see also* Gretchen Wall et al., *Meeting Report: Key Outcomes from a Collaborative Summit on Agricultural Water Standards for Fresh Produce*, 18 COMPREHENSIVE REVS. IN FOOD SCI. & FOOD SAFETY 723, 729 (2019) (distinguishing between hazard and risk in the context of agricultural water quality standards for fresh produce); INT'L COMM'N ON MICROBIOLOGICAL SPECIFICATIONS FOR FOODS (ICMSF), MICROORGANISMS IN FOODS 7: MICROBIOLOGICAL TESTING IN FOOD SAFETY MANAGEMENT 1-3 (2d ed. 2018) [hereinafter ICMSF] (describing the relationship between hazard control and risk management in food safety systems).

25. *See* Gregory Bounds, *Challenges to Designing Regulatory Policy Frameworks to Manage Risks*, *in* RISK AND REGULATORY POLICY, *supra* note 4, at 15, 19-20; Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 PENN. L. REV. 1255, 1275 (2004).

26. Bounds, *supra* note 25, at 19-20; Coglianese & Marchant, *supra* note 25, at 1275-76.

A. Unmeasurable Hazards

Foodborne illness is a nationwide public health problem. The Centers for Disease Control and Prevention ("CDC") estimates that contaminated food causes forty-eight million cases of acute gastroenteritis each year, resulting in 128,000 hospitalizations, 3,000 deaths, and $1.8 billion in healthcare costs.[27] More than twice as many Americans are sickened every year by foodborne pathogens than contracted COVID-19 in 2020.[28] And more than double the number of Americans fall victim to foodborne illness annually than suffer injuries from traffic accidents, falls, cuts, natural disasters, cycling, poisoning, and burns combined.[29]

Fresh produce is a vehicle for foodborne illness of particular concern. According to a 2015 report by the Center for Science and the Public Interest, "[p]roduce caused more illnesses than any other food category and had the largest number of outbreaks for any single food category."[30] Within

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27. *Burden of Foodborne Illnesses: Findings*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://perma.cc/8BX8-VQ7B (last updated Nov. 5, 2018); SANDRA HOFFMANN ET AL., U.S. DEP'T OF AGRIC., EIB-140, ECONOMIC BURDEN OF MAJOR FOODBORNE ILLNESSES ACQUIRED IN THE UNITED STATES 11 (2015), https://perma.cc/77TZ-E3NM (including cost of medical care for fifteen leading foodborne illnesses, which constitute approximately 95% of the total). For analysis of these estimates, see TIMOTHY D. LYTTON, OUTBREAK: FOODBORNE ILLNESS AND THE STRUGGLE FOR FOOD SAFETY 3-8, 243-45 (2019). These estimates define acute gastroenteritis as diarrhea or vomiting that lasts more than one day or restricts daily activities. Elaine Scallan et al., *Foodborne Illness Acquired in the United States—Major Pathogens*, 17 EMERGING INFECTIOUS DISEASES 7, 9 (2011).

28. *CDC COVID Data Tracker*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://perma.cc/2KNM-93A7 (last updated Dec. 31, 2020) (reporting 19,663,976 total COVID-19 cases in the United States between January 21, 2020, and December 31, 2020).

29. LYTTON, *supra* note 27, at 6.

30. NILS FISCHER ET AL., CTR. FOR SCI. IN THE PUB. INT., OUTBREAK ALERT! 2015: A REVIEW OF FOODBORNE ILLNESS IN THE U.S. FROM 2004-2013, at iv (2015), https://perma.cc/UM5X-4EUW; *see also* RENEE JOHNSON, CONG. RSCH. SERV., IF11092, FOODBORNE ILLNESS AND OUTBREAKS FROM FRESH PRODUCE (2019), https://perma.cc/PZ85-GU3F (summarizing data regarding foodborne illness outbreaks associated with fresh produce generally and leafy greens in specifically); John A. Painter et al., *Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by Using Outbreak Data, United States, 1998-2008*, 19 EMERGING INFECTIOUS DISEASES 407, 409 (2013) (finding that produce commodities accounted for 46% foodborne illness outbreaks between 1996 and 2008 with an implicated food vehicle and a single etiological agent); Zeynal Topalcengiz et al., *Contributions of Pathogens from Agricultural Water to Fresh Produce*, *in* PRESENT KNOWLEDGE IN FOOD SAFETY: A RISK-BASED APPROACH THOUGH THE FOOD CHAIN at 357, 357 (Michael E. Knowles et al. eds, 2023) ("In the United States, fresh produce-related outbreaks have accounted for a large proportion of all reported foodborne illness outbreaks over the last several decades."); INTERAGENCY FOOD SAFETY ANALYTICS COLLABORATION, FOODBORNE

the fresh produce sector, leafy greens are a leading cause of foodborne illness outbreaks.[31]

Our case study begins in the fertile valleys of California and Arizona, which collectively produce 95% of the leafy greens sold in the United States.[32] Growers in this region have been unable to rid their fields of virulent microbial pathogens that have caused widespread illness.[33] Since 1983, public health officials have attributed 110 US foodborne-illness outbreaks to leafy greens.[34] Between 2014 and 2021 alone, the CDC identified seventy-eight outbreaks involving 2,028 illnesses, 477 hospitalizations, and eighteen deaths from tainted leafy greens.[35]

ILLNESS SOURCE ATTRIBUTION ESTIMATES FOR 2020 FOR *SALMONELLA*, *ESCHERICHIA COLI* O157, AND *LISTERIA MONOCYTOGENES* USING MULTI-YEAR OUTBREAK SURVEILLANCE DATA, UNITED STATES 9 (2022) (reporting that 58.1% of *E. coli* O157 illnesses in identified outbreaks were attributed to vegetable row crops); U.S. FOOD & DRUG ADMIN., FINAL QUALITATIVE ASSESSMENT OF RISK TO PUBLIC HEALTH FROM ON-FARM CONTAMINATION OF PRODUCE 11-13 (2015) [hereinafter FOOD & DRUG ADMIN., FINAL QUALITATIVE ASSESSMENT OF RISK], https://perma.cc/GCD6-4XKJ.

31. Lisa L. Gill, *10 Risky Recalled Foods You Should Know About*, CONSUMER REPS. (Mar. 30, 2023), https://perma.cc/SNL9-VZDG (listing leafy greens first in a ranking of ten foods linked to serious food safety recalls and foodborne illness outbreaks); ICMSF, *supra* note 24, at 386 (reporting that an international panel of experts convened by the Codex Alimentarius Commission concluded that "control of pathogens on RTE [ready to eat] leafy green vegetable products was of highest concern among all produce categories"); *id.* at 387 (citing CDC data documenting twenty-four outbreaks related to *E. coli* in RTE leafy vegetables and 950 reported cases of illness from 1998 to 2008); *id.* at 388 (estimating 18,200 cases of Enterohemorrhagic E. coli cases in the United States annually).

32. *A Look at Year-Round Lettuce Production – from California's Leafy Greens Marketing Agreement*, CAL. DEP'T OF FOOD & AGRIC.: PLANTING SEEDS (Oct. 24, 2017), https://perma.cc/25JN-DTDJ.

33. These pathogens include Enterohemorrhagic *E. coli*, *Salmonella*, *Listeria* monocytogenes, *Cyclospora*, and norovirus. *Lettuce, Other Leafy Greens, and Food Safety*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://perma.cc/FU78-M79X (last updated Apr. 26, 2023).

34. Marler, *supra* note 1; *see also Almost 6 Dozen Outbreaks Traced to Leafy Greens Since 1995*, FOOD SAFETY NEWS (Apr. 20, 2018), https://perma.cc/TPV7-8GP4 (listing seventy-eight outbreaks between 1995 and 2017); Katherine E. Marshall et al., *Lessons Learned from a Decade of Investigations of Shiga Toxin-Producing* Escherichia Coli *Outbreaks Linked to Leafy Greens, United States and Canada*, 26 EMERGING INFECTIOUS DISEASES 2319, 2320 (2020) (analyzing forty outbreaks of Enterohemorrhagic *E. coli* illness linked to leafy greens between 2009 and 2018); Kevin Loria, *Leafy Greens Safety Guide: In an Age of Rampant Romaine Contamination, Can Our Salads Be Saved?*, CONSUMER REPS. (Jan. 27, 2020), https://perma.cc/V425-GGGB (reporting forty-six *E. coli* outbreaks traced to leafy greens between 2006 and 2019).

35. *Lettuce, Other Leafy Greens, and Food Safety*, *supra* note 33.

Authorities have traced many of these outbreaks to farms in California and Arizona.[36] Outbreaks have cost the industry hundreds of millions of dollars and made consumers anxious about eating what was once considered the healthiest of foods.[37]

Investigations have discovered outbreak strains of pathogens in rivers and canals near growing fields, which suggests that agricultural water drawn from these sources may have been the vehicle of contamination.[38] The presence of these same outbreak strains in environmental samples taken from cattle and wild animal feces in the surrounding areas has led investigators to conclude that nearby cattle-farming operations or wild animal intrusions are polluting agricultural water sources.[39]

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36. *See, e.g.*, *Outbreak of E. coli Infections Linked to Romaine Lettuce*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 15, 2020, 3:00 PM), https://perma.cc/24RX-DLUN (tracing outbreak to Salinas Valley growing region in California); *FDA Investigated Multistate Outbreak of E. Coli O157:H7 Infections Linked to Romaine Lettuce from Yuma Growing Region*, U.S. FOOD & DRUG ADMIN., https://perma.cc/28LV-W48D (last updated Nov. 1, 2018) (tracing outbreak to Yuma Valley growing region in Arizona).

37. *See* KRISTIN KIESEL ET AL., E. COLI IN THE ROMAINE LETTUCE INDUSTRY: ECONOMIC IMPACTS FROM THE NOVEMBER 2018 OUTBREAK 3 (2021) (estimating the total social loss throughout the supply chain between $280 and $350 million).

38. *E.g.*, Standards for the Growing, Harvesting, Packing, and Holding Produce for Human Consumption Relating to Agricultural Water, 86 Fed. Reg. 69120, 69125-27 (Dec. 6, 2021) (to be codified at 21 C.F.R. pt. 112) (summarizing outbreak investigations indicating agricultural water as the initial source of contamination); *see, e.g.*, CAL. FOOD EMERGENCY RESPONSE TEAM, INVESTIGATION OF AN ESCHERICHIA COLI O157:H7 OUTBREAK ASSOCIATED WITH DOLE PRE-PACKAGED SPINACH 3 (Mar. 21, 2007), https://perma.cc/VS82-HYY6 (river water); ENVIRONMENTAL ASSESSMENT OF FACTORS POTENTIALLY CONTRIBUTING TO THE CONTAMINATION OF ROMAINE LETTUCE IMPLICATED IN A MULTI-STATE OUTBREAK OF E. COLI O157:H7, U.S. FOOD & DRUG ADMIN. (Nov. 1, 2018), https://perma.cc/ATU3-JRLR (irrigation canal); *see also* Topalcengiz et al., *supra* note 30, at 358.

39. Standards for Growing, *supra* note 38, at 69126-27 (attributing agricultural water contamination in outbreak investigations to nearby cattle operations and wild animal intrusion); Topalcengiz et al., *supra* note 30, at 362 ("Domesticated and wild animal feces can serve as the main sources for pathogen contamination of agricultural water sources."); *see, e.g.*, CAL. FOOD EMERGENCY RESPONSE TEAM, *supra* note 38, at 3-4*; see also* U.S. FOOD & DRUG ADMIN., INVESTIGATIVE REPORT: FACTORS POTENTIALLY CONTRIBUTING TO THE CONTAMINATION OF ROMAINE LETTUCE IMPLICATED IN THE THREE OUTBREAKS OF E. COLI O157:H7 DURING THE FALL OF 2019, at 1 (2020), https://perma.cc/7VRJ-EPSS; U.S. FOOD & DRUG ADMIN., INVESTIGATIVE REPORT: FACTORS POTENTIALLY CONTRIBUTING TO THE CONTAMINATION OF LEAFY GREEN IMPLICATED IN THE FALL 2020 OUTBREAK OF E. COLI O157:H7, at 6 (2021), https://perma.cc/YL6J-6G9R. In addition to outbreak investigations, laboratory experiments and field studies have produced findings that document increased microbial loads on plants from contaminated agricultural water. *E.g.*, J.D. Wood, *Population Dynamics of Escherichia coli Inoculated by Irrigation into the Phyllosphere of Spinach*

In short: there are animal feces containing human pathogens in the water.

When addressing this problem, preventing contamination in the field is especially important because leafy greens are frequently consumed raw, which forecloses the use of cooking to kill microbial pathogens during processing or home preparation.[40] One solution would be to use potable

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Grown Under Commercial Production Conditions, 143 INT'L J. FOOD MICROBIOLOGY 198, 198 (2010).

40. ICMSF, *supra* note 24, at 390-91 (emphasizing the importance of preventing pre-harvest contamination); *see also* M. F. Lynch et al., *The Growing Burden of Foodborne Outbreaks Due to Contaminated Fresh Produce: Risks and Opportunities*, 137 EPIDEMIOLOGY & INFECTION 307, 308-10 (2009). Washing fresh produce with chlorinated water reduces pathogen levels but is not 100% effective. Roy Costa, *The Packinghouse: Safety and Uses of Process-Water*, FOOD SAFETY NEWS (Mar. 18, 2015), https://perma.cc/MM6S-AKLR; *Ctr. for Produce Safety, Center for Produce Safety: Key Learnings* 9 (2014), https://perma.cc/9CTE-SCGR; Callum J. Highmore et al., *Viable-but-Nonculturable Listeria monocytogenes and Salmonella enterica Serovar Thompson Induced by Chlorine Stress Remain Infectious*, MBIO, Apr. 27, 2018, article no. e00540-18, at 1. Indeed, if not properly monitored, wash water can be a vehicle for cross contamination. *See* Julie Schmit, *Tainted Spinach: All Bacteria May Not Come Out in the Wash*, USA TODAY (Oct. 5, 2006, 7:54 AM), https://perma.cc/9V52-T2CT; Costa, *supra*; *Center For Produce Safety, supra*; Highmore et al., *supra*. Irradiation also reduces pathogen levels. MARION NESTLE, SAFE FOOD: THE POLITICS OF FOOD SAFETY 121-26 (2d ed. 2010); Xuetong Fan et al., *Irradiation of Fresh Fruits and Vegetables*, 62 FOOD TECH. 36, 36-37 (2008). However, it has not been widely adopted because the necessary equipment is expensive, and companies fear that many consumers will not purchase irradiated food. NESTLE, *supra*; Fan et al., *supra*. Current research on other proposed technologies for reducing contamination during processing include antimicrobial blue light and ozone. *Three Technologies with Multiple Applications!*, CTR. FOR PRODUCE SAFETY (May 25, 2022), https://perma.cc/3535-BBSJ; Rinaldo Botondi et al., *A Review into the Effectiveness of Ozone Technology for Improving the Safety and Preserving the Quality of Fresh-Cut Fruits and Vegetables*, 10 FOODS, article no. 748, Apr. 2021, https://www.mdpi.com/2304-8158/10/4/748/pdf?version=1617939149. Some producers have touted greenhouse cultivation, which greatly reduces exposure to microbial contaminants. *Coalition Launches Food Safety Program for Indoor-Grown Leafy Greens*, FOOD SAFETY NEWS (Apr. 29, 2021), https://perma.cc/UA2W-S7DL. But despite steady technological advances and increasing consumer demand, greenhouses will not be capable anytime soon of production on a scale necessary to replace outdoor cultivation. Cookson Beecher, *Safety Aspects of Indoor Farming Signal a Change in Agriculture*, FOOD SAFETY NEWS (Feb. 24, 2020), https://perma.cc/ED27-GY4Y. Moreover, even greenhouses have been found to harbor harmful pathogens. *Lettuce, Other Leafy Greens, and Food Safety*, *supra* note 33. Aquaponic and hydroponic production can mitigate some microbial hazards. *Association Contends Aquaponics Offer a Solution to Some Food Safety Issues*, FOOD SAFETY NEWS (June 22, 2021), https://perma.cc/PLJ9-SMU9. However, aquaponic and hydroponic growing systems are not immune from the hazard of microbial contamination. *Aquaponic and Hydroponic Systems Are No Escape from E. coli Contamination*, FOOD SAFETY NEWS (Apr. 22, 2020), https://perma.cc/X6FF-KJN5; *see also* Mary Ellen Shoup, *FDA Calls for Greater Food Safety Guidance for Indoor Farming*

water to irrigate California and Arizona cropland. However, most experts agree that this would be prohibitively expensive.[41] Any practical solution to the problem requires implementing agricultural water quality standards that reduce the incidence of foodborne illness to an acceptable level. Unfortunately, that is not as easy as it sounds.

Although the scientific evidence substantiating microbial contamination of agricultural water as hazardous to human health is robust and expanding,[42] this scientific evidence does not yield sufficient information to reliably quantify the impact of various levels of water quality on the incidence of foodborne illness.[43] To do so, one would need to measure how

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Companies, How is the Industry Responding?, FOOD NAVIGATOR (Jan. 19, 2022, 4:44 PM), https://perma.cc/6LVU-BHN3. Some major retailers have imposed microbial testing requirements on their suppliers. Gill, *supra* note 31. However, lot-batch testing is not a reliable method of preventive control where the defect rate is low or for foods with a limited shelf life. Robert Buchanan & Donald Schaffner, *FSMA: Testing as a Tool for Verifying Preventive Controls*, 35 FOOD PROT. TRENDS 228, 229 (2015); *see also* Eric Wilhelmsen, *The Apparent Evolution of Sampling for Food Safety*, FOOD SAFETY MAG. (Sept. 14, 2021), https://perma.cc/C3WW-U7RK; Jennifer McEntire, *Beyond HACCP and Preventive Controls: Promoting True Risk-Based Thinking Tied to Public Health Outcomes*, FOOD SAFETY MAG. (June 20, 2021), https://www.food-safety.com/articles/7215-beyond-haccp-and-preventive-controls-promoting-true-risk-based-thinking-tied-to-public-health-outcomes. Testing is more useful as a means of verifying other preventive controls. Buchanan & Schaffner, *supra; see also* Wilhelmsen, *supra* ("testing does not mitigate food safety problems"); McEntire, *supra* ("[I]n addition to the volume of food that would be wasted through [finished product testing], it is reactive and provides few if any clues as to where in the system advances are needed to improve outcomes.").

41. *See* RONALD C. GRIFFIN, WATER RESOURCE ECONOMICS 39 (2016) (estimating that tap water would cost more than forty times the cost of farm-gate water).

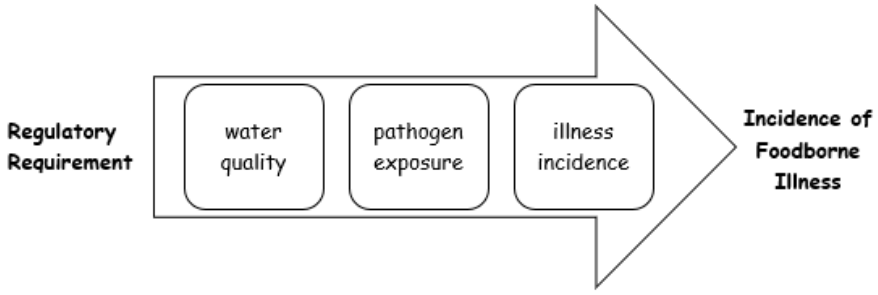
42. *See supra* notes 32-41 and accompanying text.

43. ICMSF, *supra* note 24, at 1 ("[M]etrics were established to provide a bridge between traditional food safety metrics (i.e., microbiological criteria, process criteria and product criteria) and the concept of Appropriate Level of Protection (ALOP) . . . ."). *But see id.* at 388 ("There are insufficient data to enable development of a reliable dose-response relationship for the probability of infection/illness from EHECs [in leafy greens]."). *See also* McEntire, *supra* note 40 ("[A]t present there is no practical way for an individual food company to evaluate risk to the consumer."). This is not to say that there have not been disciplined attempts to produce a reliable quantitative risk analysis. *E.g.,* U.S. FOOD & DRUG ADMIN., QUANTITATIVE RISK ASSESSMENT TO SUPPORT THE PROPOSED PRODUCE RULE (May 22, 2012), https://perma.cc/694Z-BP5M (presenting quantitative risk assessment calculating the risk of consumer illness from Enterohemorrhagic *E. coli* at various levels of generic *E. coli* in agricultural water applied to lettuce fields). Note that this quantitative risk analysis relied heavily on assumptions, expert opinion, and data taken from studies with unclear context. *See id*. It was never published in the Federal Register for comment or referenced in the final rule. UNITED FRESH PRODUCE ASS'N, QUANTITATIVE RISK ASSESSMENT (QRA) TO SUPPORT THE

dirty the water is and how clean it needs to be to reduce foodborne illness to an acceptable level, however that is defined. This is currently impossible.

Here's why. First, methods for obtaining reliable measurements of the microbial quality of agricultural water in the field have eluded experts. Second, the complex causal chain from farm to fork and the heterogeneity of risk factors for foodborne illness make it difficult to gauge consumers' exposure to pathogens when they eat leafy greens. Third, public health surveillance and outbreak investigations do not yield sufficient data from which to determine the number of illnesses attributable to contaminated agricultural water. Figure 1 illustrates these obstacles to expressing the hazard of contaminated agricultural water in terms of measurable risk. The discussion that follows describes these obstacles in greater detail.

Figure 1.



1. Measuring Contamination

Assessing the microbial quality of agricultural water in the field turns out to be remarkably difficult. Two key questions remain unresolved. One is how to test the water, and the other is what to test for.

a) How to Test

A combination of variability, heterogeneity, and lack of scientific consensus regarding sampling methodologies hinders even the most sophisticated quantitative assessments of microbial contamination of

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PROPOSED PRODUCE RULE (Apr. 12, 2012), https://perma.cc/ZQR8-2HD5. *See generally* Food & Drug Admin., Lettice, EHEC and Irrigation Water: Apply FDA-IRISK FOR RAPID RISK ASSESSMENT (2013), https://perma.cc/5K4W-JSHG. As the discussion *infra* demonstrates, numerous obstacles to reliable and robust data collection render these quantitative risk models highly speculative and of limited practical value.

agricultural water in the field.[44] Measurements of pathogen prevalence in water sources vary widely depending on the time and location of sampling.[45] Moreover, the survival of microbial contaminants varies widely depending on temperature, sunlight, pH, nutrients, indigenous biota, and mode of conveyance.[46] Additionally, there is great variability in the sensitivity of different methodologies of sampling.[47]

A 2015 review of forty-one peer-reviewed quantitative microbial risk assessments of water used in fresh produce production found that data gaps led risk assessors in the disciplines of environmental water science and food science to rely on assumptions and surrogate data. The review authors defined assumptions as "information which is accepted as true, *without* (experimental) proof for the specific setting."[48] They explained that "[a]ssumptions are frequently based on expert opinion and may well lack

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44. Variability does not necessarily imply uncertainty if one can accurately plot a stable distribution of values. However, where this is not possible, variability can introduce uncertainty. *See Uncertainty and Variability*, EPA, https://perma.cc/4CRX-LEYT (last updated Nov. 23, 2022) (explaining that uncertainty can be reduced with more data while variability cannot be reduced, only better characterized). On heterogeneity as a challenge in formulating environmental regulation, see generally Giandomenico Majone, *Science and Trans-Science in Standard Setting*, 9 SCI., TECH., & HUM. VALUES 15 (1984).

45. Trevor V. Suslow, *Standards for Irrigation and Foliar Contact Water*, PRODUCE SAFETY PROJECT 3 (2009), https://perma.cc/2675-EMLH ("The microbiological quality of water at the source and during storage, conveyance, and distribution on-farm can be highly dynamic. The flux in levels and diversity of pathogens is affected by many, often complex, interacting factors including climatic events, seasonal weather patterns, adjacent land uses, wildlife activities or migration, hydrogeologic characteristics of aquifers, agricultural activities, recreational activities and easements within agricultural settings and other forms of urban encroachment or urbanization, to name just a few."); *see also* IDS DECISION SCIS., REPORT ON AGRICULTURAL WATER TESTING METHODS 5-8 (2017) (analyzing variability in agricultural water testing); Jennifer McEntire & Jim Gorny, *Fixing FSMA's Ag Water Requirements*, FOOD SAFETY MAG. 6 (Aug. 15, 2017), https://perma.cc/98PB-4X2S ("Given the multitude of factors that can influence water testing results, arguing that the precision of CFU is needed is like arguing that you need to weigh an elephant to the fourth decimal point."); Topalcengiz et al., *supra* note 30, at 360, 364 (describing the spatiotemporal variability of water testing); *id*. at 369 (discussing the lack of scientific consensus on sampling parameters); Anne De Keuckelaere et al., *Zero Risk Does Not Exist: Lessons Learned from Microbial Risk Assessment Related to Use of Water and Safety of Fresh Produce*, 14 COMPREHENSIVE REVS. IN FOOD SCI. & FOOD SAFETY 387, 391 (2015) (analyzing various gaps in data regarding agricultural water quality).

46. Topalcengiz et al., *supra* note 30, at 365-68.

47. *See e.g.*, CTRS. FOR DISEASE CONTROL & PREVENTION & EPA, EPA 600/R-11/103, COMPARISON OF ULTRAFILTRATION TECHNIQUES FOR RECOVERING BIOTHREAT AGENTS IN WATER 29 (2011).

48. Keuckelaere et al., *supra* note 45, at 391.

consideration of variability."[49] The review authors defined surrogate data as "stand-in or substituted data . . . based on (limited) experiments or . . . data obtained for another microorganism or situation . . . used as a proxy for the pathogen or situation under study."[50] A 2017 colloquium on agricultural water testing attended by leading academic, industry, and federal government experts concluded that "[t]he variability of water monitoring data, the innumerable factors that affect microbial levels, and an incomplete understanding of how they affect microbial levels have made model development likely impossible."[51]

b) What to Test For

Selecting an appropriate analyte presents an additional challenge to assessing the microbial quality of agricultural water. Typically, the assessment of agricultural water quality relies on enumeration of generic *E. coli* bacteria population as an indicator of fecal contamination.[52] *E. coli* bacteria are commonly found in the lower intestine of humans and warm-blooded animals.[53] Most strains are harmless and are part of the normal flora of the digestive tract.[54] However, some serotypes, such as *E. coli* O157:H7, produce toxins that cause gastrointestinal illness, which can lead to kidney failure and death.[55] Consequently, generic testing for *E. coli* bacteria in agricultural water can thus indicate fecal contamination which may include harmful *E. coli* serotypes as well as other harmful microbial pathogens associated with fecal contamination.[56] The reasons for relying on indicator organisms rather than direct testing for individual pathogens include ease of enumeration (based on simple detection methods using

49. *Id.*

50. *Id.*

51. IDECISIONSCIENCES, REPORT ON AGRICULTURAL WATER TESTING METHODS 5-6 (2017), https://perma.cc/WY44-ES59; *see also* Elena Traister & Shimon Anisfeld, *Variability of Indicator Bacteria at Different Time Scales in the Upper Hoosic River Watershed*, 40 ENV'T SCI. & TECH. 4990, 4990 (2006) (discussing similar problem in environmental water quality assessment).

52. *See* Topalcengiz et al., *supra* note 30, at 359-61; *see also Coliform Bacteria in Drinking Water*, WASH. STATE HEALTH DEP'T, https://perma.cc/V4PW-V2QD (last visited May 31, 2023); *Index and Indicator Microorganisms,* MURRAY-BROWN LABORATORIES, INC., https://perma.cc/6T5K-TXBC (last visited May 31, 2023).

53. *Questions and Answers*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://perma.cc/23AR-D2LY (last updated Dec. 1, 2014).

54. *Id.*

55. *Id.*

56. *See* Bruce A. Macler & Jon C. Merkle, *Current Knowledge on Groundwater Microbial Pathogens and Their Control*, 8 HYDROGEOLOGY J. 29, 29 (2000).

inexpensive sampling techniques), relatively low cost, and short time required to obtain results.[57]

Unfortunately, fecal contamination is a poor proxy for the presence of harmful microbial pathogens. As leading industry experts Jennifer McEntire and James Gorny explain:

> [G]eneric *E. coli* is an indicator organism that provides information regarding potential overt fecal contamination, but it is not an index organism. So although it may indicate fecal contamination, its presence and concentration do not correlate well with the presence or absence of human pathogens in agricultural water. In fact, a large body of research in recent years has confirmed that quantitative testing for generic *E. coli* in agricultural water often has little predictive value regarding the presence or absence of human pathogens for many agricultural surface water sources. Recent research has demonstrated that the relationship between fecal indicator bacteria (generic *E. coli* and fecal coliforms) and *Salmonella* is complex and may have limited predictive value.[58]

A similar conclusion was reached by the Collaborative Food Safety Forum on Agricultural Water Standards and Testing Protocols, convened by The PEW Charitable Trusts and the Robert Wood Johnson Foundation in 2017.[59] Participants in the forum included officials from the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), CDC, food industry trade associations, farms, and academia.[60] According to a summary of the discussion:

> It was generally acknowledged that generic *E. coli* alone is an inadequate analyte to determine the adequacy of agricultural water and if possible better analytes or a portfolio of analytes, such as index organisms (that indicate the presence of pathogens), need to be identified to better assess the presence or absence of human pathogens in agricultural water. Generic *E. coli* can sometimes serve as an indicator of agricultural water

57. Topalcengiz et al., *supra* note 30, at 360.

58. McEntire & Gorny, *supra* note 45 (pages 3-4 of printout).

59. COLLABORATIVE FOOD SAFETY FORUM, AGRICULTURAL WATER STANDARDS AND TESTING PROTOCOLS: SUMMARY 1, 4 (2017), https://perma.cc/ZN9N-GK73.

60. *Id.* at 1.

> fecal contamination but this provides limited insights on the degree of public health risk.[61]

2. Estimating Pathogen Exposure

Even if it were possible to reliably measure the prevalence of microbial pathogens in agricultural water, the variability of pathogen survival from farm to fork hinders even the most sophisticated attempts to estimate the level of human exposure to foodborne pathogens that originate in contaminated agricultural water. To begin with, transfer rates for pathogens from water to plants vary by pathogen,[62] crop,[63] and irrigation method.[64] The growth, survival, inactivation, and removal of microorganisms vary by organism and environment during cultivation, processing, storage, and distribution.[65] Various consumer behaviors and consumption patterns influence exposure to pathogens in food, and these vary by pathogen, product, supply chain, and household.[66]

3. Determining the Incidence of Illness

In addition to the difficulty of estimating exposure to pathogens from contaminated agricultural water, resulting illnesses are rarely identified. The primary source of data regarding foodborne illness comes from public health surveillance and epidemiological investigation of foodborne illness outbreaks.[67] However, most episodes of foodborne illness are never

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61. *Id.* at 4 (emphasis omitted).

62. FOOD & DRUG ADMIN., FINAL QUALITATIVE ASSESSMENT OF RISK, *supra* note 30, at 18.

63. Stefania Truschi et al., *Foliar Roughness and Water Content Impact on* Escherichia Coli *Attachment in Baby Leafy Greens*, 12 BIOLOGY, no. 1, article 102, at 11, https://www.mdpi.com/2079-7737/12/1/102 (finding variability in the susceptibility of thirty different baby leafy green leaves consumed in salads to *E. coli* attachment).

64. De Keuckelaere et al., *supra* note 48, at 395; Topalcengiz et al., *supra* note 30, at 370; FOOD & DRUG ADMIN., FINAL QUALITATIVE ASSESSMENT OF RISK, *supra* note 30, at 18, 24.

65. De Keuckelaere et al., *supra* note 48, at 390; *see* Topalcengiz et al., *supra* note 30, at 369; Lammerding & Fazil, *supra* note 23, at 151.

66. De Keuckelaere et al., *supra* note 48, at 390 (demonstrating that variations in focus of studies yielded different findings with respect to pathogens); *see also* P. F. M. Teunis et al., *Hierarchical Dose Response of E. coli O157:H7 from Human Outbreaks Incorporating Heterogeneity in Exposure*, 136 EPIDEMIOLOGY & INFECTION 762, 767-69 (providing an overview of challenges in foodborne illness surveillance and attribution).

67. *See* Alice E. White et al., *Foodborne Illness Outbreaks Reported to National Surveillance, United States, 2009-2018*, 28 EMERGING INFECTIOUS DISEASES 1117, 1117 (2022).

recorded, and of those that are, very few are ever traced back to a possible source of contamination.[68]

Each year in the United States, contaminated food causes an estimated forty-eight million cases of acute gastroenteritis—defined as diarrhea or vomiting that lasts more than one day or restricts daily activities.[69] Although acute gastroenteritis, also known as food poisoning, is widespread, pinpointing the source of contamination is extremely rare.[70] Most victims of acute gastroenteritis manage the illness at home without seeking medical attention.[71] Of those who do visit a physician, most receive advice and palliative medications but are not asked to provide a stool sample.[72] Only if a victim submits a stool sample can a laboratory identify the pathogen causing the illness and report it to state public health authorities.[73] If these authorities are equipped and choose to analyze the pathogen's DNA, they will upload the information to a CDC database.[74] When multiple pathogens have sufficiently similar DNA fingerprints, the CDC identifies the corresponding illnesses as a cluster.[75] In most cases, state and local health departments investigate clusters to determine whether the cases involved have a common source and constitute an outbreak.[76] For

68. ICMSF, *supra* note 24, at 17-18.

69. *See Burden of Foodborne Illness: Findings*, supra note 27. This paragraph and the following two paragraphs are drawn from Timothy D. Lytton, *Using Insurance to Regulate Food Safety: Field Notes from the Fresh Produce Sector*, 52 NEW MEXICO L. REV. 282, 310-311 (2022). For a more detailed description of foodborne illness surveillance and investigation, which are summarized in this and the following two paragraphs, see *id.* at 178-200. *See also* Barbara B. Kowalcyk et al., *Improving Burden of Disease and Source Attribution Estimates, in* FOOD SAFETY ECONOMICS: INCENTIVES FOR A SAFER FOOD SUPPLY 143, 145-46 (Tanya Roberts ed. 2018); Ctrs. For Disease Control, *Steps in a Foodborne Illness Outbreak Investigation*, https://perma.cc/P5XR-3JXP (last visited May 20, 2024); JEAN C. BUZBY ET AL., U.S. DEP'T OF AGRIC., AGRICULTURAL ECON. REP. NO. 799, PRODUCT LIABILITY AND MICROBIAL FOODBORNE ILLNESS 3-7 (2001), https://perma.cc/7AUL-FF6Y; *Timeline for Identifying and Reporting Illness in Foodborne Outbreaks*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 24, 2024), https://perma.cc/M6KD-RLXN.

70. *See id.*

71. *See Gastroenteritis (Stomach Flu)*, GI SOC'Y, https://badgut.org/information-centre/a-z-digestive-topics/gastroenteritis/ (last visited Apr. 11, 2024).

72. *See id.*

73. *See Guide to Confirming an Etiology in Foodborne Disease Outbreak*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/confirming_diagnosis.html (last updated Oct. 15, 2015).

74. *See* LYTTON, *supra* note 27, at 184.

75. *See id.*

76. *See id.*

multistate clusters, the CDC may investigate, depending upon available resources and priorities.[77]

When investigating, health officials ask outbreak victims to recall all the foods that they consumed a week or more ago, depending on the incubation period of the infection.[78] Even if these interviews reveal a common food or food ingredient recalled by multiple victims, identifying the responsible company requires that at least one victim remember the brand of the food they consumed, which may be especially difficult in the case of unlabeled fresh produce. Identifying the root cause of contamination entails tracing the food product back through the supply chain. Investigators conduct environmental pathogen testing at each point of potential contamination, including final preparation, sale, distribution, processing, and growing.[79] In cases involving fresh produce, investigators typically visit farms weeks or months into an investigation, by which time growing fields have been fully harvested and frequently replanted.

Consequently, of the estimated forty-eight million episodes of foodborne illness each year in the United States, investigators link only one in 12,500 to a single category of food, and they trace only a fraction of those to a specific product with an identifiable producer.[80] When the food vehicle is

77. E-mail from Robert Tauxe, Director of Foodborne, Waterborne, and Environmental Diseases, CDC (May 27, 2020) (on file with author).

78. *Id.* at 182-86.

79. *Id.* at 189-95.

80. The CDC identified 841 foodborne illness outbreaks resulting in 14,481 illnesses in the United States in 2017. The agency identified a single food category as the source in 218 (26%) of those outbreaks. CTRS. FOR DISEASE CONTROL & PREVENTION, SURVEILLANCE FOR FOODBORNE DISEASE OUTBREAKS, UNITED STATES, 2017: ANNUAL REPORT 2 (2019), https://perma.cc/UC9K-GV2W. If one assumes, for the purposes of estimation, that that these illnesses are equally distributed throughout the outbreaks, this suggests that approximately 3,754 illnesses are associated with a single food category/vehicle (14,481 x (218/841)), which is .008% of the 48 million annual illnesses, or roughly 1 in 12,500. *See id.* CDC officials estimate that only about half of reported outbreaks are associated with a source of contamination. Laura G. Brown et al., *Outbreak Characteristics Associated with Identification of Contributing Factors to Foodborne Illness Outbreaks*, 145 EPIDEMIOLOGY & INFECTION 2254, 2256-57 (2017). Even these associations fall short of specific identification of root causes. C. A. Selman & J. J. Guzewich, *Public Health Measures: Environmental Assessment in Outbreak Investigations*, *in* 4 ENCYCLOPEDIA OF FOOD SAFETY 98, 99 (Yasmine Motarjemi et al eds., 2014). John Guzewich, a retired senior FDA food safety official estimates that less than 10% of all outbreak investigations identify root causes of contamination. E-mail from John Guzewich, former Senior Advisor for Environmental Health in the Office of Food Defense, Communication and Emergency Response, U.S. Food & Drug Admin. (May 25, 2020) (on file with the author). Robert Tauxe, the Director of the Division of Foodborne,

fresh produce, these odds are even lower, especially in the case of leafy greens sold unpackaged at retail without any brand label or bagged in a mix containing produce from many different growers.[81] Moreover, even when public health officials identify a responsible farm, they typically cannot pinpoint the root cause of contamination.[82] "It's actually very rare, in large multistate outbreaks, for (health officials) to pinpoint or find the source," explains Channah Rock, an agricultural water quality specialist at the University of Arizona.[83] Robert Tauxe, former Director of the Division of Foodborne, Waterborne and Environmental Diseases at the CDC, estimates that the federal authorities conduct a formal root cause investigation of multistate outbreaks two to four times a year for FDA regulated products.[84] These rare instances of successful root cause analysis cannot yield sufficient data to develop a dose-response curve that could link measurable microbial loads in agricultural water to rates of human illness.[85]

Waterborne and Environmental Diseases at the CDC, estimates that the FDA conducts two to four root cause investigations on farms each year. E-mail from Robert Tauxe, *supra* note 77.

81. *See* Brown et al., *supra* note 80, at 2254 (finding that contributing factors are more often identified when outbreaks are associated with high-volume food service operations subjected to environmental testing within a day of an establishment being linked to an outbreak).

82. Even in resource intensive investigations of high-profile outbreaks, conclusions regarding the source of contamination often remain speculative. *See, e.g.*, LYTTON, *supra* note 27, at 10 (2011 Jensen Farms cantaloupe *Listeria* outbreak); *id.* at 119 (2006 Dole baby spinach *E. coli* O157:H7 outbreak); *id.* at 180-81 (2008 jalapeno pepper *Salmonella* outbreak).

83. Robert Anglen, *Clues to a Deadly Medical Mystery Hide in Arizona's Romaine Lettuce Fields*, AZCENTRAL (Dec. 17, 2019, 4:21 AM), https://perma.cc/7YPU-PG8P.

84. E-mail from Robert Tauxe, *supra* note 77. For a rare example of a successful root cause analysis, see Tracie J. Gardner et al., *Outbreak of Campylobacteriosis Associated with Consumption of Raw Peas*, 53 CLINICAL INFECTIOUS DISEASES 26, 26-27 (2011). *See also* Topalcengiz et al., *supra* note 30, at 358-59 (listing the small number of successful trace back investigations of foodborne illness associated with contaminated agricultural water).

85. In addition to these severe data constraints, modeling dose-response for food contamination faces the standard challenges of modeling dose-response for environmental toxins. Robert L. Buchanan et al., *Microbial Risk Assessment: Dose-Response Relations and Risk Characterization*, 58 INT'L J. FOOD MICROBIOLOGY 159, 160-62 (2000); *see also* Gulhan Unlu, *Determining Infectious Doses of Foodborne Illness Agents*, FOOD TECH. MAG. (May 21, 2021), https://perma.cc/9KYP-4KGW. To begin with, the pathogenicity of microbial contaminants varies greatly depending on the different modes of pathogenicity within the human host of a particular species of pathogen, the relative virulence of diverse strains within a species of pathogen, the food vehicle, and the number of pathogen cells ingested, which affects the incubation period for enteric diseases and the capacity of the pathogen to overcome the host's immune response. Buchanan et al., *supra*, at 160-62 (discussing production of toxins by agent in food prior to ingestion by host and in host after ingestion); *see also* Unlu, *supra* (distinguishing between three modes of pathogenicity: intoxication, toxicoinfection, and

infection and analyzing variability based on microorganism and host). Moreover, consumers vary in their susceptibility to infection—based on myriad factors, including age, immune status, stress level, prior exposure, general health, and genetics—which introduces additional variability. Buchanan et al., *supra*; *see also* Unlu, *supra.*

Ethical constraints on human experimentation foreclose controlled human exposure studies involving life-threatening pathogens. De Keuckelaere et al., *supra* note 45, at 390. However, there are some voluntary human exposure studies for non-lethal pathogens. *See* Buchanan, Smith & Long, *supra*, at 163; Unlu, *supra*; Wagner, *The Science Charade, supra* note 10, at 1621; Martin J. Blaser & Lee S. Newman, *A Review of Human Salmonellosis: I. Infective Dose*, 4 REVS. INFECTIOUS DISEASES 1096, 1096 (1982). Animal exposure studies require the selection of an appropriate animal model with physiological and immune responses to foodborne pathogens similar to those of humans, along with assumptions that the pathogens cause disease by the same mechanism in both humans and animals and that quantitative relationships between infectivity and illness are similar for both species. Buchanan et al., *supra*, at 163; *see also* Teunis et al., *supra* note 66, at 769. This presents a significant challenge with many foodborne pathogens. Buchanan et al., *supra*, at 163; *see also* Teunis et al., *supra* note 66, at 769. In addition, some studies rely on in vitro models of human gastrointestinal tract. Unlu, *supra*. Consequently, many dose-response models are largely conjectural. Fisher, *supra* note 23, at 97.

The evolving science of Quantitative Microbial Risk Assessment (HRA) is gradually improving information regarding hazard identification, exposure assessment, risk characterization, and risk management for many pathogens. *See, e.g., About QMRA Wiki*, QMRA WIKI, https://perma.cc/8QZV-KGRJ (last visited May 21, 2023); *see also* Topalcengiz et al., *supra* note 30, at 361-62. However, as the analysis in this section explains, efforts to develop reliable population-level dose-response curves for pathogens in agricultural water have been frustrated by difficulties in measuring exposure levels and the burden of illness. *See, e.g.,* ICMSF, *supra* note 24, at 388 (noting that, in the context of agricultural water quality, "[t]here are insufficient data to enable development of a reliable dose-response relationship for the probability of infection/illness from [Enterohemorrhagic *E. coli* pathogens]"). For an attempt to model the risk of agricultural water contamination, see FOOD & DRUG ADMIN., *supra* note 43, at 1-5. *See also* Channah M. Rock et al., *Review of Water Quality Criteria for Water Reuse and Risk-Based Implications for Irrigated Produce Under the FDA Food Safety Modernization Act, Produce Safety Rule*, 172 ENV'T RSCH. 616, 624-26 (2019); CAL. AGRIC. NEIGHBORS, NEIGHBOR-TO-NEIGHBOR BEST PRACTICES TO HELP ENHANCE LOCALIZED FOOD SAFETY EFFORTS 38-40 (2022), https://perma.cc/X4Q4-TGTS.

Some researchers have extrapolated from human feeding studies to model population-level dose-response relationships, but it has proven difficult to assess the plausibility of such models. ICMSF, *supra* note 24, at 388-90. Other researchers have relied on laboratory experiments, field studies, and outbreak investigations to generate predictive models that link specific pathogen load reductions in agricultural water to specific reductions in human illness. Although the development of such predictive models may eventually resolve many of the challenges of agricultural water quality risk assessment, they are not currently sufficiently robust to overcome the obstacles to reliable exposure assessment data analyzed in this section. Topalcengiz et al., *supra* note 30, at 363-64; *see also* Teunis et al., *supra* note 66, at 761-69 (2008).

Moreover, the term "dose-response" is somewhat of a misnomer in this context. As the

4. Evaluating Interventions

The rarity of successful root cause analysis means that there are no data to provide a baseline of foodborne illness rates prior to implementing risk management efforts or changes in foodborne illness rates afterwards. A few studies have attempted to link specific food-safety precautions to rates of human illness in beef and poultry processing and fruit juice production.[86] However, the findings regarding beef and poultry are ambiguous, rely on extremely limited data, and depend on considerable speculation.[87] No data exist to support similar claims for cultivating and processing fresh produce.[88]

International Commission on Microbiological Specifications in Foods explains:

> Strictly speaking, the term 'dose-response' in relation to infections is a misnomer because the consequences of infection are largely independent of the dose ingested. Although there are some reports of disease severity being affected by the dose ingested (e.g., Mintz et al. 1994) dose-response models in the microbial food-safety literature are for probability of infection, or probability of illness upon infection and should, more correctly be called 'dose-probability of illness' models. For simplicity, however, we use the term 'dose-response model' to indicate the relationship between EHEC dose ingested and probability of infection.

ICMSF, *supra* note 24, at 388 n. 2.

For a general introduction to the use of quantitative microbiological criteria for risk assessment and risk management in food safety, see ICMSF, *supra* note 24, at 1-5.

86. *See 12 Charts Explore America's Salmonella Problem—and Steps to Solve It*, PEW CHARITABLE TRS. (Dec. 10, 2021), https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2021/12-charts-explore-americas-salmonella-problem-and-steps-to-solve-it; Travis Minor & Matt Parrett, *The Economic Impact of the Food and Drug Administration's Final Juice HACCP Rule*, 68 FOOD POL'Y 206, 206 (2017).

87. LYTTON, *supra* note 27, at 108-13 (surveying studies of the impact of USDA beef and poultry HACCP regulations); Nat'l Advisory Comm. on Microbiological Criteria for Foods, *Response to Questions Posed by the Food Safety and Inspection Service Regarding Salmonella Control Strategies in Poultry*, 82 J. FOOD PROT. 645, 647 (2019) (noting that despite a reduction in the percentage of poultry products regulated by the USDA's Food Safety Inspection Service, "the human incidence of salmonellosis reported to the Centers for Disease Control and Prevention (CDC) has not greatly changed over time"); *see also* U.S. DEP'T ARIC., SURVEY OF NOT READY-TO-EAT BREADED AND STUFFED CHICKEN PRODUCTS FOR SALMONELLA 3 (2023), https://perma.cc/6973-SFHG ("While the prevalence of Salmonella contamination in regulated poultry products has decreased by more than 50 percent in recent years, there has not been a reduction in human illnesses attributable to poultry.").

88. *See* Wall et al., *supra* note 24, at 728-32 (discussing the obstacles to risk assessment and regulatory impact assessment in the regulation of agricultural water). Although it has proven impossible to reliably assess the impact of agricultural water regulation on rates of human illness, there are data to suggests that compliance with regulations is relatively high among farmers. *See* LYTTON, *supra* note 27, at 163-66.

Numerous laboratory experiments and field studies have measured the impact of efforts to reduce the risk of microbial contamination on the microbial quality of foods,[89] and these studies include findings related to correlations between agricultural water quality and microbial loads on plants.[90] Laboratory experiments and field studies have also found that post-harvest interventions, such as washing harvested produce with chlorinated water or irradiating it, can reduce microbial loads on plants.[91] Both industry leaders and the FDA have instituted post-harvest testing programs for leafy greens to detect contamination.[92] Such efforts are essential to assessing the effectiveness of efforts to reduce contamination of leafy greens.[93] But as previously explained, even robust data regarding microbial loads on plants is a highly uncertain proxy for the risk of human illness.[94]

B. Unmanageable Risks

There is a well-known maxim in risk management: you can only manage what you can measure.[95] Unfortunately, when it comes to risk management in leafy greens cultivation, there is no reliable way to measure the prevalence of microbial contaminants in agricultural water, the subsequent pathogen exposure to consumers, or the resulting incidence of foodborne illness in the population. Notwithstanding these challenges, recurrent foodborne illness

89. *See* Minor & Parrett, *supra* note 86, at 211 (citing studies assessing the impact of regulatory interventions on the microbiological quality of foods).

90. *See, e.g.*, COLLABORATIVE FOOD SAFETY FORUM, *supra* note 59, at 3.

91. TREVOR SUSLOW, UNIV. CAL. DIV. AGRIC. & NAT. RES., POSTHARVEST CHLORINATION: BASIC PROPERTIES AND KEY POINTS FOR EFFECTIVE DISINFECTION 1 (1997), https://perma.cc/44GH-XBA5. On the limitations of postharvest chlorine washing, see Schmit, *supra* note 40; Costa, *supra* note 40; Highmore et al., *supra* note 40.

92. *E.g.*, COSTCO WHOLESALE, FOOD SAFETY AUDIT EXPECTATIONS FOR COSTCO SUPPLIERS 26 (2014), https://azzule.com/wp-content/uploads/2019/05/Master-Audit-Expectations-V1-0.pdf; *FDA Announces Targeted Leafy Green Sampling in the Salinas Valley*, FOOD SAFETY NEWS (Sept. 10, 2022), https://perma.cc/V5U3-2SLY; April Ward, California LGMA Embarks on 'Romaine Test & Learn' Study, CAL. LEAFY GREENS MKTG. AGREEMENT (LGMA) (July 10, 2023), https://perma.cc/SZN9-HMAL.

93. Wilhelmsen, *supra* note 40. On the limitations of testing as a food safety tool, see *id.;* Buchanan & Schaffner, *supra* note 40; McEntire, *supra* note 40; ICMSF, *supra* note 24, at 10; Marcel H. Zwietering et al., *All Food Processes Have a Residual Risk, Some Are Small, Some Very Small and Some Are Extremely Small: Zero Risk Does Not Exist*, 39 CURRENT OPINION IN FOOD SCIENCE 83, 83-85 (2021).

94. *See supra* note 86-88 and accompanying text.

95. F. John Reh, *You Can't Manage What You Don't Measure*, THE BALANCE (Feb. 5, 2017), https://perma.cc/V2ZD-Q4LZ.

outbreaks traced back to leafy greens and other fresh produce items have prompted regulatory responses aimed at encouraging growers to manage the risk of microbial contamination in their fields.[96] Agricultural water quality standards have been the focus of considerable attention. The development of agricultural water quality standards can be divided into two generations.

The first generation of agricultural water quality standards emerged in the late 1990s. These standards relied on voluntary guidelines that emphasized potential sources of contamination and provided nonbinding, general, qualitative recommendations for hazard mitigation.[97] The industry experts and government regulators who authored these voluntary guidelines felt constrained by the lack of evidence that could support specific, quantitative agricultural water quality criteria.[98] They anticipated that future scientific findings would enable gradual evolution of greater specificity.[99]

Additional outbreaks stimulated dissatisfaction with the vague and voluntary character of food safety regulation in the fresh produce sector.[100] Consequently, a second generation of regulatory responses emerged in the mid-2000s, consisting of mandatory rules that required growers to follow detailed testing protocols to ensure that the microbial quality of agricultural water did not exceed specific quantitative thresholds.[101] The industry experts and government regulators who authored these mandatory rules felt pressure to provide a more muscular, determinate regulatory approach.[102] Despite the lack of scientific justification for specific quantitative agricultural water quality criteria, the authors projected confidence and determination, which they hoped would calm fears and resolve the problem.[103]

Subsequent outbreaks have undermined confidence in the mandatory rules governing agricultural water quality and aroused resistance to enforcement of those rules among industry groups.[104] In response, government regulators recently signaled a willingness to abandon prescribed water testing protocols and quantitative microbial thresholds in favor of a return to more general standards.[105] Concurrently, these same industry groups, eager to assuage consumer anxiety about future outbreaks, have reaffirmed their commitment

96. *See, e.g.*, COLLABORATIVE FOOD SAFETY FORUM, *supra* note 59, at 31.
97. *See infra* notes 114-21 and accompanying text.
98. *See infra* notes 122-24 and accompanying text.
99. *See infra* notes 122-24 and accompanying text.
100. *See infra* notes 128-33 and accompanying text.
101. *See infra* notes 143-46 and accompanying text.
102. *See infra* notes 128-30 and accompanying text.
103. *See infra* note 137 and accompanying text.
104. *See infra* notes 197-207, 230-32 and accompanying text.
105. *See infra* notes 208-11 and accompanying text.

to implementing identical water testing protocols and quantitative microbial thresholds prescribed by private industry standards.[106] This is not so much a third-generation response as a mixed reaction of government retreat and industry reaffirmation when it comes to the second-generation response. Amid the complexity of this story, one theme remains constant: despite the concerted efforts of industry experts and government regulators for the past twenty-five years, no one has been able to demonstrate that the resulting agricultural water quality standards have reduced the risk of foodborne illness.

The following section of the Article analyzes first- and second-generation regulatory responses to foodborne illness outbreaks caused by contaminated agricultural water. The account presented here details how scientific uncertainty limited the ambitions of the first-generation regulatory response and undermined the credibility of the second-generation regulatory response.

1. Voluntary Standards

Food safety concerns about fresh produce are relatively recent.[107] A National Academies report in 1985 asserted that "[r]aw fruits and vegetables are not common causes of foodborne illness in the United States" and that "[t]here is little use for microbiological [safety standards] for fresh fruits and vegetables at the present time."[108] Although, the FDA had long possessed broad legal authority under the Federal Food, Drug, and Cosmetic Act to prevent adulteration of any food sold in interstate commerce, the agency had never developed regulations for fresh produce as it had for processed foods.[109]

Complacency about the safety of fresh produce ended in the mid-1990s, when public health officials began identifying contaminated fresh produce as

106. *See infra* note 230 and accompanying text.

107. This and the next paragraph are drawn from Timothy D. Lytton, *Technical Standards in Health and Safety Regulation: Risk Regimes, the New Administrative Law, and Food Safety Governance*, *in* 2 CAMBRIDGE HANDBOOK OF TECHNICAL STANDARDIZATION LAW 45, 47 (Jorge L. Contreras ed., 2019) [hereinafter Lytton, *Technical Standards*]. For a more detailed account of the history of food safety standards in the fresh produce sector, see LYTTON, *supra* note 27, at 121-47.

108. NAT'L ACAD. SCIS., AN EVALUATION OF THE ROLE OF MICROBIOLOGICAL CRITERIA FOR FOODS AND FOOD INGREDIENTS 257-58 (1985).

109. VANESSA K. BURROWS, CONG. RSCH. SERV., RS22939, FDA AUTHORITY TO REGULATE ON-FARM ACTIVITY 4-5 (2008); Varun Shekhar, Comment, *Produce Exceptionalism: Examining the Leafy Greens Marketing Agreement and Its Ability to Improve Food Safety*, 6 J. FOOD L. & POL'Y 267, 268-70 (2010).

the source of foodborne illness outbreaks.[110] Increased consumption of raw produce driven by changing dietary patterns that favored fresh salads over cooked vegetables likely contributed to a rise in outbreaks.[111] Simultaneously, advances in foodborne illness surveillance and tracing enhanced the ability of public health officials to link outbreaks to specific products and companies.[112]

The first industry guidelines and government guidance addressing food safety risk in the cultivation of fresh produce appeared in the late 1990s.[113] These voluntary standards highlighted potential sources of contamination but provided little specific advice on how to reduce risk.[114] In 1997, the International Fresh-Cut Produce Association (IFPA) and the Western Growers Association (WGA) published the first on-farm food safety standards for fresh produce. Developed by technical committees of industry, government, and academic experts, the guidelines identified several sources of potential contamination in preharvest operations, including organic fertilizers, animal intrusion, field workers, and agricultural water.[115] The standards for agricultural water quality exemplify the modest ambitions of these early guidelines.[116]

The IFPA-WGA guidelines warned that "[a]ll water used in the production of crops can act as potentially significant contributors of microbial contamination" and suggested that "water may be tested for contaminants on a periodic basis," "the frequency of testing may be determined by the water source," and "[t]esting may be considered for *E. coli* and total coliforms."[117] The guidelines offered no details concerning the frequency of water testing

110. Robert E. Brackett, Dir., Ctr. Food Safety & Applied Nutrition, U.S. Food & Drug Admin., Letter to California Firms That Grow, Pack, Process, or Ship Fresh and Fresh-Cut Lettuce (Nov. 4, 2005), https://perma.cc/R5LQ-TKQV [hereinafter FDA Letter Regarding Fresh and Fresh-Cut Lettuce].

111. *See* Matthew Kohnke, Note, *Reeling in a Rogue Industry: Lethal E. Coli in California's Leafy Green Produce & the Regulatory Response*, 12 DRAKE J. AGRIC. L. 493, 493 (2007); *see also* Loria, *supra* note 34..

112. *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables*, FOOD & DRUG ADMIN. (Feb. 2008), https://perma.cc/48XV-3GP4.

113. FDA Letter Regarding Fresh and Fresh-Cut Lettuce, *supra* note 110.

114. *Id.*

115. INT'L FRESH-CUT PRODUCE ASS'N & WESTERN GROWERS ASS'N, VOLUNTARY FOOD SAFETY GUIDELINES FOR FRESH PRODUCE 1-3 (1997), https://perma.cc/XB9M-ENZF [hereinafter IFPA & WGA].

116. *Id.* at 2. The guidelines for water quality included water quality testing standards, recommendations for environmental assessment, protection of water sources, and mitigation strategies. *Id.* The analysis in this section focuses primarily on the first of these.

117. *Id.*

or how to evaluate results. A second set of guidelines, published around the same time by the United Fresh Fruit and Vegetable Association and endorsed by a broad coalition of twenty industry associations, similarly suggested that "[w]ater sources in proximity to livestock or unusual concentrations of wildlife, and other potential contamination sources should be evaluated"—again, providing no specifics regarding how often to test water or what to do with results.[118]

Guidance issued jointly by the FDA and the USDA in 1998 suffered from the same shortcoming. It recommended that "[w]ater quality should be adequate for its intended use"[119] and defined "adequate" as "that which is needed to accomplish the intended purpose in keeping with good practice."[120] The guidance suggested that "[g]rowers interested in testing the microbial quality of agricultural water sources . . . may elect to test their water supply for microbial contamination on a periodic basis, using standard indicators of fecal pollution, such as *E. coli* tests."[121]

All three of these early documents acknowledged that the then current science could not support determinate agricultural water quality testing methods or targets. The preface to the IFPA-WGA standards explained:

> [T]hese guidelines are designed to be general and not specific. . . . There are data gaps in understanding the sources and significance of microbial hazards as well as practices to minimize them. Consequently, it is not well understood what specific impact water, manure or employees may have in contributing to foodborne disease. . . . These voluntary guidelines are not "final" in that they will be periodically revised as more information and new technology allow the industry to better understand factors impacting these issues.[122]

The United Fresh guidelines similarly began by recognizing that "[w]hile this document's purpose is to identify potential sources of contamination and

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118. UNITED FRESH FRUIT & VEGETABLE ASS'N, INDUSTRYWIDE GUIDANCE TO MINIMIZE MICROBIAL FOOD SAFETY RISKS FOR PRODUCE 8 (1997) [hereinafter UNITED FRESH], https://perma.cc/5KC4-BK54.

119. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS FOR FRESH FRUITS AND VEGETABLES 10 (Oct. 1998) [hereinafter FDA, 1998 GUIDANCE FOR INDUSTRY], https://perma.cc/2UVA-3W26. For additional details on the adoption of industry guidelines into this government guidance, see LYTTON, *supra* note 27, at 123-24.

120. FDA, 1998 GUIDANCE FOR INDUSTRY, *supra* note 119, at 6.

121. *Id.* at 12.

122. IFPA & WGA, *supra* note 115, at ii-iii.

examples of mitigation steps, further research is essential to understand more fully the risks and effectiveness of intervention measures."[123] The joint FDA-USDA guidance conceded that "[t]here are a number of gaps in the science upon which to base a microbial testing program for agricultural water and microbial testing of agricultural water may be of limited usefulness" and recommended that "[g]rowers concerned about water quality should first focus their attention on good agricultural practices (such as manure management and runoff controls) to maintain and protect the quality of their water sources."[124]

To encourage compliance with these voluntary standards, large commercial buyers of fresh produce—wholesalers, supermarkets, restaurant chains, and commercial caterers—began requiring their suppliers to undergo food safety audits and obtain a certificate of conformity with the industry guidelines and FDA-USDA guidance.[125] An extensive infrastructure of private food safety auditing firms rapidly emerged to meet the demand.[126] Additionally, the USDA launched a relatively small program of on-farm food safety audits available on a fee-for-service basis.[127]

When additional foodborne illness outbreaks associated with fresh produce occurred in the early 2000s, the FDA pressured industry executives to develop commodity specific food safety standards for what the agency deemed high-risk crops, such as leafy greens.[128] In 2004 and 2005, the agency issued warning letters urging industry action.[129] These letters threatened enforcement proceedings against companies and criminal prosecution of executives who sold contaminated produce.[130] In response, the IFPA, the WGA, United Fresh, and the Produce Marketing Association consulted leading fresh produce food safety experts in industry, government, and academia and, in the spring of 2006, jointly published commodity specific

123. UNITED FRESH, *supra* note 118, at 4.

124. FDA, 1998 GUIDANCE FOR INDUSTRY, *supra* note 119, at 12.

125. *See* LYTTON, *supra* note 27, at 127-30.

126. *Id.*

127. *Id.* at 208.

128. *Id.* at 125-26.

129. *See, e.g.*, Terry C. Troxell, Dir., Office of Plant & Dairy Foods, FDA, Letter to Firms That Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes (Feb. 5, 2004) [hereinafter FDA Letter Regarding Fresh Lettuce and Fresh Tomatoes], https://perma.cc/9VS3-WZXB; FDA Letter Regarding Fresh and Fresh-Cut Lettuce, *supra* note 110.

130. FDA Letter Regarding Fresh Lettuce and Fresh Tomatoes, *supra* note 129; FDA Letter Regarding Fresh and Fresh-Cut Lettuce, *supra* note 110.

standards for leafy greens.[131] Although scientific studies published after the initial guidelines provided additional evidence concerning the potential sources of microbial contamination, they did not offer any findings to support more detailed guidance.[132] Consequently, the industry's commodity specific standards merely reiterated the earlier general advice to growers.[133] A few months after the rollout of the commodity specific guidelines for leafy greens, an outbreak of unprecedented magnitude prompted industry leaders to change course.

2. Mandatory Rules

During the fall of 2006, bags of fresh baby spinach from California contaminated with a toxic strain of *E. coli* bacteria caused a nationwide outbreak resulting in 205 reported cases of acute illness.[134] These cases included 103 hospitalizations, of which thirty-one involved kidney failure and three involved death.[135] As reports of illness accumulated, the FDA warned consumers to avoid spinach. Overnight, the market collapsed. According to one estimate, California's leafy greens producers suffered nearly $100 million in losses because of the outbreak.[136]

Following the baby spinach outbreak, industry executives needed to restore confidence in the safety of leafy greens among their commercial buyers and calm consumer fears.[137] Leading supermarket chains banded together to demand immediate action by fresh produce trade associations to implement "specific, measurable, and verifiable" food safety standards to be enforced through third-party audits.[138] The powerful National Restaurant Association assembled a working group to develop more stringent food

131. *See* INT'L FRESH-CUT PRODUCE ASS'N ET AL., COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE LETTUCE AND LEAFY GREENS SUPPLY CHAIN (1st ed. 2006), https://perma.cc/8DNN-69HL. For a more detailed account, see LYTTON, *supra* note 27, at 125-26.

132. *See, e.g.*, Suslow, *supra* note 45, at 3-5; Topalcengiz, *supra* note 30, at 362-63 (citing studies published after 2006 of agricultural water as a source of microbial contamination of fresh produce).

133. *See* INT'L FRESH-CUT PRODUCE ASS'N ET AL., *supra* note 131.

134. The account in this paragraph is adapted from LYTTON, *supra* note 27, at 119-20.

135. *Id.*

136. *Food Safety: Current Challenges and New Ideas to Safeguard Consumers, Hearing of the Comm. on Health, Educ., Lab., and Pensions,* 109th Cong. 71 (2006) (testimony of fresh produce food safety expert Robert Whitaker estimating industry losses from the 2006 Dole baby spinach outbreak at $100 million).

137. Suslow, *supra* note 45, at 2; *see also* LYTTON, *supra* note 27, at 133.

138. LYTTON, *supra* note 27, at 254-56.

safety standards for fresh produce suppliers to restaurants.[139] High profile lawsuits filed by outbreak victims against growers, processors, and retailers sustained ongoing media coverage about the dangers of contaminated leafy greens.[140] Industry executives also faced government pressure to improve food safety on farms.[141] California state senator Dean Florez held committee hearings and introduced legislation proposing mandatory food safety measures for fresh produce operations backed by regular inspections conducted by state officials and paid for by growers.[142]

In response, fresh produce executives gathered food safety experts from industry, government, and academia to develop a more rigorous approach to food safety in the leafy greens sector.[143] They established the California Leafy Greens Handler Marketing Agreement (LGMA)—a compact among handlers (companies that process and package fresh produce) that required handlers to buy leafy greens exclusively from growers who agree to follow strict rules and undergo routine audits to verify compliance.[144] Membership in the compact entitled handlers to affix an LGMA food safety mark on their products.[145] Audits were to be conducted by California Department of Food and Agriculture inspectors and paid for by annual LGMA membership dues.[146]

Within a year, fifty-one handlers, who sold more than 90% of the leafy greens grown in California, had joined the LGMA. This number eventually rose to seventy-one handlers, responsible for more than 99% of California's leafy greens.[147] In Arizona, handlers established a similar LGMA, and collectively, the two LGMAs covered more than 90% of the U.S. leafy greens market.[148]

The LGMA founders crafted new food safety rules for leafy greens cultivation that went beyond general admonitions to specify quantitative metrics for managing risk. The preamble to the LGMA metrics explains how they did this:

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139. *Id.*
140. *Id.* at 147-48.
141. *Id.* at 253-54.
142. *Id.*
143. *Id.* at 133-34.
144. *Id.* at 135-36.
145. *Id.*
146. *Id.*
147. *Id.* at 136-37.
148. April Ward, *2015 Crop Report Shows Large Volume of Leafy Greens Grown Under Government Inspection*, LEAFY GREENS HANDLER MKTG. AGREEMENT (Aug. 2015), https://perma.cc/XXR4-KWCQ.

> [A] three-tier approach was used to identify these metrics in as rigorous a manner as possible:
>
> 1. A comprehensive literature review was conducted to determine if there was a scientifically valid basis for establishing a metric for the identified risk factor or best practice.
> 2. If the literature research did not identify scientific studies that could support an appropriate metric, standards or metrics from authoritative or regulatory bodies were used to establish a metric.
> 3. If neither scientific studies nor authoritative bodies had allowed for suitable metrics, consensus among industry representatives and/or other stakeholders was sought to establish metrics.[149]

The LGMA founders could not identify scientific studies that would support quantitative metrics for preharvest agricultural water quality (tier 1), so they adopted an established metric used by the federal Environmental Protection Agency (EPA) for regulating recreational water quality (tier 2).[150]

That metric is a rolling geometric mean across five samples for generic *E. coli* of 126 per 100 mL with single sample maximums of 235 per 100 mL for foliar applications where the water contacts edible portions of the crop (e.g., overhead sprinkler irrigation), and 576 for nonfoliar applications where the water does not contact edible portions of the crop (e.g., drip irrigation).[151] The LGMA guidelines require a sanitary survey prior to the start of every growing season that covers a farm's "entire water system, including water source, facilities, and equipment, for the purpose of identifying conditions that may result in microbial contamination."[152] The guidelines instruct

149. CAL. LEAFY GREENS HANDLER MKTG. AGREEMENT (LGMA), COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS 7 (2d ed. 2007) [hereinafter CA LGMA (2007)], https://perma.cc/AS76-A9F8.

150. CAL. LEAFY GREENS HANDLER MKTG. AGREEMENT (LGMA), APPENDIX B: TECHNICAL BASIS DOCUMENT FOR COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE LETTUCE AND LEAFY GREENS SUPPLY CHAIN, 2ND EDITION 3 (2007) [hereinafter CA LGMA (2007) APPENDIX B], https://perma.cc/XWU8-MTPW.

151. CA LGMA (2007), *supra* note 149, at 12-13. The microbial counts here refer to colony forming units or most probable number, which the metrics treat as equivalent. *Id.*

152. CAL. LEAFY GREENS HANDLER MKTG. AGREEMENT (LGMA), APPENDIX A TO THE COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS: SANITARY SURVEYS AND REMEDIATION GUIDELINES FOR WATER

growers to test water for generic *E. coli* during the initial survey and at least monthly thereafter.[153]

The guidelines explain how growers should employ the criteria for agricultural water quality.

> Ideally, preharvest water should not contain generic *E. coli*, but low levels do not necessarily indicate that water is unsafe. Investigation and/or remedial action SHOULD be taken when test results are higher than normal, or indicate an upward trend. Investigation and remedial action SHALL be taken when acceptance criteria are exceeded.[154]

Remedial action includes discontinuing the use of contaminated water, conducting an additional sanitary survey to identify possible sources of contamination, repairing wells, relocating livestock, removing debris, sanitizing irrigation equipment, disinfecting water with chlorine, sampling water more frequently, and testing exposed crops for specific pathogens and discarding any crops that test positive.[155] Thus, the LGMA guidelines employ the preharvest agricultural water quality criteria as an action level—a threshold that triggers mandatory remedial measures.[156] In subsequent revisions, the LGMA has expanded its guidelines regarding the details of sanitary surveys and water treatment for water sources in proximity to concentrated animal feedlot operations, but it has retained its original action levels for preharvest agricultural water quality.[157]

The LGMA guidelines explain that the presence of generic *E. coli* in water is an indicator of fecal contamination, but it does not necessarily indicate the presence of pathogenic bacteria, concentrations of which may vary widely in fecal matter.[158] Testing directly for pathogenic microbes might not detect fecal contamination, and frequent testing for a large variety of pathogenic

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RESOURCES at ii (2007) [hereinafter CA LGMA (2007) APPENDIX A], https://perma.cc/HP65-KDK6.

153. CA LGMA (2007), *supra* note 149, at 12.

154. *Id.*

155. *See* CA LGMA (2007) APPENDIX A, *supra* note 151, at 1-6.

156. CA LGMA (2007), *supra* note 149, at 16.

157. CAL. LEAFY GREENS HANDLER MKTG. AGREEMENT (LGMA), COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS 22-25 (Sept. 28, 2018), https://perma.cc/P447-FBJS; CAL. LEAFY GREENS HANDLER MKTG. AGREEMENT (LGMA), COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS 32-34 (Aug. 20, 2020) [hereinafter CA LGMA (2020)], https://perma.cc/B7WZ-L9EE.

158. CA LGMA (2007) APPENDIX B, *supra* note 150, at 3.

microbes would be prohibitively expensive.[159] Moreover, current testing methods are unable to detect all types of pathogens.[160] Thus, the LGMA standards caution:

> Although increasing levels of generic *E. coli* in a water source are likely to correlate with increasing health risk, "bright line" levels of generic *E. coli* above which health risks are unacceptable cannot rationally be established. Action levels based on generic *E. coli* concentrations should not be considered as separating "safe" or "unsafe" levels—they should only be considered as indicators of fecal contamination or increasing bacteriological densities.[161]

By relying on the EPA's recreational water quality criteria, the LGMA founders were self-conscious about adopting rules with a degree of specificity that could not be justified by science. David Gombas, a microbiologist who directed food safety efforts at United Fresh at the time recalls:

> Everyone was looking around for an answer to the question "What is water of adequate quality?" and there was no science to come up with a number. So, the closest thing that they could come up with was, "Well the EPA is saying that recreational water standards are safe enough to swim in—and if it's safe enough to swim in, it must be safe enough to irrigate with." . . . People wanted numbers, hard numbers. The problem was that there was no science—no science to support how many, how far, how often. So, we used the best available science and, in many regards, we just simply guessed. If you look at the original leafy greens metrics, they explain that we are using these numbers as a best estimation, in the sincere hope that science would provide better answers in the future.[162]

Robert Whitaker, who at the time was vice president for food safety at a major grower and was a principal architect of the LGMA, similarly recalls:

> There wasn't good science in place at the time. So, the measure that was adopted was basically the recreational water standard the

159. *Id.* at 2-3.

160. *Id.*

161. *Id.* at 3.

162. Telephone Interview with David Gombas, former Senior Vice President of Food Safety and Technology, United Fresh Produce Association (June 6, 2016).

> EPA had put in place. The feeling was, "It's really no more scientific than this: that if water is good enough quality to allow someone to swim in it, then it ought to be good enough quality to irrigate a crop with." . . . In 2006 and 2007, when those metrics were being developed, that's what the decision was based on. We didn't have data.[163]

Trevor Suslow, a plant pathologist at the University of California-Davis and a leading expert on the contamination of fresh produce by waterborne pathogens, who provided technical advice to the LGMA founders, opined in 2010: "The choice to adopt EPA recreational-water criteria at the time, and especially in retrospect, did not appear to be a sound, science-based selection for direct application of irrigation water; however, in the absence of a publicly available database from extensive testing, it was deemed the best option."[164] One reason for this choice was that, at the time, growers were unaware whether their agricultural water could pass a more stringent test, and they were worried that alternative sources of water or adequate means of water treatment might be unavailable.[165]

While the LGMAs in California and Arizona were implementing their new metrics in leafy greens production, the FDA was developing its own commodity specific guidance for leafy greens. In a 2009 draft guidance, the FDA acknowledged that industry groups had developed specific metrics, but the agency refused to adopt them because it had not "verified" them.[166] Shortly after the release of the FDA draft guidance, Suslow commented:

> [R]ecognizing the limitations of the current irrigation standards, the FDA's recently released Draft Commodity Specific Guidance documents for leafy greens, melons and tomatoes provides no

163. Telephone Interview with Robert Whitaker, former Chief Science Officer, Produce Marketing Association (June 1, 2016).

164. Suslow, *supra* note 45, at 9; *see also* Rock et al., *supra* note 85, at 623 ("[T]here is currently no scientific basis for the use of recreational water quality criteria in irrigated agriculture, where unique factors such as irrigation methods, degree of pathogen transfer to the produce, and survival of pathogens need to be taken into consideration."). The EPA's recreational water quality criteria have been criticized as inadequately justified by scientific evidence. *See* National Resources Defense Council, Comment on the Draft Recreational Water Quality Criteria 5-7, 9-12 (Feb. 21, 2021), https://perma.cc/E8AM-KMPS (characterizing the EPA's recreational water quality criteria as "arbitrary, capricious and an abuse of discretion").

165. E-mail from David Gombas, former Senior Vice President of Food Safety and Technology, United Fresh Produce Association (June 21, 2019) (on file with author).

166. *Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens*, U.S. FOOD & DRUG ADMIN. (July 2009), https://perma.cc/2QTQ-7U48.

> specifics, critical limits, or metrics based on indicators or pathogen prevalence in a standardized sample volume of any size. Producers are held to self-determination of the broadly applicable position that water should be "of appropriate quality for its intended use, obtaining water from an appropriate source, or treating and testing water on a regular basis and as needed to ensure appropriate quality." It is an understandable position for a regulatory authority in the face of substantial scientific uncertainty.[167]

The FDA's reluctance to endorse specific agricultural water quality metrics in the face of substantial scientific uncertainty would yield shortly thereafter to demands for more rigorous food safety regulation.

Additional outbreaks attributed to contaminated produce created growing public pressure for reform. The Center for Science in the Public Interest, a leading consumer advocacy group, petitioned the FDA to issue mandatory on-farm food safety regulations for fresh produce.[168] Mounting public pressure prompted Congress to pass the federal Food Safety Modernization Act (FSMA), which President Obama signed in 2011.[169] One of FSMA's central provisions was a mandate that the FDA develop within two and a half years "science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water" to reduce contamination of fresh produce.[170] The agency struggled in vain to find a scientific basis for quantitative minimum standards,[171] consequently missed the statutory deadline, and, after being successfully sued by consumer advocacy organizations,[172] finally published the Produce Safety Rule in November 2015,[173] with plans to phase in compliance with the agricultural water requirements between 2019 and 2021, depending on the size of the farm.[174]

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167. Suslow, *supra* note 45, at 7-8 (citation omitted).

168. LYTTON, *supra* note 27, at 142.

169. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

170. 21 U.S.C. § 350h(a)-(b).

171. *See infra* notes 189-96 and accompanying text.

172. *See* RENEE JOHNSON, CONG. RSCH. SERV., R43724, IMPLEMENTATION OF THE FDA FOOD SAFETY MODERNIZATION ACT (FMSA, P.L. 111-353) 6 (2015).

173. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74354 (Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 11, 16, 112).

174. *See* RENEE JOHNSON, CONG. RSCH. SERV., R43724, IMPLEMENTATION OF THE FDA FOOD SAFETY MODERNIZATION ACT (FMSA, P.L. 111-353) 9 (2015).

Like the LGMA, the FDA's Produce Safety Rule required an annual inspection at the beginning of each growing season of a farm's agricultural water systems "to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce."[175] The rule required testing during an initial survey to "develop a microbial water quality profile" for each agricultural water source, with the profile consisting of four samples collected during the growing season (or a year for untreated ground water) and twenty samples collected within no less than two and no more than four years.[176] Thereafter, growers were required to obtain one sample per year for untreated ground water and five samples per year for untreated surface water to calculate the geometric mean and statistical threshold value based on a rolling data set of four samples for untreated ground water and twenty samples for untreated surface water.[177]

Following the example of the LGMA founders, the FDA adopted the EPA's recreational water quality criteria. The agency's rule required a rolling geometric mean for generic *E. coli* of 126 per 100 mL for preharvest agricultural water.[178] The agency slightly modified the LGMA model by setting a sample maximum based on a statistical threshold value of 410 per 100 mL.[179] If growers determined that their agricultural water does not meet these criteria, the rule instructed them to take remedial measures "as soon as practicable and no later than the following year."[180] Remedial options included allowing time for bacterial die-off prior to harvesting; washing produce after harvest; re-inspecting, identifying problems, fixing those problems, and retesting; and treating water with antimicrobial agents.[181]

The rule allowed growers to substitute their own agricultural water quality criteria if they were supported by "adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection . . . and would not increase the likelihood that . . . covered produce [would] be adulterated."[182] The grower could develop the supporting scientific data and information, or the grower could source the data from the scientific literature or a third party. A grower using alternative

175. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Final Rule, 80 Fed. Reg. at 74554.

176. *Id.* at 74555.

177. *See id.* at 74556.

178. *Id.* at 74416.

179. *See id.*

180. *Id.* at 74555.

181. *Id*.

182. *Id.* at 74553.

criteria would not need to notify or seek prior approval from the FDA, although the grower would have to establish and maintain documentation of the scientific data and information that justifies the alternative criteria.[183]

Comments on the FDA's proposed Produce Safety Rule raised concerns about the sufficiency of scientific support for precise, mandatory microbial thresholds and urged the agency to undertake additional research before imposing them. Some comments argued that "the current status of produce safety research is inadequate to establish the quantitative metrics as applicable to all commodities and regions and all situations"[184] and that the FDA should "limit the metrics to those for which sufficient scientific evidence exists that such standards will protect public health and reduce risk."[185] Other comments suggested that "guidance would be a more appropriate vehicle to convey quantitative metrics, as recommendations rather than requirements, because there is such variation in region, operations, and commodities, and because guidance is easier to amend than a regulation"[186] and urged that "further research is needed to determine appropriate standards for water quality."[187] An additional comment recommended "that FDA conduct a risk assessment based on research findings and seek public comment on the results of the risk assessment, prior to finalizing a standard(s) for the quality of agricultural water."[188]

Both the LGMA and the FDA recognized the need for additional scientific research. Shortly after launching the LGMA, the LGMA founders established the Center for Produce Safety, a collaboration between trade associations, state agencies, and academics to conduct and disseminate new research.[189] As the LGMA founder Bob Whitaker explained, the goal is to conduct "hands on, boots-on-the-ground research to begin filling some of those knowledge gaps so that, where we were just surmising what a best practice should be based on logic, we might be able to get some data to actually give it more direction."[190] As the FDA rolled out its final Produce Safety Rule, the agency identified "certain data gaps and research needs" and reassured critics that "we do support additional research as a means of facilitating implementation of this rule and continuing advancement of

183. *See id.*
184. *Id.* at 74371.
185. *Id.*
186. *Id.*
187. *Id.* at 74427.
188. *Id.*
189. LYTTON, *supra* note 27, at 138.
190. Telephone Interview with Robert Whitaker, *supra* note 163.

scientific knowledge in this area."[191] The agency explained that it is actively engaged in partnerships with industry groups, other agencies, and academic institutions to pursue and fund research on agricultural water that could serve as "a basis for possible future rulemaking in this area."[192]

Nevertheless, the FDA insisted that "we have an adequate basis on which to finalize the metrics in this rule"[193] and that "[w]e do not agree that more research, followed by a risk assessment based on that research, is needed for us to finalize the provisions of this rule relating to agricultural water."[194] Notably, the agency explained that

> we have conducted a qualitative assessment of risk of hazards associated with produce production, which indicates that agricultural water is a potential route of contamination of produce during growing, harvesting, and on-farm postharvest activities and that use of poor agricultural practices could lead to contamination and illness even where the potential for contamination is relatively low. The science-based minimum standards . . . address this on-farm route of contamination.[195]

This response involves a non sequitur: the agency argued that its qualitative risk assessment regarding the potential sources of contamination justified its adoption of quantitative water quality metrics.[196] Thus, the FSMA mandate from Congress to implement "science-based minimum standards" for agricultural water within a set timeframe backed by a federal court order appeared to have overcome the agency's earlier reticence to endorse the LGMA's reliance on the EPA recreational water quality criteria in the face of substantial scientific uncertainty.

3. Second Thoughts

Following FDA's publication of a final rule for produce safety, industry leaders continued to complain about the lack of scientific evidence to support the agency's agricultural water quality metrics. They raised concerns during

191. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Final Rule, 80 Fed. Reg. at 74376, 74427.

192. *Id.* at 74427.

193. *Id.* at 74371.

194. *Id.* at 74427.

195. *Id.*

196. Interestingly, the FDA made no reference in the Federal Register to its 2012 QUANTITATIVE RISK ASSESSMENT TO SUPPORT THE PROPOSED PRODUCE RULE, *supra* note 43.

multiple stakeholder meetings in 2015, 2016, 2017, and 2018.[197] They argued that the agency's water sampling requirements and its insistence on precise thresholds for microbial concentrations were arbitrary given the wide variability among individual samples that is typical of water testing.[198] They cited consensus among experts that "generic *E. coli* alone is an inadequate analyte to determine the adequacy of agricultural water."[199] They complained the new rules relied on a "one-size-fits-all" approach that failed to account for differences in the sources of agricultural water, modes of application, crop characteristics, climatic conditions, and the rates at which different pathogens die off between water application and harvest.[200] Jennifer McEntire and James Gorny, vice presidents for food safety and technology at United Fresh and the Produce Marketing Association respectively, expressed the widely shared view that "[i]t's a stretch to suggest that the likelihood of illness associated with swallowing pool or lake water is the same as the likelihood of illness associated with eating fresh produce irrigated with water of swimming quality."[201] Additionally, stakeholders

197. *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water, 86 Fed. Reg. 69120, 69123-25 (Dec. 6, 2021) (to be codified at 21 C.F.R. pt. 112).

198. *See id.* at 69123-24.

199. COLLABORATIVE FOOD SAFETY FORUM, *supra* note 59, at 4.

200. *See* Wall et al., *supra* note 24, at 729-31; COLLABORATIVE FOOD SAFETY FORUM, *supra* note 59, at 3, 8.

201. McEntire & Gorny, *supra* note 45. The EPA's recreational water quality criteria are based on point-source contamination by untreated human wastewater in downstream river water presumably ingested during swimming. Suslow, *supra* note 45, at 3-9. By contrast, agricultural water comes from many sources, including rivers, streams, ponds, wells, and municipal water supplies. *See* Wall et al., *supra* note 24, at 728. Contamination of agricultural water is more typically from treated wastewater and animal feces. *See* Suslow, *supra* note 45, at 4; COLLABORATIVE FOOD SAFETY FORUM, *supra* note 59, at 4. Agricultural water is applied to crops in a variety of ways, including flood, overhead, drip, and seep irrigation or foliar applications. Suslow, *supra* note 45, at 4; Wall et al., *supra* note 24, at 724. Consumers are exposed to any resulting pathogens after additional growing time, harvest, processing, and storage, during which die off may reduce microbial loads. COLLABORATIVE FOOD SAFETY FORUM, *supra* note 59, at 4; Topalcengiz et al., *supra* note 30, at 360; Rock et al., *supra* note 85, at 623 ("The FDA regulation suggests the use of the primary contact recreational water quality contact standard . . . developed by the U.S. EPA. While this guideline was based on epidemiological studies among bathers on recreational waters, it has no direct relationship to risk associated with infection or illness rates that might result from irrigation waters used for produce production.").

Even the FDA has expressed unresolved doubts about this assumption. FDA scientists recognized these concerns, conceding in a memo that the use of recreational water quality criteria for pre-harvest agricultural water was "an imperfect fit." Memorandum from Kruti

pointed to the absence of epidemiological data to connect water quality standards to health outcomes.[202] As the summary document from one meeting put it, "[T]he current PSR agricultural water testing requirements do not seem worthwhile because there is no broadly-accepted evidence that they will significantly improve public health outcomes above current routine practices by the produce industry."[203]

The bottom line for many stakeholders was that the specific water quality metrics required by the FDA's Produce Safety Rule "are not scientifically defensible."[204] During a presentation in 2018 on the Produce Safety Rule's agricultural water standard at the annual conference of the International

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Ravaliya et al., Dep't of Health & Hum. Servs., Review of Water Quality Standards in Development of Proposed Microbial Standard in §122.44(c) of the Proposed Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Sept. 16, 2014), https://perma.cc/7BPK-KV35. The memo's conclusions are ambivalent:

> [W]e believe that the chance of incidental consumption of recreational water can reasonably be compared to the consumption of freshly harvested, packed, purchased and consumed produce containing residual pathogens from irrigation water applied using a direct application method . . . . We cannot directly compare the rates of exposure because the available science is based on different activities (e.g. exposure per serving of produce, per swimming event, and per year). However, we believe it is reasonable to consider that the incidental ingestion of agricultural water associated with consumption of freshly harvested, packed, purchased and consumed produce (5 ml per 40g serving) may be similar to, or lower than, the incidental ingestion of recreational water of around 16 ml per person per swimming event. . . . Importantly, we expect a difference in estimated exposure rates between that associated with the incidental ingestion of water while swimming in recreational water and the consumption of produce that has been directly exposed to agricultural water of the same quality during growing. This difference can be attributed to the fact that there is direct human exposure in incidental ingestion during recreational water use, while the exposure of residual water through the consumption of raw produce offers a less direct route . . . . Although there are differences in the overall expected health outcomes of a recreational water standard and an agricultural water standard, we believe that the underlying science supporting the recreational water standard serves as an appropriate basis on which to develop standards suitable for agricultural water.

Id. at 7-8. In defining appropriate agricultural water quality criteria based on existing recreational water quality criteria, the authors of the memo recommended unspecified "appropriate adjustments based on differences in the relevant context . . . ." *Id*. at 9.

202. COLLABORATIVE FOOD SAFETY FORUM, *supra* note 59, at 13 ("Epidemiological data are not currently available to conduct a [qualitative microbial risk assessment] for agricultural water.").

203. *Id.* at 2.

204. Wall et al., *supra* note 24, at 733.

Association for Food Protection, Suslow repeatedly emphasized that "[t]here is no justification for a strict quantitative standard."[205] As for the agency's allowance of alternative agricultural water criteria, stakeholders pointed out that neither they nor the FDA possessed a reliable method for evaluating whether an alternative would "provide the same level of public health protection as the [agency's microbial water quality criteria]."[206] In response to these criticisms, in 2019 the agency delayed enforcement of its agricultural water quality metrics until between 2022 and 2024, depending on the size of the farm.[207]

Then, in 2021, the agency changed course altogether. It proposed replacing its quantitative microbial water quality criteria and testing requirements with qualitative "pre-harvest agricultural water quality" assessments.[208] This revision would require growers, at least once annually, to "[i]dentify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards" onto produce or equipment and to "[d]etermine whether measures are reasonably necessary to reduce the potential for contamination" to ensure that agricultural water is "safe and of adequate sanitary quality for its intended use."[209] The proposed regulations direct growers' attention to factors that may affect the microbial quality of agricultural water: the location and nature of the water source, the method of application, crop characteristics, and climatic conditions.[210] If growers determine that their agricultural water is "not safe or is not of adequate sanitary quality for its intended use(s)," then they are required to "make necessary changes, and take adequate measures to determine if [the] changes

205. John Ravenscroft & Trevor Suslow, Risk-Based Approach to Identify Hazards, Provide Context for Monitoring and Inform Decision Making and Kiss: The Merits of a Simplified Approach to Agricultural Water Testing, Presentation at the International Association for Food Protection Annual Meeting (July 9, 2018), https://perma.cc/RHN4-32K6.

206. COLLABORATIVE FOOD SAFETY FORUM, *supra* note 59, at 4; *see also* Wall et al., *supra* note 24, at 726, 728, 732.

207. *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E, 84 Fed. Reg. 9708 (Mar. 18, 2019).

208. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water, 86 Fed. Reg. 69120, 69121, 69129 (Dec. 6, 2021) (to be codified at 21 C.F.R. pt. 112); Press Release, Nat'l Sustainable Agric. Coalition, "Flawed Science" Delays Roll Out of Food and Drug Administration's "Water Rule" (Mar. 15, 2019), https://perma.cc/M3UJ-KF8Z.

209. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water, 86 Fed. Reg. at 69151-52.

210. *Id.*

were effective" or treat the water "in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use(s)."[211] The absence of quantitative water quality criteria and of specific testing requirements and the reliance on terms such as "reasonably likely," "reasonably foreseeable," "reasonably necessary," "adequate sanitary quality," and "adequate measures" signal a shift from specific rules back to general standards. In 2024, the FDA published a final rule establishing these standards.[212]

4. Doubling Down

By contrast, industry leaders have reaffirmed their commitment to the LGMA's quantitative water quality metrics. For ten years following the founding of the LGMA, the metrics were credited with reducing foodborne illness. In 2016, California LGMA CEO Scott Horsfall asserted that "there are fewer *E. coli* outbreaks and illnesses, and regulators and folks who track these things have been very quick to say that the steps taken by the industry, including the LGMA, have led to these kinds of improvements."[213] That same year, Bill Marler, the nation's leading plaintiffs' attorney for foodborne illness cases and a leading advocate for food-safety reform, expressed a similar view: "[I]f success is measured by a lack of spinach outbreaks of the size that we've previously seen, I would say that looks like success."[214] Although outbreaks attributed to spinach and leafy greens occurred in the years following implementation of the LGMA metrics, none were of comparable magnitude to or prompted such widespread public fear as the 2006 baby spinach *E. coli* O157:H7 outbreak.[215]

All that changed in April 2018, when contaminated romaine lettuce grown in Yuma, Arizona, caused the largest outbreak of *E. coli* O157:H7 infections in a decade.[216] The outbreak caused 210 reported cases of illness spanning thirty-six states, and ninety-six victims required hospitalization, twenty-

211. *Id.* at 69153-55.

212. Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water, 89 Fed. Reg. 37448 (May 6, 2024) (codified at 21 C.R.R. pt. 112).

213. Telephone Interview with Scott Horsfall, CEO, Cal. Leafy Greens Handler Mktg. Agreement (LGMA) (2016).

214. Telephone Interview with Bill Marler, Attorney, Marley Clark, Inc. (May 31, 2016).

215. *See* LYTTON, *supra* note 27, at 166.

216. *See* Lyndsay Bottichio et al., *Shiga Toxin-Producing* Escherichia coli *Infections Associated with Romaine Lettuce—United States, 2018*, 71 CLINICAL INFECTIOUS DISEASES e323 (2020).

seven suffered kidney failure, and five died.[217] Responding to this crisis, Marler posted a blog titled "12 Years Later: Seems Like the Same *E. coli* Nightmare," which expressed the concern shared by many that perhaps the LGMA metrics were not as effective as everyone believed.[218] Six months later, another *E. coli O157:H7* outbreak occurred, and this one was traced back to romaine lettuce grown in California's central coastal region. This outbreak involved sixty-two reported cases of illness in sixteen states, and twenty-five victims were hospitalized, including two with kidney failure.[219] Following this outbreak, calls for reform mounted.[220] Notably, the outbreak strain was the same as that identified in a November 2017 *E. coli O157:H7* outbreak, which was also traced back to leafy greens grown in California's central coastal region. This 2017 outbreak resulted in twenty-five cases spanning fifteen states where nine victims were hospitalized, two of those victims developed kidney failure, and one died.[221]

In April 2019, the California LGMA announced "[n]ew, more stringent" requirements for agricultural water quality.[222] The revised metrics required agricultural water used for overhead irrigation or pesticide application within twenty-one days of harvest to contain no detectable generic *E. coli*.[223] Where necessary to meet this standard, the revised metrics required treatment with

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217. *Environmental Assessment of Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in a Multi-State Outbreak of E. coli O157:H7*, U.S. FOOD & DRUG ADMIN. (Nov. 1, 2018), https://perma.cc/ATU3-JRLR; *Multistate Outbreak of* E. coli *O157:H7 Infections Linked to Romaine Lettuce (Final Update)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (June 28, 2018, 3:30 PM), https://www.cdc.gov/ecoli/2018/o157h7-04-18/index.html.

218. LYTTON, *supra* note 27, at 165; Bill Marler, *12 Years Later: Seems Like the Same E. coli Nightmare*, MARLER BLOG (June 1, 2018), https://www.marlerblog.com/legal-cases/12-years-later-seems-like-to-same-e-coli-nightmare/.

219. *Outbreak of* E. coli *Infections Linked to Romaine Lettuce*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 9, 2019, 4:30 PM), https://perma.cc/2P6M-GJ55.

220. *Food Safety Voices Heard During 2019*, FOOD SAFETY NEWS (Dec. 26, 2019), https://perma.cc/S4YG-G8A2.

221. *Multistate Outbreak of Shiga Toxin-Producing* Escherichia coli *0157:H7 Infections Linked to Leafy Greens (Final Update)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 25, 2018, 11:00 AM), https://perma.cc/LX7C-YSCV; *see also* Michelle A. Waltenberg et al., *Two Multistate Outbreaks of a Reoccurring Shiga Toxin-Producing Escherichia coli Strain Associated with Romaine Lettuce: USA, 2018-2019*, 150 EPIDEMIOLOGY & INFECTION 1, 1 (2021).

222. April Ward, *New, More Stringent Food Safety Practices Adopted to Prevent Outbreaks*, CAL. LEAFY GREENS HANDLER MKTG. AGREEMENT (Apr. 19, 2019), https://perma.cc/4V6H-C4EM.

223. *See* CA LGMA (2020), *supra* note 157, at 26.

an antimicrobial agent such as chlorine.[224] For earlier overhead applications and all non-foliar applications, the metrics retained the original action level of a rolling geometric mean across 5 samples for generic *E. coli* of 126 per 100 mL.[225] LGMA founder and Produce Marketing Association Chief Science Officer Bob Whitaker heralded the revised metrics as "a paradigm shift in ag water management."[226] Jennifer McEntire, Vice President for Food Safety and Technology at United Fresh, characterized the revision as "a fundamental shift to better reflect well-established scientific knowledge on how we should think about water quality and risk."[227] Following the 2018 outbreaks, FDA Commissioner Scott Gottlieb requested that the Produce Marketing Association and United Fresh convene a new Romaine Task Force, which would address "ongoing safety problems with romaine lettuce."[228] The task force, composed of "roughly 100 industry and association leaders, regulatory and public health professionals and academic scientists," urged all romaine growers to comply with the revised LGMA metrics.[229] Five of the nation's largest food retailers—Walmart, Costco, Kroger, Wegmans, and Yum! Brands (which owns Pizza Hut, Taco Bell, and KFC)—endorsed the revised LGMA metrics.[230]

From a purely scientific perspective, the LGMA's response to the romaine outbreaks of 2018, championed by many of the same industry experts who mounted a sustained and successful campaign against the FDA's microbial water quality profile rules, appears surprising. The LGMA reaffirmed its commitment to EPA recreational water quality thresholds as the basis for its agricultural water quality metrics for non-foliar applications and foliar applications more than twenty-one days before harvest—the same thresholds targeted by industry attacks on the FDA's quantitative agricultural water

224. *Id.*

225. *See id.* at 33; *Arizona Leafy Greens Marketing Agreement Approved New Water and Field Metrics Enhanced Guidelines Adopted in Time for the 2020-2021 Growing Season*, ARIZ. LEAFY GREENS MKTG. AGREEMENT (Sept. 18, 2020), https://perma.cc/BU3H-9PG2.

226. Dan Flynn, *Produce Industry Lines Up Behind New Agriculture Water Standards*, FOOD SAFETY NEWS (Apr. 26, 2019), https://perma.cc/P6FQ-KEZR.

227. *Id.*

228. Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on the Current Romaine Lettuce E. coli 0157:H7 Outbreak Investigation (Nov. 26, 2018), https://perma.cc/UC5X-CVJ8.

229. *Romaine Task Force Final Report and Recommendations*, INT'L FRESH PRODUCE ASS'N (Sept. 2019), https://perma.cc/VL8P-RPWS.

230. *Five Major Food Companies Forms Leafy Greens Safety Coalition*, FOOD SAFETY MAG. (Oct. 16, 2019), https://perma.cc/ZL55-FM7S.

quality criteria.[231] Moreover, the LGMA possessed no evidence that any of its metrics had reduced foodborne illness attributable to leafy greens.[232] Annual LGMA reports document high rates of compliance with the metrics among growers, and independent surveys indicate that the LGMA has prompted growers to invest more in food safety precautions.[233] However, high compliance rates and increased investment provide no evidence that the metrics have made leafy greens any safer for consumers. According to a 2015 review of the LGMA's performance commissioned by the LGMA board and the Western Growers Association, a distinguished panel of four leading food safety experts "expressed confidence that the [LGMA] Guidelines have likely contributed to reducing the human pathogen contamination risk in leafy greens," but they "struggled with finding supportive data to prove their general positive sense of a decreased risk."[234] Moreover, as Part III will discuss, even if specific data proved that the LGMA metrics reduced the risk of contamination in the fields, that finding would not be sufficient to demonstrate that the metrics have reduced the illness rates among consumers.

Spring of 2019 ostensibly marked a new era in agricultural water quality risk management for leafy greens cultivation, but outbreaks traced back to contaminated romaine lettuce continued. During the fall of 2019, an outbreak, which was traced back to California romaine and involved the same strain of *E. coli* O157:H7 from the fall 2017 and 2018 outbreaks, generated 167 reported cases of illness in twenty-seven states, and eighty-five victims were hospitalized, fifteen of whom developed kidney failure.[235] The fall of 2020 brought additional *E. coli* O157:H7 outbreaks linked to romaine, and

231. *See supra* notes 197-206 and accompanying text.

232. *See* Rock et al., *supra* note 85, at 623 ("The FDA regulation suggests the use of the primary contact recreational water quality contact standard . . . developed by the U.S. EPA. While this guideline was based on epidemiological studies among bathers on recreational waters, it has no direct relationship to risk associated with infection or illness rates that might result from irrigation waters used for produce production.").

233. LYTTON, *supra* note 27, at 163-64; *see also* GREGORY ASTILL ET AL., U.S. DEP'T AGRIC., ECONOMIC INFORMATION BULLETIN NO. 210, U.S. PRODUCE GROWERS' DECISIONMAKING UNDER EVOLVING FOOD SAFETY STANDARDS, at iv (2019), https://perma.cc/8Q9H-K5UG (finding that growers invested in food safety measures due to competitive market pressures despite uncertainty about the benefits in terms of risk reduction).

234. IDECISIONSCIENCES, EXPERT PANEL REVIEW OF THE COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS 6 (Nov. 19, 2015), https://perma.cc/3BN9-EVYV.

235. *Outbreak of* E. coli *Infections Linked to Romaine Lettuce*, *supra* note 36.

these outbreaks caused illnesses across twenty states that, once again, led to hospitalizations and, in some cases, kidney failure.[236]

These outbreaks have taken a toll on consumer confidence. In a 2019 survey of consumers conducted by Consumer Reports, 52% of respondents reported "being concerned about getting sick from leafy greens—more than those who are worried about poisonings from beef, chicken, or eggs."[237] Market data compiled by Nielson in the same year found that annual sales of romaine dropped by $98 million—from $563 million in 2017 to $465 million following the 2018 outbreaks.[238] Notably, iceberg lettuce replaced romaine as the most popular lettuce in the United States.[239]

Both the industry and government tried to reassure consumers. "We are doing everything we can as an industry," LGMA CEO Scott Horsfall told Consumer Reports at the end of 2019.[240] FDA Deputy Commissioner for Food Policy and Response Frank Yiannas said he was "hopeful" that ongoing field research to identify potential pathways of contamination would make leafy greens safer.[241] By contrast, James E. Rogers, the Director of Food Safety Research and Testing at Consumer Reports, insisted that "this system is broken."[242]

C. Known Unknowns

Contaminated agricultural water exemplifies the general phenomenon of a known unknown—an identifiable hazard that poses an unquantifiable risk of causing harm. The nature and sources of the hazard are well known. Experts have identified a broad array of human pathogens in agricultural water that cause thousands of cases of illness each year. These pathogens are conveyed by fecal contamination traceable to wild animal intrusion and nearby cattle operations. However, state-of-the-art science cannot measure the impact of water quality on the incidence of human illness because the

236. *Outbreak of* E. coli *Infections Linked to Leafy Greens*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 22, 2020, 4:00 PM), https://perma.cc/Z6BW-234C; *Outbreak of* E. coli *Infections – Unknown Source 3*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 18, 2020, 3:00 PM), https://perma.cc/4HB5-8UK9.

237. Loria, *supra* note 34.

238. *Id.*

239. *Id.*

240. *Id.*

241. *Id.*

242. *Id.*

quality of the water, the level of pathogen exposure, and the incidence of illness are all unknown.[243]

At this point, a few clarifications are necessary. By unknown, I mean beyond the current frontier of quantitative science, not necessarily unknowable. Advances in water testing, microbiology, and public health surveillance, might someday generate data and models that can reliably measure what is currently unknown. By unmeasurable, I mean to a degree of precision that is policy relevant, not unmeasurable in an absolute sense. From what we know about the hazard of contaminated agricultural water, eliminating neighboring cattle operations or constructing greenhouses to enclose lettuce fields might reduce the incidence of human illness to so great an extent that it would be noticeable and, in that sense, measurable. However, such radical measures are neither politically nor economically feasible. By unmeasurable, what I mean is not quantifiable to a degree that could justify a decision within the current parameters of policy choice. Thus, known unknowns are unknown at the present time given the current frontier of science and unmeasurable to a degree that could justify a regulatory standard within the current parameters faced by policymakers.

What makes known unknowns difficult to regulate is the pressure to establish specific, science-based quantitative standards for managing hazards notwithstanding the lack of science to justify such standards. In the long run, this may be a temporary problem, as science and technology advance, and the hazard in question becomes measurable in terms of risk. However, regulators do not always have the option to wait. The next Part explains the pathological regulatory dynamics that result.

II. The Limits of Risk Regulation

Pressure to respond quickly to pressing concerns based on incomplete information is a common feature of regulatory policymaking.[244] Regulatory theory offers various administrative strategies to manage this problem, and they can be grouped into three broad approaches—risk-based regulation, stakeholder participation, and new governance.

Each of these three administrative approaches to managing scientific uncertainty in regulatory policy reflects a distinct institutional logic. An institutional logic is a set of shared assumptions, values, and beliefs upon

243. COLLABORATIVE FOOD SAFETY FORUM, *supra* note 59, at 13. For the most sophisticated model to date, see QUANTITATIVE RISK ASSESSMENT TO SUPPORT THE PROPOSED PRODUCE RULE, *supra* note 43. *See also* Rock et al., *supra* note 85, at 624-26.

244. Majone, *supra* note 4, at 94-100.

which actors rely in analyzing problems and crafting solutions.[245] Risk-based regulation is characterized by an institutional logic of economic expertise. This approach frames risk regulation as an economic problem which is best addressed by policy experts trained in identifying and assessing the comparative benefits and costs of various policy options. From this standpoint, the goal of policymakers is efficient resource allocation.

Stakeholder participation is characterized by an institutional logic of democratic accountability. This approach frames risk regulation as a political problem and emphasizes that those affected by a risk have meaningful opportunities to participate in policymaking. Within this framework, the goal of policymakers is to create a process that has political legitimacy.

New governance is characterized by an institutional logic of systems thinking. This approach views risk regulation as a mixed regime of interdependent public and private efforts, and it recommends that government regulators harness private-sector capacities for innovation, experimentation, feedback, and learning. Under this approach, the goal of policymakers is to promote continual improvement.

Each of these three administrative approaches attempts to respond rationally to the problem of scientific uncertainty in risk regulation. As their distinct logics suggest, rationality can come in various forms: economic, political, and systemic. In this Part of the Article, I argue that each of these administrative approaches has incentivized both the LGMA and the FDA to conceal, ignore, or outsource—rather than confront—their inability to regulate the hazard of contaminated agricultural water using the standard tools of risk assessment and risk management. Consequently, this case study suggests that inherent in the drive for rational justification may be a tendency to suppress anxiety about scientific uncertainty. It appears that institutional logics can lead to administrative dysfunction.

A. The Science-Policy Gap

Risk regulation requires reliance on a mix of scientific evidence and policy considerations that are not dictated by science.[246] These considerations may

245. PATRICIA H. THORNTON ET AL., THE INSTITUTIONAL LOGICS PERSPECTIVE: A NEW APPROACH TO CULTURE, STRUCTURE, AND PROCESS 1 (2012).

246. Wagner, *The Science Charade*, *supra* note 10, at 1619 ("[C]ontemporary science is incapable of completely resolving the level at which a chemical will pose some specified, quantitative risk to humans."); Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 729 (1979) ("[A]gencies and courts increasingly have been

include judgments by scientists about how to interpret data or how to determine the reliability of statistical models, analysis by economists about efficient resource allocation, calculations by managers about administrative feasibility, opinions by lawyers about legality, and assessments by officials about political priorities.[247] Legal scholar Tom McGarity coined the term "science policy questions" to describe the combination of considerations necessary to produce health and safety regulations for exposure to environmental toxins.[248] As legal scholar Wendy Wagner explains, "To reach a final quantitative standard, policy considerations must fill in the gaps that science cannot inform."[249] I will use the term "science-policy gap" to denote the scientific uncertainty that requires policymakers to rely on policy considerations in establishing quantitative risk regulations.

By employing the concept of a science-policy gap, I do not mean to imply a sharp boundary that defines where science ends and other types of considerations take over. The boundaries of science are contested and often ambiguous, and scholars have developed multiple accounts of the ways in which policy-relevant science (variously characterized as "trans-science"[250] or "regulatory science"[251]) may stretch traditional ideas about scientific methodology and generate hybrid forms of analysis where legal or policy imperatives lead scientists to make strong assumptions or loosen standards

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called upon to resolve scientific questions about which there is much uncertainty, and even dispute, within the scientific community.").

247. TED GREENWOOD, KNOWLEDGE AND DISCRETION IN GOVERNMENT REGULATION 13 (1984) (discussing the role of professional & value judgments in policy discretion); McGarity, *supra* note 246, at 742 (describing how scientists may differ in their interpretation of policy-relevant data); Thomas O. McGarity, *Science and Policy in Setting National Ambient Air Quality Standards: Resolving the Ozone Enigma*, 93 TEX. L. REV. 1783, 1798 (2015) (observing that air quality standards are determined by "a mixture of scientific judgment, policy considerations, intuition, and even the personal values of the scientists making the choices"); Simon Shackley & Brian Wynne, *Global Climate Change: The Mutual Construction of an Emergent Science-Policy Domain*, 22 SCI. & PUBL. POL'Y 218, 220 (1995) (noting the role of legal opinions in setting toxics standards).

248. McGarity, *supra* note 246, at 732.

249. Wagner, *The Science Charade*, *supra* note 10, at 1622.

250. Alvin M. Weinberg, *Science and Trans-Science*, 10 MINERVA 209 (1974); Ted Greenwood, *The Myth of Scientific Incompetence of Regulatory Agencies*, 9 SCI., TECH. & HUM. VALUES 83, 86 (1984); Majone, *supra* note 44, at 15; Gil Eyal, *Trans-Science as a Vocation*, 19 J. CLASSICAL SOCIO. 254 (2019).

251. Sheila Jasanoff, *Technologies of Humility: Citizen Participation in Governing Science*, 41 MINERVA 223 (2003); Shackley & Wynne, *supra* note 247, at 219; Majone, *supra* note 4, at 99.

of proof.[252] Moreover, the frontiers of science typically expand over time.[253] As Ted Greenwood, a leading scholar on risk regulation, explained over three decades ago:

> The boundary between knowledge and discretion—particularly discretion in answering scientific and engineering questions in the face of deficient knowledge—is very fuzzy. In some areas it shifts constantly because knowledge is expanding. In many areas, it cannot be precisely defined. What one person calls knowledge based on scientific judgment, another may call the exercise of discretion based on values or policy preferences. Inference rules, both ad hoc and generic, and decision algorithms so entwine discretion in the detailed, technical aspects of a subject that distinguishing the knowledge that constrains agency choices from the discretion that determines them can be extraordinarily difficult.[254]

As Greenwood and others note, the science-policy distinction, which Greenwood refers to as "the boundary between knowledge and discretion," inheres in science itself when scientists are called upon as experts to opine on the implications of scientific findings for regulatory policy.[255]

Nor do I wish to suggest that reliance on non-scientific considerations means that a policy is not based on science. Observing that scientific evidence was supplemented by interpretive judgments, economic analysis, feasibility calculations, legal reasoning, and political calculations to reach a policy decision is not the same as claiming that the decision was devoid of science. Even the highest quality policy-relevant science typically produces incomplete and ambiguous results.[256] Consequently, creating science-based

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252. Simon Shackley & Brian Wynne, *Global Climate Change: The Mutual Construction of an Emergent Science-Policy Domain*, 22 SCI. & PUB. POL'Y 218, 220 (1995).

253. Giandomenico Majone, *Science and Trans-Science in Standard Setting*, SCI., TECH., & HUM. VALUES, Winter 1984, at 15, 19 ("New understanding, therefore, often increases rather than reduces the cognitive complexity of regulatory problems.").

254. GREENWOOD, *supra* note 247, at 243.

255. Eyal, *supra* note 250, at 266. More critical theories argue that non-scientific considerations run deep in science. *See, e.g.*, Christie Aschwanden, *There's No Such Thing as "Sound Science,"* FIVETHIRTY EIGHT (Dec. 6, 2017), https://perma.cc/Z3ZH-4MCF.

256. *See generally* Inger Lise Johansen & Marvin Rausand, *Defining Complexity for Risk Assessment of Sociotechnical Systems: A Conceptual Framework*, 228 J. RISK & RELIABILITY 272 (2014) (discussing the role of complexity and uncertainty in risk assessment of sociotechnical systems); Zwietering et al., *supra* note 93 (residual risk in food safety regulation); McGarity, *supra* note 247, at 1789 (remaining uncertainty in air quality

regulations normally requires decision makers to fashion policy directives from limited scientific findings.[257]

Moreover, I do not want to denigrate the quality of the science underlying efforts to regulate agricultural water quality. The identification of agricultural water as a source of microbial contamination is based on peer-reviewed laboratory experiments, field studies, and outbreak investigation findings, all of which have been published in academic journals during the past two decades.[258]

Finally, I do not question the commitment of industry leaders and FDA officials to find a solution to the problem of agricultural water quality contamination. As Part I.B. detailed, there is abundant evidence that these policymakers did their best to advance plausible solutions to complex problems despite limited information.

That said, known unknowns present a type of science-policy gap that stymies risk regulation: science can provide a detailed qualitative analysis of the hazard but cannot measure the risk that it poses. Stephen Dovers and his colleagues explain this type of science-policy gap by distinguishing between risk and uncertainty.[259] Risk, they explain, applies to situations "where believable probability distributions can be assigned to possible outcomes; that is, we know the odds."[260] By contrast, uncertainty pertains "where the direction of change is believed to be known, but precision in predicting the scale or probability of impacts is not possible and believable probability distributions cannot be assigned."[261] Other scholars similarly distinguish between degrees of uncertainty.[262] Normal uncertainty "can be described adequately in statistical terms" whereas "deep uncertainty" denotes "the condition in which analysts do not know or the parties to a decision cannot agree upon (1) the appropriate models to describe interactions among a system's variables, (2) the probability distributions to represent uncertainty about key parameters in the models, and/or (3) how to value the desirability of alternative outcomes."[263] Therefore, when attempting to regulate a known

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standards); Majone, *supra* note 4, at 99 (irreducible uncertainty in regulatory science generally).

257. *Id.* at 279.

258. *See supra* notes 30-31, 34-47 and accompanying text.

259. Dovers et al., *supra* note 5, at 248-49; *see also* Kasperson, *supra* note 5, at 337.

260. Dovers et al., *supra* note 5, at 249.

261. *Id.*

262. *See* Walker et al., *supra* note 5, at 397.

263. *Id.*

unknown, policymakers confront more than just ordinary uncertainty. They must grapple with deep uncertainty.

As described in Part I, regulatory agencies find themselves in an untenable position when they are under a legal mandate to implement specific science-based enforceable risk regulation metrics in the face of deep uncertainty. Industry experts face a similar challenge when economic pressures require them to do the same. The leading approaches to risk regulation offer little help. Indeed, as the next three sections demonstrate, they make the situation worse.

B. Risk-Based Regulation

Risk-based regulation relies on quantification. As political scientist Giandomenico Majone explains, although "it is obvious that risk regulators operate on the basis of great, and in many cases irreducible, uncertainty. Such uncertainty is too important to be treated in a purely intuitive and qualitative way; rather, it should be expressed in terms of numerical probabilities."[264] Majone and other scholars are acutely aware of the ways in which uncertainty hinders quantitative risk assessment and risk management, but they insist that even rough, subjective estimates "break down the whole decision problem into separate but coherent components," which bring rationality, consistency, and accountability to policymaking.[265] Risk-based regulation refers to a family of administrative approaches that rely on quantifying risk to set regulatory goals, determine regulatory priorities, and allocate regulatory resources.[266]

From a bureaucratic perspective, quantification lends legitimacy to agency decision making. As historian of science Theodore Porter explains:

> In a political culture that idealizes the rule of law, it seems bad policy to rely on mere judgment, however seasoned. . . . The appeal of numbers is especially compelling to bureaucratic officials who lack the mandate of a popular election, or divine right. Arbitrariness and bias are the most usual grounds upon which such officials are criticized. A decision made by the numbers (or by explicit rules of some other sort) has at least the appearance of being fair and impersonal. Scientific objectivity thus provides an answer to a moral demand for impartiality and

264. Majone, *supra* note 4, at 94 (citation omitted); *see also* Fisher, *supra* note 23, at 55.

265. Majone, *supra* note 4, at 94, 103.

266. Julia Black, *Risk-Based Regulation: Choices, Practices and Lessons Being Learnt*, *in* RISK AND REGULATORY POLICY, *supra* note 4, at 185, 187.

> fairness. Quantification is a way of making decisions without seeming to decide. Objectivity lends authority to officials who have very little of their own.[267]

Legislative mandates requiring agencies to develop "science-based" regulations and administrative requirements that agencies demonstrate that the benefits of any proposed rule outweigh its costs institutionalize this tendency towards quantitative risk analysis.[268]

The legitimacy that comes from scientific justification and the legal requirement to produce it have lead agency officials to conceal the science-policy gap.[269] Wendy Wagner observes that "[a]gency scientists and bureaucrats engage in a 'science charade' by failing first to identify the major interstices left by science in the standard-setting process and second to reveal the policy choices they made to fill each trans-scientific gap."[270] In seeking to justify their quantitative agricultural water quality criteria, both the LGMA and the FDA marshalled experts to obscure the limits of the underlying science and the professional judgments, policy values, and speculation that were necessary to bridge the science-policy gap.

1. LGMA Puffery

Initially, the LGMA's website merely stated that its metrics "were developed by university and industry scientists, food safety experts and farmers, shippers and processors."[271] Nevertheless, by 2014, the LGMA began claiming on its website that the metrics constituted a "rigorous science-

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267. THEODORE M. PORTER, TRUST IN NUMBERS: THE PURSUIT OF OBJECTIVITY IN SCIENCE AND PUBLIC LIFE 8 (2020).

268. Under FSMA, Congress mandated that the FDA publish "science-based" produce-safety regulations. 21 U.S.C. §350(h)(a) & (b). FDA in turn produced a regulatory-impact analysis. U.S. FOOD & DRUG ADMIN., FDA-2011-N-0921, STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION: FINAL REGULATORY IMPACT ANALYSIS (2015), https://perma.cc/V4YL-F63M [hereinafter FDA, FINAL REGULATORY IMPACT ANALYSIS].

269. GREENWOOD, *supra* note 247, at 252; Wagner, *The Science Charade*, *supra* note 10, at 1617, 1628-29; Coglianese & Marchant, *supra* note 25, at 1258, 1265.

270. Wagner, *The Science Charade*, *supra* note 10, at 1629; *see also* Coglianese & Marchant, *supra* note 25, at 1258, 1260, 1262-3 (on agency exaggeration of the role of science in policy making); SILVIO O. FUNTOWICZ & JEROME R. RAVETZ, UNCERTAINTY AND QUALITY IN SCIENCE FOR POLICY 25-28 (1990) (discussing "uncertainty-avoidance in bureaucracies").

271. *About Us*, CAL. LEAFY GREENS HANDLER MKTG. AGREEMENT (LGMA) (2012), https://perma.cc/4HJU-2JR6 (last visited June 2, 2023). For a detailed account, *see supra* notes 143-65 and accompanying text.

based food safety system."[272] In 2015, the LGMA commissioned an "expert panel review" coordinated by the Western Growers Association and designed by iDecisionSciences ("IDS"), LLC, a consulting firm that works with companies in the fresh produce sector to manage food safety risk.[273] The panel consisted of four experts holding PhDs with experience in government, industry, and academia.[274] IDS presented the panel with the LGMA guidelines and a comparison prepared by IDS of the best practices in both the guidelines and the provisions of the FDA's proposed Produce Safety Rule. IDS then asked the experts to answer three questions "using their professional judgment":

> 1. Do the practices in the current edition of the Guidelines represent the most current microbial food safety best practices for the production and harvest of lettuce and leafy greens?
>
> 2. Do the CALGMA's accepted food safety practices (the Guidelines) provide the same level of public health protection as the applicable requirements proposed in the Produce Rule?
>
> 3. Has the implementation of these guidelines in California and Arizona, coupled with the California Department of Food and Agriculture (CDFA) audit program reduced the risk of human pathogen contamination in lettuce and leafy green crops?[275]

According to IDS, "overall," the experts answered all three questions affirmatively.[276] The impressionistic nature of the analysis is apparent in the IDS summary of panelists' responses to the third question. The summary states that "[a]ll the reviewers expressed confidence that the Guidelines have likely contributed to reducing the human pathogen contamination risk in leafy greens although some struggled with finding supportive data to prove their general positive sense of a decreased risk." One panelist grounded his opinion in "common sense," and another "acknowledged the difficulty in definitively quantifying that reduction."[277]

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272. *About Us*, CAL. LEAFY GREENS HANDLER MKTG. AGREEMENT (LGMA) (2014), https://perma.cc/4KD2-C2NG (last visited June 2, 2023).

273. *See generally* IDECISIONSCIENCES, *supra* note 234.

274. *Id.* at 4.

275. *Id.* at 5.

276. *Id.*

277. *Id.* at 6.

2. FDA Pretense

Like the LGMA, the FDA insists that the specific criteria in its Produce Safety Rule "are based in science" to an extent that obscures the role of professional judgment, policy values, and speculation.[278] The FDA's response to comments on its proposed agricultural water quality standards demonstrates how the agency deploys science rhetoric to justify agency judgment. In response to comments suggesting that "further research is needed to determine appropriate standards for water quality," the agency wrote that

> *there is sufficient scientific information from which we conclude* that the requirements in this rule minimize the risk of serious adverse health consequences and death, and are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated.[279]

Given that the EPA recreational water quality criteria, from which the FDA's agricultural water quality criteria derives, is based on an "accepted gastrointestinal illness rate" of thirty-six per 100,000 swimmers, it is unclear what the FDA means by "minimize the risk of serious adverse health consequences and death."[280] Moreover, it is not readily apparent what "reasonably necessary," "reasonably foreseeable," and "reasonable assurances" mean or how they are determined by "sufficient scientific information." The language of reasonableness suggests an exercise of discretion that, while informed by science, is not, as the agency's rhetoric implies, *determined* by science.

In several instances, the agency both signals and conceals its exercise of policy discretion by acknowledging the limits of scientific findings or unresolved disagreement among scientific experts and then asserting "we conclude" that the science supports the agency's choice of a standard. For example, in discussing its reliance on testing for *E coli* as a means of assessing health risks, the agency asserted the following:

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278. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74354, 74371 (Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 11, 16, 112).

279. *Id.* at 74427 (emphasis added).

280. *Id.* at 74443. The FDA's agricultural water criteria derives from the 2012 EPA revision of its recreational water-quality criteria. 2012 Recreational Water Quality Criteria, 77 Fed. Reg. 71191, 71192 (Nov. 29, 2012).

> We . . . recognize that, despite widespread use of and support for generic *E. coli* as an indicator of fecal contamination, its ability to signal contamination events is not without challenges. . . . Nevertheless, *based on our review of current literature*, we conclude that generic *E. coli* serves as the most appropriate microbial indicator of fecal contamination at this time.[281]

Similarly, the agency explained: "We acknowledge the difficulty of associating specific indicator concentrations with specific produce related health risks. Even so, we conclude that such difficulty does not negate the value of applying generic *E. coli* test results to the criteria . . . ."[282] The point here is not to question the FDA's professional judgment but rather to show that scientific evidence alone does not account for the agency's agricultural water quality criteria and highlight that the agency appears eager to downplay the role of discretion in its decision making.[283]

To be fair, the agency was between a rock and a hard place. On one hand, it had been sued by consumer advocacy groups when it was reticent to publish the Produce Safety Rule for lack of, what it considered, sufficient scientific justification.[284] On the other hand, the agency risked potential lawsuits from industry if it failed to produce a scientific justification that could withstand judicial scrutiny.[285] Thus, the FDA faced powerful incentives to use scientific rhetoric to conceal the science-policy gap.

Additionally, like the LGMA, the FDA relied on the "common sense" impressions of scientific experts to justify the Produce Safety Rule. In its regulatory impact analysis, the agency asserted that the rule would avert between 331,964 and 362,059 illnesses per year. To calculate the rule's influence on the rate of foodborne illness, the agency first estimated the rule's impact on the risk of contamination.[286]

To obtain this estimate, the agency relied on a method called "expert elicitation." A consulting firm under contract with the FDA asked a panel of

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281. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. at 74428 (emphasis added).

282. *Id.*

283. *Cf.* Nat'l Advisory Comm. on Microbiological Criteria for Foods, *supra* note 87, at 646 (admitting that "it is currently not possible to establish a science-based threshold" in poultry production).

284. *See supra* notes 168-174 and accompanying text.

285. *See* Wendy E. Wagner, *The CAIR RIA: Advocacy Dressed Up as Policy Analysis*, *in* REFORMING REGULATORY IMPACT ANALYSIS 56, 59, 71-72, 78 (Winston Harrington et al. eds., 2009) (discussing the use of regulatory impact analysis to reduce the risk of litigation).

286. FDA, FINAL REGULATORY IMPACT ANALYSIS, *supra* note 268, at 55-56.

six recognized food safety experts to indicate, using a series of scenarios, whether the risk of contamination in a scenario using a particular agricultural practice was less than, equal to, or greater than a baseline scenario without it.[287] The experts were asked to quantify the magnitude of the difference using a scale of zero to one hundred, placing the baseline scenario at fifty as a benchmark.[288] For example, the agricultural practice might be the use of treated flowing surface water for irrigation, and an expert might assign a relative risk value to this practice of twenty-five relative to a baseline scenario of using untreated flowing surface water set at fifty. The consulting firm conducted two such studies, one estimating the effect of interventions on *E. coli* O157 contamination of leafy greens and the other estimating their effect on *Salmonella* contamination in tomatoes.[289]

Using the numerical values from each set of scenarios, the agency calculated a risk ratio for implementing each food safety intervention, which it expressed as the reduction in the risk of contamination that would be achieved through the particular intervention.[290] For instance, if the average relative risk value for all six experts for treated, flowing surface water was twenty-five, the agency would infer that the use of treated flowing surface water for irrigation would mitigate 50% of the risk of produce contamination from using untreated flowing surface water. The agency then similarly calculated the reduction from other interventions aimed at risks from other sources, such as animal intervention, soil amendments, and worker hygiene.[291] By aggregating the estimates for each intervention, the agency calculated that "taken together, this adds up to about a 56.43 percent reduction in risk of contamination."[292]

Having "estimated" the rule's impact on the risk of contamination, the agency then considered its impact on the risk of foodborne illness. "To

287. *Id.*

288. *Id.*

289. ALEXIS ROBERT AT AL., EASTERN RSCH. GRP., EGR TASK NO. 0193.16.002.001, THE EFFECTIVENESS OF HARVEST AND POST-HARVEST MEASURES FOR REDUCING E. COLI ON LEAFY GREEN PRODUCTION (Mar. 20, 2009), http://perma.cc/7DYM-4TBM (report submitted to the FDA); ALEXIS ROBERT ET AL., EASTERN RSCH. GRP., EGR TASK NO. 0193.16.003.001, COST EFFECTIVENESS OF PRACTICES INTENDED TO PREVENT TOMATO-RELATED ILLNESS (Mar. 18, 2009), https://perma.cc/7FGE-SQ2N (report submitted to the FDA); *see also* U.S. Food & Drug Admin., *Technical Appendix: Estimation of Contamination Risk Mitigated Based on External Expert Elicitation Studies of Leafy Greens and Tomatoes* 2 (Dec. 6, 2015), https://perma.cc/4F74-8QFU.

290. FDA, FINAL REGULATORY IMPACT ANALYSIS, *supra* note 268, at 56-57.

291. *Id.*

292. *Id.* at 58; LYTTON, *supra* note 27, at 166-69.

translate this percentage reduction in farm contamination to human health outcomes, we estimated that a reduced probability of contamination will result in a corresponding reduction in the expected number of illnesses."[293] By this, the agency meant that a 56.43% reduction in the risk of contamination would mean a 56.43% reduction in the rate of foodborne illness.[294]

The agency's assertion that the Produce Safety Rule would prevent a quantifiable number of foodborne illnesses rests on a questionable methodology and an unsupported assumption. Expert elicitation produces quantitative risk reduction estimates based on an aggregation of educated estimates, but given that there were only six experts in this case, the precision of the resulting risk reduction percentages obscures the impressionistic nature of these estimates and the arguably inadequate sample size.[295] Moreover, despite the agency's claims that it "estimated that a reduced possibility of contamination will result in a corresponding reduction in the expected number of illnesses," it appears, from the lack of any additional explanation, that the agency merely assumed this relationship. Of course, it is not at all counterintuitive to think that reducing the risk of contamination will result in a lower rate of illness, but the agency offered no basis for its assertion of a linear, 1:1 relationship between reduction in the risk of contamination and the rate of illness.[296]

Once again, to be fair, OMB oversight required the agency to produce a quantitative cost-benefit analysis as a condition of fulfilling its legal

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293. FDA, FINAL REGULATORY IMPACT ANALYSIS, *supra* note 268, at 56.

294. *Id.*

295. For a defense of expert elicitation, see W. P. Aspinall et al., *Evaluation of a Performance-Based Expert Elicitation: WHO Global Attribution of Foodborne Diseases*, 11 PLOS ONE, no. 3, article no. e0149817, at 1, 11 (Mar. 1, 2016), https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0149817&type=printable. *See also* ICMSF, *supra* note 24, at 4, 6, 7 (describing reliance on expert elicitation in food safety risk management).

296. FDA, FINAL REGULATORY IMPACT ANALYSIS, *supra* note 268, at 56. The FDA is explicit about this assumption in FDA, FINAL QUALITATIVE RISK ASSESSMENT, *supra* note 30, at 58 ("For the purposes of this assessment, we make the assumption that the risk of illness is directly proportional to the likelihood of exposure, meaning that we assume that there is not a dose-response relationship, and any amount of contamination would be expected to cause illness."). For a similar critique of the FDA's prospective regulatory impact analysis in support of it egg rule, see Randall Lutter, *How Effective Are Federal Food Safety Regulations? The Case of Eggs and* Salmonella *Enteritidis* (Resources for the Future, Discussion Paper No. RFF DP 15-24, 2015), https://perma.cc/S9MT-W6JD. *See also* Wagner, *Science Charade, supra* note 10, at 1698 (discussing "incentives for agencies to overstate the dependability of economic calculations in order to justify a selected standard").

obligation to publish the Produce Safety Rule.[297] Agency officials used the limited scientific evidence that was available to reduce the risk of a known hazard, as the law required them to do. However, the agency was also compelled—by Congressional mandate and White House oversight—to publicly misrepresent in the preamble to its rule and its regulatory impact analysis the extent to which scientific evidence justified its quantitative agricultural water quality standards.

To summarize: the pressure to rationalize regulatory policymaking through risk-based regulation has incentivized both the LGMA and the FDA to conceal their inability to measure the risk posed by contaminated agricultural water. In the absence of supportive data, the LGMA's expert panel review, which concluded that the Guidelines "have likely contributed to reducing the human pathogen contamination risk," offers little more than puffery. And the FDA's repeated assertions that "sufficient scientific information" exists to justify quantitative agricultural water quality criteria are pretense.[298]

C. Stakeholder Participation

Stakeholder participation begins with a critique of overreliance on unjustified quantification in risk regulation. As social scientist Sheila Jasanoff puts it:

> The analytic ingenuity of modern states has been directed toward refining what we may call the 'technologies of hubris'. To reassure the public, and to keep the wheels of science and industry turning, governments have developed a series of predictive methods (e.g., risk assessment, cost-benefit analysis, climate modelling) that are designed, on the whole, to facilitate management and control, even in areas of high uncertainty.[299]

According to Jasanoff, these technologies of hubris generate predictive analysis out of what is known and, in the process, filter out risk factors that are inconveniently inimical to quantitative analysis.[300] Consequently, they "produc[e] overconfidence in the accuracy and completeness of the pictures

297. Exec. Order No. 12,866, §§ 1(b)(6) & 6(a)(3)(C), 58 C.F.R. 51734 (1993) .
298. IDECISIONSCIENCES, *supra* note 250, at 6.
299. Jasanoff, *supra* note 251, at 238.
300. *Id.* at 238-39.

they produce" and a "false impression that analysis is not only rigorous, but complete."[301] Their "[c]laims of objectivity hide the exercise of judgment."[302]

When these predictions turn out to be inaccurate, the public has a tendency not merely to fault the predictive capacities of the analysts but also to question the integrity of science itself. When political differences over the value choices required for policymaking encompass the available scientific evidence, scientific evidence cannot be an agreed upon starting point for policy deliberation. As sociologist Gil Eyal puts it: "As science was called upon to play an increasingly central role in orchestrating the legitimacy of democratic states, it has become itself polluted and is increasingly losing the ability to do so. . . . [T]he 'scientization of politics' has led to the 'politicization of science.'"[303]

Advocates of stakeholder participation call for greater transparency regarding the limits of science and more inclusive deliberation over the value-informed judgments required to make policy. Philosophers Silvio Funtowicz and Jerome Ravetz propose a distinction between traditional laboratory science and modern regulatory science:

> Whereas science was previously understood as steadily advancing in the certainty of our knowledge and control of the natural world, now science is seen as coping with many uncertainties in policy issues of risk and the environment. . . . The science appropriate to this new condition will be based on the assumptions of unpredictability, incomplete control, and a plurality of legitimate perspectives. . . . In this, uncertainty is not banished but managed, and values are not presupposed but are made explicit. The model for scientific argument is not a formalized deduction but an interactive dialogue.[304]

To engage in this dialogue, Funtowicz and Ravetz call for an "extended peer community, consisting not merely of persons with some form or other of institutional accreditation, but rather of all those with a desire to participate in the resolution of the issue and for policy deliberation where "the traditional

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301. *Id.* at 239.

302. *Id.*; *see also* S. FUNTOWICZ & J. RAVETZ, INTERNET ENCYCLOPAEDIA OF ECOLOGICAL ECONOMICS: POST-NORMAL SCIENCE 1 (Feb. 2003), https://perma.cc/8J3J-6JVT (discussing "pathologies of reductionism and pseudo-quantification").

303. Eyal, *supra* note 255, at 266.

304. Silvio O. Funtowicz & Jerome R. Ravetz, *Science for the Post-Normal Age*, 25 FUTURES 739, 739-40 (1993).

domination of 'hard facts' over 'soft values' has been inverted."[305] Jasanoff echoes this call for more democratic deliberation over regulatory science: "We need disciplined methods to accommodate the partiality of scientific knowledge and to act under irredeemable uncertainty. Let us call these the technologies of humility."[306]

Advocates of stakeholder participation see risk as fundamentally a political problem. As Jasanoff explains:

> "Risk," on this account, is not a matter of simple probabilities, to be rationally calculated by experts and avoided in accordance with the cold arithmetic of cost-benefit analysis. Rather, it is part of the modern human condition, woven into the very fabric of progress. The problem we urgently face is how to live democratically and at peace with the knowledge that our societies are inevitably "at risk."[307]

Jasanoff recognizes the dangers of characterizing policymaking as politics all the way down, and she cautions against a "full-blown deconstruction of science."[308] Her goal is to rehabilitate science, not to destroy it. According to the institutional logic of democratic accountability, it will take more inclusive politics to redeem the place of science in policymaking. As Jasanoff explains, "the credibility of regulatory science ultimately rests upon factors that have more to do with accountability in terms of democratic politics, than with the quality of science as assessed by scientific peers."[309]

Ironically, in deliberations over agricultural water quality regulation, robust stakeholder participation has fueled the science charade. Indeed, demands from key constituencies—commercial buyers, consumers, and farmers—have been a primary source of pressure on the LGMA and the FDA to conceal the extent to which quantitative agricultural water quality criteria are unjustified by scientific evidence and instead rely heavily on professional judgments, policy values, and speculation. Broad stakeholder deliberation

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305. *Id.* at 750; FUNTOWICZ & RAVETZ, *supra* note 302, at 7; Michael Gibbons, *Science's New Social Contract with Society*, 402 NATURE C81, C82 (1999) (advocating an extended group of experts beyond scientific peers to make science policy decisions).

306. Sheila Jasanoff, *Technologies of Humility*, 450 NATURE 33, 33 (2007).

307. Jasanoff, *supra* note 251, at 224.

308. Sheila Jasanoff, *Transparency in Public Science: Purposes, Reasons, Limits*, L. & CONTEMP. PROBS., Summer 2006, at 21, 37; *see also* Eyal, *supra* note 250, at 266 (warning that that "modeling trans-science upon institutionalized partisanship is a recipe for polarization, discord, and paralysis").

309. Jasanoff, *supra* note 251, at 233.

has been less an exercise in confronting the limits of science and the inevitability of risk than seeking comfort in the salvation of technical experts.

1. Commercial Buyers

Immediately following the 2006 baby spinach outbreak, commercial buyers, including retail supermarkets, restaurants, and food service companies, demanded specific quantitative food safety standards for leafy greens. Executives from eight leading supermarkets and food service companies—including Kroger, Costco, Safeway, SuperValu, Wegmans, and Sysco—formed a working group calling themselves the Initiative for Food Safety.[310] The group sent a letter to the Western Growers Association, the United Fresh Produce Association, and the Produce Marketing Association demanding that the associations formulate "specific, measurable, and verifiable" food safety standards that could be enforced through third-party audits and a certification program.[311] The working group threatened that if such a system were not implemented by the end of 2006, then the buyers would design and administer one themselves.[312] Simultaneously, the powerful National Restaurant Association formed the Produce Safety Working Group to develop new food safety standards for fresh produce suppliers.[313] Shortly before the launch of the LGMA in the spring of 2007, a third group of leading buyers—including Walmart, Publix, McDonald's, and Disney—calling itself the Food Safety Leadership Council, announced that it was developing its own set of on-farm food safety standards that were more stringent than the LGMA metrics.[314] The Food Safety Leadership Council metrics demanded an agricultural water quality threshold of less than 1.1 generic *E. coli* MPN per 100 mL, less than one hundredth the level set by the LGMA standard of 126 MPN per mL.[315]

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310. *Buyer Led Food Safety Effort Leaves Open Question of Buyer Commitment*, JIM PREVOR'S PERISHABLE PUNDIT (Oct. 30, 2006), https://perma.cc/RGN7-TURY.

311. *Id.*

312. *See id.* ("[O]ur options include fast-tracking our own working group to establish a meaningful certification program with objective criteria.").

313. *NRA Forms Produce Safety Working Group*, JIM PREVOR'S PERISHABLE PUNDIT (Nov. 7, 2006), https://perma.cc/TP2E-KFEY. Note that "NRA" refers here to the National Restaurant Association, not the National Rifle Association.

314. *Food Safety 'Arms War' Claimed as WGA Responds to Publix' Demand for 'Enhanced' Produce Standards*, JIM PREVOR'S PERISHABLE PUNDIT (Dec. 27, 2007), https://perma.cc/H5BM-QFVP.

315. FOOD SAFETY LEADERSHIP COUNCIL, FOOD SAFETY LEADERSHIP COUNCIL ON-FARM PRODUCE STANDARDS 3 (2007), https://perma.cc/R4XS-TZGV ("The Most Probable Number

The LGMA's agricultural water quality metrics were a direct response to this pressure by commercial buyers. The LGMA implemented quantitative agricultural water quality metrics and persuaded the Initiative for Food Safety and the Produce Safety Working Group to give the LGMA a chance to work.[316] Responding to the Food Safety Leadership Council's more stringent standards, United Fresh president Thomas Stenzel denounced them as motivated more by "liability placement than actual sound, scientific and achievable food safety practices."[317] The LGMA called on Food Safety Leadership Council members to "engage in real scientific and professional dialogue" rather than promote standards that "are inherently based on opinion and judgment where science is insufficient" and represent "an escalating, unscientific approach . . . a slippery slope without real science to guide these judgments."[318] Thus, the LGMA donned the mantle of science to fend off attempts by buyers to impose what the LGMA founders considered excessively stringent food safety standards, sometimes referred to as "supermetrics."[319]

2. Consumer Advocates

Consumer advocates have consistently demanded mandatory and specific quantitative agricultural water quality criteria. Following the 2006 baby spinach outbreak, Caroline Smith DeWaal, then Director of Food Safety for the Center for Science in the Public Interest, a leading consumer advocacy group, petitioned the FDA for new regulations requiring growers to assess the microbial quality of agricultural water.[320] In her congressional testimony, DeWaal advocated that the "FDA should develop standardized criteria for use by the farmers for such items as water quality."[321] More recently, in 2019, Sarah Eskin, then Project Director for the Safe Food Project at The Pew Charitable Trusts, demanded that the FDA implement mandatory agricultural

(MPN) method is a statistical, multi-step assay used to estimate the number of organisms present in a given sample.").

316. LYTTON, *supra* note 27, at 255.

317. *Id*. at 256.

318. *Id.*

319. *Id.*

320. Ctr. for Sci. in the Pub. Int., Citizen Petition to FDA (Nov. 15, 2006), https://perma.cc/F8RQ-XQH3.

321. *Food Safety: Hearing Before a Subcomm. of the S. Comm. on Appropriations*, 110th Cong. 15 (Mar. 12, 2007) [hereinafter *Food Safety: Hearing*], https://www.google.com/books/edition/Food_Safety/jGbVNi-Q94sC?hl=en&gbpv=1.

water quality criteria.[322] In a blog post titled "Romaine Lettuce Contamination Reinforces Need for Agricultural Water Quality Rule," Eskin wrote that the agency should "promptly finish any revisions to the initial water standard" and "quickly implement evidence-based, mandatory agricultural water requirements for produce growers nationwide."[323] In 2020, Michael Hanson, a senior scientist at Consumer Reports, argued that "[t]he FDA needs to implement stricter water testing rules that were laid out in the Food Safety Modernization Act."[324]

Satisfying these demands for science-based, specific quantitative agricultural water quality criteria has led the LGMA and the FDA to conceal the science-policy gap. Commenting on the LGMA's initial adoption of the EPA's recreational water quality criteria, Suslow explains:

> Although the contamination sources, water type, and route of infection are dramatically different between swimming at beaches and consumption of fresh fruits and vegetables, the recreational water criteria are easily accessible and are anchored to a recognized federal agency rather than a produce industry-sponsored study or self-generated data assessment. In the absence of deep scrutiny this starting point for establishing industry performance standards seemed palatable to the general public.[325]

3. Farmers

In 2010, shortly before the passage of FMSA, The Pew Charitable Trusts sponsored a series of nationwide "stakeholder meetings" to discuss produce safety reforms, and growers at these meetings "strongly recommended that the new produce safety rule be risk-based and that science drive the requirements and standards."[326] Over the past two decades, retail stores, restaurants, and food service buyers of fresh produce have, in response to outbreaks, imposed a multiplicity of increasingly stringent audit standards on their suppliers, which has led to "audit fatigue" among growers.[327] Many large growers are subject to multiple audits under various standards imposed

322. Sandra Eskin, *Romaine Lettuce Contamination Reinforces Need for Agricultural Water Quality Rule*, PEW CHARITABLE TRUSTS (Jan. 7, 2019), https://perma.cc/7S7L-RWJU.

323. *Id.*

324. Loria, *supra* note 34.

325. Suslow, *supra* note 45, at 6.

326. PRODUCE SAFETY PROJECT, STAKEHOLDERS' DISCUSSION SERIES, FEBRUARY 19TH – APRIL 27TH 2010, at 3 (2010), https://perma.cc/Z2N2-NGAR.

327. *Id.* at 17.

by different buyers.[328] This fatigue breeds skepticism since there is no evidence that growers' increasing investments in food safety compliance has yielded any measurable reduction in the risk of foodborne illness. A 2008 survey of forty-nine leafy greens growers found that respondents' food safety compliance costs more than doubled following implementation of the LGMA.[329] To justify imposing these costs, the LGMA seeks to convince growers that its metrics are a "rigorous science-based food safety system" that, according to leading experts in industry, government, and academia, "have likely contributed to reducing the human pathogen contamination risk in leafy greens."[330] The LGMA assured growers that its metrics were "prepared by industry scientists" and "scientifically peer reviewed by a nationally renowned science panel."[331] The FDA has similarly made efforts to assure farmers that its agricultural water quality criteria are justified by scientific evidence.[332]

D. New Governance

New governance begins with the observation that risk regulation encompasses more than legal requirements enforced by government agencies.[333] Risk management typically includes nongovernmental entities and private standards. For example, consider company managers who oversee conformity to health and safety standards during production.[334] These standards may be legal requirements or private standards developed by the company, a trade association, or an independent standard-setting entity.[335] Instead of focusing narrowly on the role of government agencies in regulating risk, the new governance perspective thinks more broadly in terms

328. LYTTON, *supra* note 27, at 130.

329. *Id.* at 163-66.

330. *Id.* at 165.

331. CAL. DEP'T OF FOOD & AGRIC. MKTG. BRANCH, CALIFORNIA LEAFY GREEN PRODUCTS HANDLER MARKETING AGREEMENT 2 (2015), https://perma.cc/K4UN-8QZF.

332. *See supra* notes at 269-70 and accompanying text.

333. Lytton, *Technical Standards*, *supra* note 107, at 45-46.

334. *The Role of Management in Maintaining Health and Safety Compliance*, HSE NETWORK (Feb. 17, 2023), https://perma.cc/7QBD-3ZTG.

335. JULIA BLACK, CRITICAL REFLECTIONS ON REGULATION 6 (2002) (discussing the concept of decentered regulation); Jody Freeman, *Private Parties, Public Functions and the New Administrative Law*, 52 ADMIN. L. REV. 813, 816-17 (2000) (analyzing regulation as a regime of "mixed administration").

of "risk regimes" that comprise a system of interdependent efforts by public and private entities relying on legal rules and voluntary standards.[336]

New governance approaches to risk regulation often involve government harnessing the capacities of private entities to assess and manage risk.[337] As legal scholar Cary Coglianese explains, "the underlying concept is to deploy regulatory authority in a way that leverages the private sector's knowledge about its particular circumstances and engages firms in developing their own internal procedures and monitoring practices that respond to risks."[338] One example of such harnessing is what Coglianese calls "management-based regulation," in which "firms are mandated to study their operations comprehensively and develop their own management strategies suited to the risks they identify in their operations."[339] Coglianese contrasts management-based regulation to means-based regulation, whereby government agencies mandate specific measures to manage risk, and performance-based regulation, whereby government agencies set specific risk targets.[340] Coglianese explains that management-based regulation is a good regulatory strategy when a one-size-fits all approach is inappropriate due to diversity among company operations and government regulators cannot easily assess compliance—that is, when regulated entities are heterogeneous and regulatory performance is hard to measure.[341]

Coglianese presents management-based regulation as an effective strategy to address the regulatory challenges presented by scientific uncertainty in assessing and managing food safety risk. He extolls the use of management-based regulation in reducing foodborne illness in beef production.[342] The analysis that follows suggests that, contrary to this rosy assessment, management-based regulation in food safety merely outsources the burden of scientific uncertainty onto industry and suffers from the science charade no less than other regulatory strategies.

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336. CHRISTOPHER HOOD ET AL., THE GOVERNMENT OF RISK: UNDERSTANDING RISK REGULATION REGIMES 3 (2001) (analyzing the concept of risk regulation regimes); *see also* Freeman, *supra* note 335, at 857 (discussing the concept of "*regulatory regimes* in which agencies are in dynamic relationships with private actors").

337. Lesley K. McAllister, *Harnessing Private Regulation*, 3 MICH. J. ENV'T & ADMIN. L. 291, 293 (2014).

338. Cary Coglianese, *Management-Based Regulation: Implications for Public Policy*, *in* RISK AND REGULATORY POLICY, *supra* note 4, at 159, 160.

339. *Id.*

340. *Id.* at 162-63.

341. *Id.* at 169 ("Management-based regulation is worth considering any time the government confronts hard-to-assess risks generated by many diverse firms.").

342. *Id.* at 170.

1. HACCP

Many industrial food producers employ a management-based system for identifying and reducing contamination known as Hazard Analysis Critical Control Points, or HACCP (pronounced "hassip").[343] HACCP is often described in terms of seven components. First, a company identifies contamination hazards in its production process. Second, the company identifies critical points in the process at which it can implement controls to prevent, eliminate, or reduce the risk of contamination. Third, the company establishes threshold values for measurable biological, chemical, or physical qualities that must be maintained to control particular food safety hazards. Fourth, company personnel monitor each critical control point using specific procedures and routines. Fifth, when monitoring indicates that a critical threshold has been exceeded, company managers identify the source of the problem and take steps to ensure that it will not occur again. Sixth, senior managers verify that the company's HACCP plan is scientifically valid and that it is being implemented as designed. Seventh, the company maintains records concerning the design and implementation of its HACCP plan.[344]

Advocates of HACCP contend that it provides a rigorous methodology for managing food safety.[345] Proponents also point out that HACCP's reliance on company expertise and implementation enables government agencies to stretch their limited resources because it shifts primary responsibility for monitoring food safety to companies and leaves government inspectors to perform the less burdensome task of verifying implementation by reviewing plant records and conducting cursory inspections.[346] Finally, HACCP defenders assert that it offers companies greater flexibility and efficiency in managing food safety.[347]

HACCP originated in the 1960s when NASA engineers developed it to prevent contamination of food produced for astronauts.[348] During the 1970s, the FDA incorporated HACCP principles into regulations for canned foods.[349] During the 1990s, the FDA required it for seafood production,[350]

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343. LYTTON, *supra* note 27, at 67-68.

344. For a more detailed analysis of the seven components of HACCP, see *id*.

345. *Id.* at 86.

346. *Id.*

347. *Id.*

348. *Id.* at 65-66. For a more detailed account of the origins of HACCP, its application to food processing, and an evaluation of its performance, see *id.* at 63-85.

349. *Id.* at 69-74.

350. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65096 (Dec. 18, 1995).

and the USDA required it in regulations for meat and poultry production.[351] In the early 2000s, the FDA published HACCP regulations for juice processors.[352] In 2015, the FDA published regulations requiring that all food production facilities—with the exception of those already covered by HACCP regulations and farming operations—have in place a seven-step HACCP-like risk management system.[353] Other governments that have HACCP regulations include the European Union, Japan, Australia, and China.[354] According to Coglianese, HACCP is "[t]he most prominent and globally extensive example of a management-based regulation."[355]

Evidence demonstrating the effectiveness of HACCP is limited and varies by sector. A recent statistical analysis by economists at the USDA and FDA of the FDA's Juice HACCP rule estimates that the regulations "led to an annual reduction of between 462 and 508 foodborne illnesses associated with juice-bearing products."[356] Anecdotal evidence from industry managers and most studies document reductions associated with HACCP in the prevalence of contamination or microbial loads on food, but they cannot link those findings to any reduction in foodborne illness because of the reasons explained in Part I.[357]

Several studies conducted by USDA and CDC officials associate the implementation of HACCP with decreases in the percentage of raw ground beef samples that test positive for *E. coli* O157:H7 and with fewer reported cases of foodborne illness caused by *E. coli* O157:H7 infection.[358] However, the study authors are careful to acknowledge several important limitations of the evidence for their conclusions. The authors of one study caution that USDA data regarding the prevalence of *E. coli* O157:H7 were likely affected by factors other than HACCP implementation that they could not control.[359] The authors also lacked information regarding when processing plants

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351. LYTTON, *supra* note 27, at 101-05.

352. Hazard Analysis and Critical Control Points (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6138 (Jan. 19, 2001) (to be codified at 21 C.F.R. pt. 120).

353. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55908, 55911 (Sept. 17, 2015).

354. Karen, *Is HACCP Required by Law?*, QSE ACADEMY (Jan. 5, 2021), https://www.qse-academy.com/is-haccp-required-by-law/.

355. Coglianese, *supra* note 338, at 165.

356. Minor & Parrett, *supra* note 86, at 206.

357. LYTTON, *supra* note 27, at 108-11; *see also* ICMSF, *supra* note 24, at 1-5 (summarizing efforts to link HACCP metrics to reduction in the risk of human illness).

358. *See* LYTTON, *supra* note 27, at 108-10.

359. *Id.* at 109.

actually implemented the HACCP controls being evaluated.[360] Additionally, decreases in foodborne illness are likely influenced by factors other than HACCP implementation, such as quicker outbreak response by public health authorities and underreporting due to new rapid diagnostic tests (which help clinicians more quickly diagnose and treat bacterial infections but do not identify the particular pathogen responsible).[361] USDA data regarding the impact of HACCP implementation on the percentage of broiler chickens testing positive for *Salmonella* and the rates of foodborne illness caused by *Salmonella* infection are similarly inconclusive.[362]

2. Fresh Produce

Applying management-based regulation to the fresh produce sector is not a new idea. Consumer advocates and industry experts called for mandatory HACCP regulations for the fresh produce industry following the 2006 baby spinach outbreak.[363] Bill Marler has characterized the FDA's current approach to agricultural water quality—which requires farmers to conduct their own annual hazard analysis and design controls to reduce the potential for contamination—as a "HACCP program for produce."[364] However, there is no reason to think that management-based regulation offers viable solutions to the challenges that plague efforts to regulate the risk of microbial contamination from agricultural water.

Management-based regulation would merely relocate the burden of scientific uncertainty from the LGMA and the FDA to farmers. The absence of reliable methods for measuring the microbial quality of agricultural water, the heterogeneity of risk factors related to microbial contamination, and the complexity of causal chains that link microbial contamination of plants to foodborne illness impede the design, implementation, and evaluation of an individual HACCP plan no less than the design, implementation, and evaluation of uniform standards by the LGMA and the FDA. The problem cannot be solved by "leverag[ing] the private sector's knowledge about its particular circumstances and engag[ing] firms in developing their own

360. *Id.*

361. *Id.*

362. *Id.* at 109-10.

363. FISCHER ET AL., *supra* note 30, at 1; *Food Safety: Hearing*, *supra* note 321, at 4, 13, 27, 39, 72 (recording testimony by multiple experts in favor of HACCP regulations for the fresh produce industry).

364. Bill Marler, *Publisher's Platform: Is FDA Creating a HACCP Program for Produce?*, FOOD SAFETY NEWS (Dec. 3, 2021), https://perma.cc/M2CM-K97J.

internal procedures and monitoring practices that respond to risks."[365] Everything the private sector knows about agricultural water quality has already been incorporated into the LGMA's metrics and the FDA's produce safety regulations. There are no untapped wells of expertise that management-based regulation can access more effectively than more traditional approaches, which have relied heavily on technical committees populated by leading experts from industry, government, and academia, and have solicited extensive feedback from a broad array of stakeholders.[366] Moreover, the most likely result of mandatory HACCP, which would require individual farmers to design and implement measurable controls with critical thresholds and to verify their validity, is mass noncompliance and reproduction of the science charade at the farm level.

The new governance approach does more to illuminate the intractability of the problem than it does to resolve it. By highlighting the interdependence of the many public and private efforts involved in food safety governance, the new governance perspective reveals how scientific uncertainty pervades the system. As of now, it appears that administrative reforms cannot overcome the obstacles to risk regulation when it comes to agricultural water quality and contaminated greens.

E. The Science Charade

This case study of efforts to regulate agricultural water quality exposes the limits of risk regulation when dealing with known unknowns. It suggests that legal, administrative, and economic pressures to characterize a known unknown in terms of measurable risk incentivize regulatory agencies and private standard setting organizations to perpetrate a charade. All three of the leading approaches to risk regulation surveyed here—risk-based regulation, stakeholder participation, and new governance—generate this pressure and facilitate the charade.

Risk-based regulation insists that rational regulation of a known unknown requires quantification.[367] This approach informs FSMA's legislative mandate that the FDA design and implement "science-based minimum standards" for agricultural water.[368] This mandate was reinforced by White House Office of Budget and Management requirements that agency rules be

365. *Executive Summary*, *in* RISK AND REGULATORY POLICY, *supra* note 4, at 11, 12.
366. LYTTON, *supra* note 27, at 138.
367. *See supra* notes 246-49 and accompanying text.
368. 21 U.S.C. § 350h (a) & (b).

justified by quantitative cost-benefit analysis.[369] It was further reinforced by the specter of judicial review, which requires agencies to justify regulatory standards by pointing to "relevant data" and "a 'rational connection between the facts found and the choice made.'"[370] The combination of legislative mandates, OIRA oversight, and judicial "hard look" review overdetermine an agency's incentive to engage in the science charade when faced with a known unknown. The FDA's RIA for the agricultural water quality standard is a clear example.

Stakeholder participation assumes that, in the absence of sufficiently determinate scientific justification, input from those most likely to be affected by a hazard will, at least, produce a democratic outcome. The anxiety of these groups—commercial buyers, consumer advocates, and farmers—created irresistible market pressure on the LGMA to produce specific agricultural water quality metrics and to hire leading scientific experts to vouch for them, despite the LGMA's knowledge throughout the process that quantitative metrics were scientifically indefensible.

New governance led the FDA to partner with the fresh produce industry, on the theory that industry expertise and experience could solve a problem that the agency could not. As detailed in Part I, this initially took the form of warning letters in 2004 and 2005 threatening the industry with enforcement actions and criminal prosecutions if it failed to develop specific agricultural water quality standards for high-risk crops.[371] These threats complemented pressure from stakeholders to produce quantitative metrics and pretend that they reduced the risk of foodborne illness.

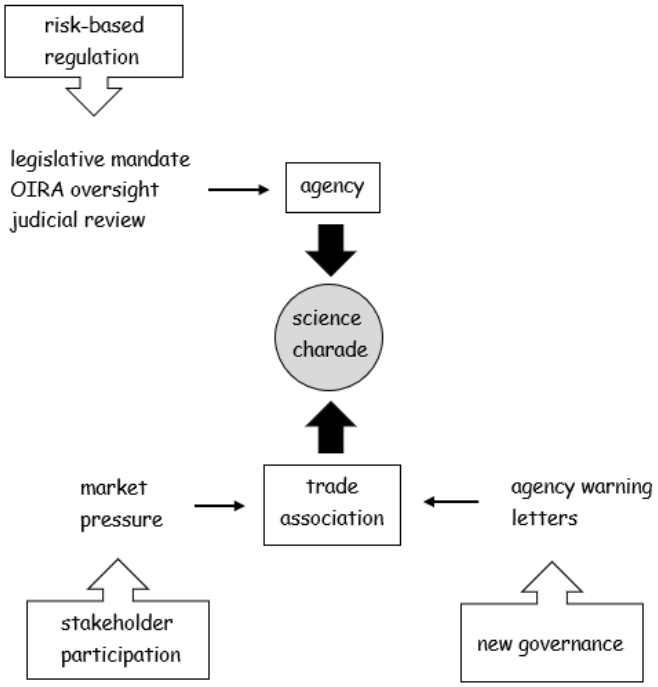
Thus, all three leading approaches to risk regulation encourage the science charade. Figure 2 illustrates these dynamics.

369. MAEVE P. CAREY, CONG. RSCH. SERV., IF12058, COST-BENEFIT ANALYSIS IN FEDERAL AGENCY RULEMAKING (2022).

370. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)).

371. *See supra* notes 129-30 and accompanying text.

Figure 2.



In light of these dynamics, the next Part of the Article proposes four strategies for helping regulators cope with known unknowns.

III. Coping Strategies

Part I of this Article described how the inability to characterize a known unknown in terms of measurable risk has, for more than two decades, frustrated the concerted efforts of highly skilled and deeply committed industry experts, government officials, and academic microbiologists to reduce the risk of microbial contamination of leafy greens from agricultural water. Part II of the Article demonstrated that leading approaches to risk regulation are inadequate to overcome this problem.[372] This Part presents

372. Food safety experts are well aware of these challenges. *See, e.g.*, ICMSF, *supra* note 24, at 9 (discussing alternatives to risk regulation where quantitative metrics for risk regulation are not obtainable).

four practical recommendations to help regulators cope with the deep uncertainty that characterizes known unknowns and stymies risk regulation. These recommendations are informed by my analysis of the three approaches to risk regulation surveyed in Part II.

From risk-based regulation, I endorse the admonition to refrain from reflexively embracing greater risk reduction in response to outbreaks. Even if risk-risk tradeoffs are incalculable, striving for zero tolerance or always erring on the side of precaution is, in most cases, no more justified in the face of deep uncertainty than when optimal risk is knowable.[373] Despite the intuitive appeal of ratcheting up the level of precaution in response to recurrent outbreaks, there is no basis for believing that doing so has reduced foodborne illness. By the same token, where risk-risk tradeoffs are incalculable, precaution is no *less* justified than holding off on more stringent regulation. Thus, although deep uncertainty renders inoperative the analytic methods of risk-based regulation, a risk-based-regulation sensibility may be useful in neutralizing the prevailing bias towards more stringent and detailed regulation, as well as claims that it is always preferable to delay regulation until it can be scientifically justified. The basic idea is to let go of unfounded general presumptions favoring or opposing greater regulatory stringency and specificity.

From stakeholder participation, I adopt skepticism of reliance on increasingly sophisticated quantitative predictive analysis as a response to anxiety about known unknowns. Sometimes regulators have no choice but to rely on ballpark guesses by experts, and they should be honest about the impressionistic nature of those judgments. Cloaking ballpark guesses in highly speculative statistical models and technical jargon undermines the integrity of scientific expertise, which leads, ultimately, to diminished trust in experts and policymaking institutions.[374] I share Gil Eyal's fear that the breakdown of what is left of public deference to expert judgment "is a recipe for polarization, discord, and paralysis."[375] Transparency, in this context, is essential to the integrity of regulatory efforts.

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373. Erring on the side of precaution may be more justifiable where the risk in question is catastrophic or there are few identifiable benefits to be gained by taking the risk. *See* Farber, *supra* note 5, at 11 (discussing justifications for a precautionary approach to regulation in the face of catastrophic risks).

374. On the loss of public faith in scientific expertise, see generally WILLIAM D. ARAIZA, REBUILDING EXPERTISE: CREATING EFFECTIVE AND TRUSTWORTHY REGULATION IN AN AGE OF DOUBT (2022).

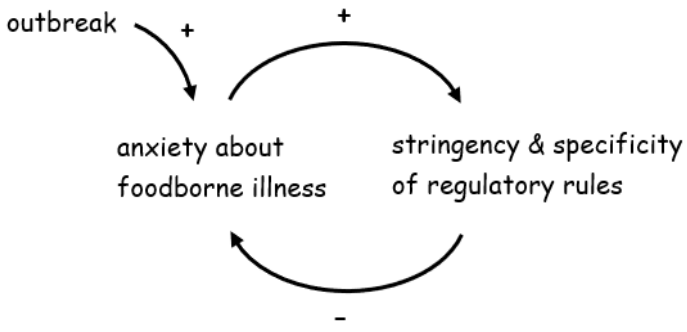
375. Eyal, *supra* note 255, at 266.

From new governance, I embrace the faith that decentralized experimentation, feedback, and learning can only help. Whatever marginal improvements may be realistically obtainable are more likely when regulators leverage all available sources of expertise, encourage innovation, and reward honest performance evaluation, even if it yields disappointing results or inconclusive findings. We might be better served if we judged the success of regulatory efforts based, at least in part, on how much knowledge they yield rather than on how much risk-reduction they purport to achieve. However, one must be mindful that experimentation is costly and may not always be worth it.[376] Thus, ultimately, there is no escaping the need to accept some measure of uncertainty and tolerate a certain amount of risk. With these insights and caveats in mind, I now offer five guiding principles for coping with deep uncertainty.[377]

A. Resist the Science Compulsion

In the case of leafy greens, relentless pressure for science-based risk management has fueled a dynamic of anxiety-driven regulation. In a pattern illustrated in Figure 3 below, outbreaks prompt anxiety about the risk of foodborne illness, and regulators address this anxiety by proposing stricter and more specific regulatory rules, which temporarily relieve the anxiety but fail to prevent subsequent outbreaks, which start the process all over again.

Figure 3.



Such a regulatory regime suffers from what might be characterized as a science compulsion—a repeated behavior that provides temporary relief

376. PETER H. SCHUCK, WHY GOVERNMENT FAILS SO OFTEN AND HOW IT CAN DO BETTER 61 (2014) (noting the cost of policy evaluation).

377. *See* Kasperson, *supra* note 5, at 339 (discussing the concept of "uncertainty management").

from a recurring anxiety but that is ultimately ineffective in eliminating the anxiety.[378] Environmental scientist Roger Kasperson explains that regulators frequently assume that "with work, situations of deep uncertainty can be converted into tractable risk problems."[379] He cautions, however, that "some uncertainties are essentially irreducible."[380]

Resisting the science compulsion requires advancing science where we can, going with the incomplete science we have, and accepting the remaining uncertainty. Consequently, Part III.B. recommends prioritizing feedback and learning in regulatory design to advance policy-relevant science and reduce the science-policy gap. Part III.C. advocates compliance with state-of-the-art standards that cannot be fully justified by science. Part III.D. prescribes learning to tolerate irreducible uncertainty as a better long-run risk management strategy than indulging the science compulsion. My aim is to resist the science compulsion without giving up on science altogether. Moreover, these coping strategies offer the FDA an alternative to the science charade without running afoul of the agency's statutory mandate to implement science-based minimum standards for agricultural water quality.

B. Prioritize Verifiable Harm Reduction That Generates New Policy-Relevant Information

Additional investment in public health surveillance and supply-chain tracing can reduce the impact of foodborne illness outbreaks and yield policy-relevant information about the root causes of contamination. In 1996, the CDC established a network of public health and food regulatory laboratories to analyze bacterial isolates obtained from foodborne illness victims.[381] Laboratories in the network, known as PulseNet, originally applied a technique called pulsed-field gel electrophoresis which enables scientists to discern the DNA "fingerprint" of each isolate to determine whether an instance of foodborne illness is merely a single case of endemic sporadic disease or part of an outbreak affecting multiple victims.[382] When outbreaks are identified, investigators can interview victims to collect information

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378. *Compulsion*, AM. PSYCH. ASS'N, https://dictionary.apa.org/compulsion (last updated Apr. 19, 2018); *see also* LYTTON, supra note 27, at 240 (discussing the "logic of uncertainty" that characterizes the regulatory dynamics of food safety more generally).

379. Kasperson, *supra* note 5, at 339.

380. *Id.*

381. LYTTON, *supra* note 27, at 186-87.

382. For a history and analysis of PulseNet, see Angie Marlene Boyce, Fast but Right: Outbreak Surveillance and Foodborne Knowledge Infrastructure, 216-259 (Aug. 18, 2014) (Ph.D. Dissertation, Cornell University) (ProQuest). *See also* LYTTON, *supra* note 27, at 184-86.

about what they ate recently with the goal of identifying a common food vehicle for the infection.[383] Investigators can rely on laboratory testing of samples taken from any uneaten food to see if it contains pathogens with DNA fingerprints that match the isolates obtained from outbreak victims.[384] Once the food vehicle is identified, the FDA can issue a warning to consumers, and sellers can remove it from store shelves. By tracing an identifiable food vehicle back to the producer, investigators can obtain environmental samples—for example, from agricultural water sources—to determine the possible origin of contamination.[385]

As detailed above in Part I, investigations of outbreaks associated with fresh produce are relatively rare, costly, and typically inconclusive.[386] However, recent advances in DNA fingerprinting of bacterial pathogens using a technology called Whole Genome Sequencing ("WGS") have enabled PulseNet to identify outbreaks based on as few as two matching fingerprints, allowing authorities to identify outbreaks earlier and intervene more quickly to contain the spread of illness.[387] In addition to PulseNet, the FDA has created GenomeTrakr, a data network which collects WGS fingerprints of bacterial samples from food and production facilities.[388] Using PulseNet and GenomeTrakr to identify matching WGS fingerprints, outbreak investigators can link illness victims to contaminated foods and production facilities. Increasingly powerful and affordable computers have reduced the time necessary to analyze bacterial samples and enabled a growing number of labs to obtain WGS equipment.[389] CDC surveillance data reflect that PulseNet and WGS have steadily increased the number of outbreaks that agency officials identify each year and that the number of cases per outbreak has decreased over time.[390] A 2016 study of listeria outbreaks found an increasing number of food vehicle identifications and a decreasing number

383. *Id.* at 184-86.

384. *Id.* at 187.

385. *Id.* at 189-95.

386. *See supra* notes 80-88 and accompanying text.

387. LYTTON, *supra* note 27, at 187-88. A "matching fingerprint" means a statistical association. *Id.* at 188.

388. *Id.* at 187.

389. *Id.*

390. Robert Tauxe, Ctrs. for Disease & Control Prevention, Presentation at the Georgia Emerging Infections Program, Annual Conference: Whole Genome Sequencing and the Transformation of Public Health Surveillance (for Enteric Infections) (Mar. 24, 2017), https://perma.cc/L4VL-95UC.

of cases per outbreak in the three years following adoption of WGS in PulseNet.[391]

Digitization of supply chain management information promises to enhance the process of tracing foods linked to outbreaks back to growers. Industry leaders have adopted barcode and radio frequency identification labels to track individual lots of produce from harvest through processing, distribution, and sale.[392] Automatic cloud storage and blockchain recording of this information has been shown to reduce traceback times and the pace of recalls.[393]

These technology-driven advances in surveillance and tracing reduce the number of foodborne illness victims by identifying outbreaks earlier, which leads to earlier consumer warnings and quicker removal of contaminated product from store shelves.[394] They also generate information about the root causes of foodborne illness that further enhance the capacity of experts to identify food safety hazards[395] and perhaps eventually even begin to develop quantitative risk models.[396] New information can inform ongoing research.

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391. *Id.* at 16 (citing Brendan R. Jackson et al., *Implementation of Nationwide Real-Time Whole-Genome Sequencing to Enhance Listeriosis Outbreak Detection and Investigation*, 63 CLINICAL INFECTIOUS DISEASES 380 (2016)).

392. LYTTON, *supra* note 27, at 225-27.

393. *See* Walter G. Johnson, *Blockchain Meets Genomics: Governance Considerations for Promoting Food Safety and Public Health*, J. FOOD L. POL'Y, Spring 2019, at 74, 75 ("[P]ilot projects suggest blockchain . . . promises increased traceability of food products . . . .").

394. For a similar approach to uncertain hazards, see Edward L. Rubin, *Beneficial Precaution: A Proposed Approach to Uncertain Technological Dangers*, 22 VAND. J. ENT. L. & TECH. 359 (2020) (recommending the adoption of strategies that will ameliorate an uncertain future disaster while providing immediate benefits in the present).

395. *E.g.*, Tracie J. Gardener et al., *Outbreak of Campylobacteriosis Associated with Consumption of Raw Peas*, 53 CLINICAL INFECTIOUS DISEASES 26, 26 ("This investigation established a rare laboratory-confirmed link between a campylobacterosis outbreak and an environmental source and identified wild birds as an underrecognized source of produce contamination."); E-mail from Robert Tauxe, *supra* note 77 (describing how identification of wild birds as the source of produce contamination as documented in this study led to precautions related to sanitizing harvesting and field washing equipment that prevented future contamination).

396. P. F. M. Teunis et al., *Hierarchical Dose Response of* E. coli *O157:H7 from Human Outbreaks Incorporating Heterogeneity in Exposure*, 136 EPIDEMIOLOGY INFECTION 761, 769 (2007) (concluding that more outbreak data will enable more valid quantitative risk assessment); Norval J.C. Strachan et al., *Dose Response Modelling* of Escherichia coli *O157 Incorporating Data from Foodborne and Environmental Outbreaks*, 103 INT'L J. FOOD MICROBIOLOGY 35, 45 (2005) (finding that more outbreak data are required for further validation of quantitative risk models).

However, these advances are not without considerable costs. Although I have no sound basis for recommending any specific level of investment, I do believe that government should be primarily responsible for surveillance and investigation, and industry should be primarily responsible for tracing. Only the federal government has the resources and reach required to coordinate the extensive informational and institutional infrastructure necessary to identify and investigate multistate foodborne illness outbreaks. By contrast, the proliferation of supply chain tracking systems relies on the commitment of tens of thousands of individual growers, processors, shippers, and sellers to create and maintain reliable records at each stage of production—a task that requires the type of industrywide commitment most effectively championed by dominant firms and powerful trade associations.[397] If policymakers and industry experts hope to develop science-based risk regulations that can achieve verifiable harm reduction, they should prioritize surveillance and tracing.

C. Rely on State-of-the-Art Standards Endorsed by Stakeholders

When deep uncertainty renders optimal risk unknowable, regulators should focus on creating incentives for compliance with state-of-the-art food safety standards endorsed by stakeholders. Even if current scientific evidence cannot justify state-of-the-art food safety standards—such as the LGMA's agricultural water quality metrics—these standards nevertheless represent the best that leading experts under economic, political, and legal pressure can come up with. They are informed by two decades of ongoing deliberation among industry experts, government officials, academics, and consumer advocates participating in industry technical committees, public hearings, stakeholder meetings, and professional conferences.[398] In the absence of a scientific justification, broad stakeholder participation at least gives the standards democratic legitimacy. Consequently, it seems reasonable to demand that all members of the industry conform to these standards unless they are engaged in a rigorous effort to improve them or can otherwise justify a departure from them.

The lack of stakeholder consensus that led to the FDA's retreat from agricultural water quality criteria modeled on the LGMA metrics suggests that a single national standard for all fresh produce lacks the legitimacy of

397. On the importance of a private sector institutional culture of compliance in food safety, see FRANK YIANNAS, FOOD SAFETY CULTURE: CREATING A BEHAVIOR-BASED FOOD SAFETY MANAGEMENT SYSTEM 85 (2009); Douglas A. Powell et al., *Enhancing Food Safety Culture to Reduce Rates of Foodborne Illness*, 22 FOOD CONTROL 817 (2011).

398. *See supra* Section II.B.

the LGMA's regional standard for a single sector. FSMA's mandate that the FDA establish science-based, minimum agricultural water quality standards for all fresh produce is an impossible task. The agency's rational response has been to engage in the science charade. To their credit, agency officials have cultivated broad stakeholder deliberation and responded to widely shared concerns—first by delaying implementation of specific agricultural water quality criteria and then by retreating from them. However, one might argue that the agency should have seen this coming. Stakeholder opposition had defeated an earlier six-year attempt, starting in 2007, by the USDA to create a national LGMA.[399]

Instead of merely settling now for a less detailed national standard for all fresh produce, the FDA should pressure regional stakeholders in distinct industry sectors to develop what they consider to be state-of-the-art standards. The FDA's mistake in looking to the LGMA as a model was attempting to nationalize and universalize its substantive standards rather than to replicate its process for establishing regional, commodity-specific standards endorsed by a broad range of stakeholders. Three features of this process stand out.

First, the LGMA has institutionalized stakeholder participation in a process that mimics notice-and-comment rulemaking.[400] In response to criticism that the original LGMA leafy greens metrics were developed in unannounced, private meetings by a small, self-selected group of executives from large processing companies, the Western Growers Association implemented a process for developing new and revised standards that provides public notice at every stage of the process, encourages broad stakeholder input, responds to comments, provides written justification for decisions, subjects final proposals to open public hearings with a written record before the LGMA's technical committee, and includes two post-hearing reviews by the LGMA Board and the California Secretary of Agriculture before a change is approved.[401]

Second, the LGMA relies on brand-sensitivity and private supply chain leverage to achieve high rates of compliance.[402] The LGMA has achieved nearly universal adoption of its standards among California leafy greens growers by making handlers the subjects of the marketing agreement.[403] A small group of handlers has a particularly high stake in preventing outbreaks,

399. LYTTON, *supra* note 27, at 138-41.
400. *See id.* at 176 (discussing institutional isomorphism in food safety governance).
401. *Id.*
402. *Id.* at 136-37.
403. *About Us*, *supra* note 272.

and it commands a level of market power that gives it considerable influence over growers. Although outbreaks can affect everyone in the leafy greens industry, they pose the greatest threat to handlers who produce leading brands of fresh-cut bagged produce. These companies lack the anonymity among consumers that shields growers and handlers of unmarked whole produce. Packaging bearing a brand name makes it easier to identify a particular company as the source of an outbreak. A few of leading brand name handlers dominate the market.[404] This small group of highly brand-sensitive handlers had both the motivation and the leverage to encourage widespread implementation of the new standards among growers. Six months after approval of the LGMA, fifty-one handlers, responsible for more than 90% of the leafy greens produced in California, had joined the LGMA.[405] Annual LGMA reports documented increasing rates of compliance in the first ten years of operation that have remained consistent ever since.[406]

Third, LGMA's reliance on handler fees to pay for government inspectors avoids problems associated with publicly funded government inspection and private third-party food safety audits of farms. In general, resource constraints have limited the role of conventional federal government inspections as a means of overseeing food safety practices on farms that grow fresh produce. The FDA has had jurisdiction over food safety on farms since passage of the Federal Food, Drug, and Cosmetic Act of 1938, but the agency has never conducted routine inspections of farms.[407] And given that the Department of Health and Human Services Inspector General and the Government Accountability Office have intensely criticized the FDA's food safety inspection efforts for more than two decades, there is little ground for optimism.[408] For example, in 2017, when the Department of Health and

404. In 2006, four companies—Fresh Express (owned by Chiquita), Dole, Ready Pac, and Earthbound Farms—accounted for 86% of the Market. LYTTON, *supra* note 27, at 137.

405. *Id.*

406. *Id.* at 163-64.

407. BURROWS, *supra* note 109, at 2-6.

408. *See, e.g.*, OFF. OF THE INSPECTOR GEN., DEP'T OF HEALTH & HUM. SERV., OEI-02-14-00420, CHALLENGES REMAIN IN FDA'S INSPECTIONS OF DOMESTIC FOOD FACILITIES 8 (2017) [hereinafter CHALLENGES REMAIN]; U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-183, FOOD SAFETY: ADDITIONAL ACTIONS NEEDED TO HELP FDA'S FOREIGN OFFICES ENSURE SAFETY OF IMPORTED FOOD (2015); U.S. GOV'T ACCOUNTABILITY OFF., GAO-12-933, FOOD SAFETY: FDA CAN BETTER OVERSEE FOOD IMPORTS BY ASSESSING AND LEVERAGING OTHER COUNTRIES' OVERSIGHT RESOURCES (2012); OFF. INSPECTOR GEN., DEP'T OF HEALTH & HUM. SERVS., OEI-02-09-00430, VULNERABILITIES IN FDA'S OVERSIGHT OF STATE FOOD FACILITY INSPECTIONS (2011); OFF. INSPECTOR GEN., DEP'T OF HEALTH & HUM. SERVS., OEI-02-08-00080, FDA INSPECTIONS OF DOMESTIC FOOD FACILITIES (2010); OFF. INSPECTOR GEN., DEP'T

Human Services Office of Inspector General conducted a review of the FDA's inspection program for food-production facilities, the Office found:

> FDA did not always take action when it uncovered significant inspection violations . . . . When it did take action, it commonly relied on facilities to voluntarily correct the violations. Also, it rarely took advantage of the new administrative tools provided by FSMA. Moreover, FDA's actions were not always timely nor did they always result in the correction of these violations. FDA consistently failed to conduct timely followup inspections to ensure that facilities corrected significant inspection violations. For almost half of the significant inspection violations, FDA did not conduct a followup inspection within 1 year; for 17 percent of the significant inspection violations, FDA did not conduct a followup inspection of the facility at all.[409]

A February 2023 letter sent by Illinois Senator Dick Durbin to FDA Commissioner Robert Califf complained that annual inspections of food facilities under the agency's jurisdiction dropped 60% from 2011 to 2021, from 10,635 to 4,535.[410]

Administrative shortcomings aside, it is unclear whether even massive funding increases for FDA inspections would allow the agency to

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OF HEALTH & HUM. SERVS., OEI-02-06-00210, TRACEABILITY IN THE FOOD SUPPLY CHAIN (2009); U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-873 FOOD SAFETY: AGENCIES NEED TO ADDRESS GAPS IN ENFORCEMENT AND COLLABORATION TO ENHANCE THE SAFETY OF IMPORTED FOOD (2009); U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-435T, *Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical* (2008); U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-1047, FOOD SAFETY: IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE (2008); U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-909T, FEDERAL OVERSIGHT OF FOOD SAFETY: FDA HAS PROVIDED FEW DETAILS ON THE RESOURCES AND STRATEGIES NEEDED TO IMPLEMENT ITS FOOD PROTECTION PLAN (2008); U.S. GOV'T ACCOUNTABILITY OFF., GAO-05-213, OVERSIGHT OF FOOD SAFETY ACTIVITIES; FEDERAL AGENCIES SHOULD PURSUE OPPORTUNITIES TO REDUCE OVERLAP AND BETTER LEVERAGE RESOURCES (2005); OFF. INSPECTOR GEN., DEP'T OF HEALTH & HUM. SERVS., OEI-01-98-00400, FDA OVERSIGHT OF STATE FOOD FIRM INSPECTIONS: A CALL FOR GREATER ACCOUNTABILITY (2000).

409. CHALLENGES REMAIN, *supra* note 408, at 19.

410. Letter from Richard J. Durbin, U.S. Senator, & Rosa L. DeLauro, Member of Congress, to Robert M. Califf, Comm'r, U.S. Food & Drug Admin. (Feb. 23, 2023), https://perma.cc/J3B4-57VR.

competently oversee the estimated 120,000 farms that grow fresh produce intended for retail sale to consumers.[411]

Private food safety audits of farms also suffer from chronic problems. Typically, buyers of fresh produce—such as handlers or distributors or retailers—insist that growers obtain private third-party food safety audits to ensure regulatory compliance and standards conformity, and these buyers insist that the growers select and pay auditors directly, creating a conflict of interest that incentivizes auditors to cut corners and inflate audit scores to please growers.[412] Furthermore, high demand coupled with inadequate training and experience has created a shortage of qualified private auditors.[413] The LGMA's system of paying government inspectors from handler assessments eliminates these problems.[414]

Endorsing compliance with state-of-the-art food safety standards has not discouraged efforts to advance science and innovation. In addition to participation in the LGMA, industry stakeholders have encouraged ongoing laboratory research, field studies, and pilot projects.[415] The industry's Center for Produce Safety and the USDA provide funding for these efforts.[416] Assessing whether additional funding would be a justifiable investment is difficult to determine given that it is currently impossible to assess the impact of these efforts on reducing foodborne illness. Moreover, demands for additional funding as a reflexive response to incomplete information are part of the science compulsion. However, regardless of one's views on how much industry and government should invest in improving standards in the future,

411. FDA, FINAL REGULATORY IMPACT ANALYSIS, *supra* note 268, at 40 (estimating the number of U.S. farms that grow fresh produce intended for retail sale to consumers).

412. For more detail, see Timothy D. Lytton & Leslie K. McAllister, *Oversight in Private Food Safety Auditing: Addressing Auditor Conflict of Interest*, 2014 WISC. L. REV. 289, 297-304 (analyzing conflict of interest in private food safety auditing).

413. *See id.* at 307.

414. *See* Timothy D. Lytton, *Exposing Private Third-Party Food Safety Auditors to Civil Liability for Negligence: Harnessing Private Law Norms to Regulate Private Governance*, 27 EUR. REV. PRIV. L. 353, 357-59 (2019) (noting the advantages of LGMA inspections by government inspectors over private third-party inspections). For analysis of a failed attempt to scale up the LGMA into a national leafy greens marketing agreement, see LYTTON, *supra*, note 27, at 138-41.

415. *See, e.g.*, Jonan Pilet, *IAFP Features Round Table on the Challenges and Strategies for Implementing Water Treatment in the Field*, FOOD SAFETY NEWS (Oct. 29, 2020), https://perma.cc/K79M.

416. *See Awards List*, CTR. FOR PRODUCE SAFETY, https://perma.cc/84TR-36VJ (last visited June 5, 2023) (list of research project sponsored by CPS); *Food Safety Research Projects Database Search*, U.S. DEP'T OF AGRIC., https://perma.cc/R8Z4-T23E (last visited June 5, 2023).

it seems reasonable, in the meantime, to endorse private-public cooperation in compliance with current standards.

To encourage such cooperation, it might make sense to allow waivers for growers who can demonstrate that they are engaged in good faith efforts to conduct rigorous pilot projects or who can otherwise justify deviating from state-of-the-art standards. However, this would require careful consideration since experience with such waivers has not been encouraging. The FDA allows growers to employ alternatives to its agricultural water quality testing methods and criteria if they can provide "appropriate scientific support" and demonstrate that any alternative provides "the same level of public health protection."[417] But in practice, the lack of scientific evidence to justify any specific agricultural water quality methods or criteria has prevented farmers from experimenting.[418]

Additionally, the FDA's Produce Safety Rule exempts small farmers because of the economic burden that the regulations would place on them. The regulations do not apply to farms with annual produce sales less than $500,000 that market directly to consumers, local restaurants, food service operations, or grocery stores.[419] According to the FDA, more than 93% of U.S. farms fall below this threshold of $500,000 in annual sales.[420] The justifiability of this exemption is questionable. It has left consumers who eat

417. *See supra* note 182 and accompanying text.

418. *Supra* notes 197-202 and accompanying text; *see also* McEntire & Gorny, *supra* note 58 (discussing the lack of scientific evidence to support any quantitative agricultural water quality criteria).

419. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74354, 74356 (Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 11, 16, 112). Farms with between $25,000 and $500,000 in average annual sales are eligible for a "qualified exemption," which imposes recordkeeping and reporting requirements, but not compliance with the Produce Safety Rule's standards for water quality, soil amendment, animal intrusion, worker hygiene, and equipment sanitation. *Standards for Produce Safety: Coverage and Exemptions/Exclusions for 21 Part 112,* U.S. FOOD & DRUG ADMIN. (Nov. 13, 2015), https://perma.cc/K9U4-WLWR; *see Has Our Food Become Safer in the Last 10 Years?*, CIVIL EATS (May 13, 2019), https://perma.cc/6G57-RP8U (citing one small-farm advocate calling for "right-sized regulation, or scale-sensitive regulation").

420. GREGORY ASTILL ET AL., ECON. RSCH. SERV., EIB-194, BEFORE IMPLEMENTATION OF THE FOOD SAFETY MODERNIZATION ACT'S PRODUCE RULE: A SURVEY OF U.S. PRODUCE GROWERS 48 (2018) (stating that, according to the FDA's Final Regulatory Impact Analysis, 6.8% of farms that grow produce have sales of at least $500,000 and, according to the USDA's Produce Grower Food Safety Practices Surveys of 2015 and 2016, 29.8% of farms that grow fresh produce have sales of at least $500,000); *see also* U.S. Dep't of Agric., Econ. Info. Bulletin No. 214, *America's Diverse Family Farms* 21 (Dec. 2019), https://perma.cc/LJ86-FPQN (stating that farms with gross cash farm income below $350,000 account for 90% of the U.S. farm count and operate almost half of the farmland).

locally grown fresh produce largely unprotected by the federal government's new produce safety regime. A recent study by the University of California-Davis found generic *E. coli*—an indicator of fecal contamination—on one third of fresh produce samples sold at Northern California farmers markets, which were certified by local environmental health agencies as compliant with state health regulations for food facilities.[421]

D. Encourage Transparency About the Limits of Science

The science charade is a self-defeating strategy for reducing public anxiety about the risk of foodborne illness. The charade leverages public trust in scientific expertise to conceal professional judgments, policy values, and speculation that might not withstand public scrutiny and, by doing so, ultimately erodes public trust in scientific expertise.[422] The solution to this problem is not to pretend that increasingly stringent and specific regulatory rules are reflections of expanding scientific understanding. Instead, industry experts and government officials should be transparent about the limits of science and the experimental nature of regulation.[423]

This is easier said than done. Industry executives face intense pressure from consumers to reduce the risk of foodborne illness. Loss of consumer confidence following major outbreaks has cost the industry hundreds of millions of dollars.[424] And although the science charade may have helped to restore consumer confidence in the short run, it will not prevent recurring

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421. Dan Flynn, *Farmers Market Fresh Produce Often Comes with a Fecal Load Included in Price,* FOOD SAFETY NEWS (Nov. 18, 2020), https://perma.cc/4M7N-MYAG; *see also* Joshua A. Scheinberg et al., *A Comprehensive Needs Assessment of Food Safety Practices of Farmers' Market Vendors in Pennsylvania Using Direct Concealed Observations, Self-Reported Surveys, and State Sanitarian Surveys*, 38 FOOD PROTECTION TRENDS 421, 433-35 (2018) (documenting shortcomings in food safety among farmers market vendors in Pennsylvania).

422. *See* Wagner, *The Science Charade*, *supra* note 10, at 1688 (discussing loss of public confidence in science as a result of the science charade); Eyal, *supra* note 250, at 266 (noting that the politicization of science impedes its ability to legitimate policy decisions); ARAIZA, *supra* note 374, at 3-5 (analyzing the decline of public faith in scientific expertise).

423. *See* ARAIZA, *supra* note 374, at 215 (advocating greater transparency in regulatory decisionmaking). *But cf.* William Funk, *Better Procedures and Regulations Are Not an Answer to the Loss of Trust in Government*, YALE J. ON REGULATION: NOTICE & COMMENT (Mar. 24, 2023), https://perma.cc/C9KD-A9H5 (asserting that "increasing transparency in agency rulemaking . . . will not likely increase trust in the federal government and federal regulatory agencies" and that "there is empirical support for the opposite: that increased transparency leads to distrust of government"); Kasperson, *supra* note 5, at 339 (asserting that "deep uncertainty is a field for creativity and experimentation").

424. *See supra* notes 37, 237-39 and accompanying text.

outbreaks. In the long run, the science charade is likely to undermine consumer confidence more than honestly admitting that the industry is doing the best it can with full knowledge that its efforts are not sufficient to completely protect consumers.

Similarly, the FDA faces legal pressure to justify its regulations based on science and political pressure to respond ever more vigorously in the wake of outbreaks.[425] Court injunctions and OIRA requirements have compelled the agency to present scientific justifications for scientifically unjustifiable regulations. Self-righteous politicians routinely heap blame on agency officials in open congressional hearings to make themselves appear responsive to public concerns.[426] Here again, the charade is merely a short-term fix that, in the long run, is likely to damage the agency's reputation and undermine public confidence in government regulation.[427]

Instead of trying to convince consumers and agency overseers that agricultural water-quality criteria are justified by science, industry experts and government officials should be open about the limits of their knowledge and explain the process by which they set standards. Better that the public view industry experts and government officials as inadequate to the task than untrustworthy. Advances in science may, overtime, improve the adequacy of regulatory efforts. However, nothing but a sustained policy of honesty can build trust in them.

Greater transparency regarding the limits of science will force consumers and agency overseers to confront the reality that eating fresh greens carries the irreducible risk of foodborne illness. As agricultural water quality expert Chana Rock puts it, "There are risks in everything we do . . . . How do we have a conversation among society who wants safe food, industry who wants to produce safe food, and scientists who have to grapple with the vast set of uncertainties?"[428] For starters, that conversation needs to be honest about current constraints on risk regulation. Additionally, the conversation should be driven by the same constellation of stakeholders who have shaped current regulatory efforts. No one else is better informed about the risk of eating fresh greens. Risk communication must be no less the subject of broad stakeholder deliberation than risk assessment and risk reduction. In the long run, public

425. *See supra* notes 166-74 and accompanying text.

426. *Food Safety: Hearing*, *supra* note 321, at 2 (comments of Sen. Herb Kohl) (recounting "troublesome" facts about the FDA's food safety inspection and enforcement efforts).

427. On the importance of the FDA' reputation for the effectiveness of its regulatory efforts, see generally DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA (2010).

428. Anglen, *supra* note 83.

trust in science and the regulatory institutions that struggle to translate it into risk regulation depend upon honest and effective risk communication.

Whether agency candor regarding the inadequacy of available scientific evidence to justify rules would survive judicial review remains an open question. Courts have, in some cases, made allowances for evidentiary gaps in agency reasoning, so long as the "cumulative effect" of the evidence provides a rational basis for regulations.[429] Courts should be sensitive to the predicament in which agencies find themselves and exercise their review power to advance rather than stymie good faith attempts to fulfill unrealistic legislative mandates for science-based regulations.

E. Maintain a Broad Perspective on the Hazard

The regulatory challenges posed by known unknowns result from unobtainable data, heterogeneity of risk factors, and the complexity of causal chains. By maintaining a broad perspective on the hazard, opportunities may emerge to shift focus to alternative risk factors at various points in the causal chain where data is easier to obtain. For example, instead of struggling to measure agricultural water quality, regulators might shift their attention to risk factors on the cattle ranches from which much of the fecal contamination originates or to post-harvest interventions during processing. On cattle ranches, vaccination might verifiably eliminate harmful pathogens from manure, and more secure containment might verifiably eliminate the migration of fecal material.[430] Within the production process, emerging technologies using radiation, ozone, or blue light might greatly reduce microbial loads on leafy greens at little cost to processors.[431]

Of course, such alternatives may not always be available, or they may be costly, or they may involve unknown tradeoffs. Thinking outside the box may simply be an attempt to wish the problem away. Costly interventions with unknown benefits don't do much to resolve the problem of known unknowns. And new technologies that involve unknown tradeoffs may simply trade a known unknown for an unknown unknown that might be worse. Nevertheless, regulators should be on the lookout for low-cost

429. *Ethyl Corp. v. Env't Prot. Agency*, 541 F.2d 1, 38 (D.C. Cir. 1976) (opinion of J. Skelly Wright).

430. Kelly Crowe, *Is There a Way to Keep E. coli Out of Romaine Lettuce?*, CBC NEWS (Dec. 3, 2018), https://perma.cc/G9MR-HCCB; *see* Louise Matthews et al., *Predicting the Public Health Benefit of Vaccinating Cattle Against* Escherichia coli *O157*, 110 PROC. NAT'L ACAD. SCI. 16265, 16265 (2013).

431. *See supra* note 40.

alternatives that provide significant and verifiable hazard reduction using familiar technologies.

IV. Implications for Regulatory Theory

Part I of this Article described the phenomenon of known unknowns as identifiable hazards that pose an unquantifiable risk. These hazards are well known, and we know much about what causes them, but we cannot predict their occurrence with reasonable certainty due to some combination of limited data, heterogeneity of causal factors, and complex causal chains. Consequently, these hazards are not amenable to risk assessment and risk management. Part II argued that the leading approaches to risk regulation incentivize regulators to conceal, ignore, or outsource the deep uncertainty that characterizes known unknowns. These three responses are part of a charade by which regulators misrepresent the extent to which scientific evidence justifies the precision with which they attempt to regulate known unknowns. Part III presented what I have described as coping strategies for regulating known unknowns without engaging in this science charade.

My analysis of known unknowns relies on a case study of agricultural water contamination that causes foodborne illness. Beyond food safety, known unknowns can be found in many areas of regulation. For example, although we know that carbon pollution causes climate change, climate science cannot justify precise emissions standards that will predictably achieve specific benchmarks.[432] Similarly, although we know that interpersonal proximity transmits infectious diseases, science alone cannot justify precise social distancing and masking requirements.[433] There are examples of known unknowns beyond health and safety regulation. For instance, the causal links between interest rates and economic growth are well understood, but specific monetary policy standards rely significantly on strong assumptions and educated guesses to compensate for unobtainable data, heterogeneity, and complex causation.[434] The sophistication of

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432. *See* Farber, *supra* note 5, at 1, 7-11; Sunstein, *supra* note 5, at 20.

433. *See* Emily Anthes, *Three Feet or Six? Distancing Guideline for Schools Stirs Debate*, N.Y. TIMES (Mar. 16, 2021), https://perma.cc/36ZN-4QR5 (quoting an expert on viral transmission at Virginia Tech University opining that the CDC's six-foot social distancing recommendation was "almost like it was pulled out of thin air"); Martin & Hanna, *supra* note 20 (warning that "scientists will be the ones who suffer if they overstep their knowledge or understate their uncertainty").

434. *See* MITCHEL Y. ABOLAFIA, STEWARDS OF THE MARKET: HOW THE FEDERAL RESERVE MADE SENSE OF THE FINANCIAL CRISIS 156-71 (2020) (describing the limits of technical

economic modeling by regulators obscures the impressionistic nature of their policy decisions.[435]

Detailed analysis of these other examples is beyond the scope of this Article. Instead, this Part of the Article discusses two general implications of the coping strategies offered here as regulatory responses to known unknowns. The first pertains to debates between proponents of risk-based regulation and advocates of the precautionary principle. The second concerns the role of private standards in public regulation.

A. Degrees of Uncertainty and a Place for Precaution

The rise of cost-benefit analysis in regulatory policymaking has fueled an ongoing debate between proponents of risk-based regulation and advocates of the precautionary principle. As discussed in Part II.B., risk-based regulation relies on the quantification of risk to set regulatory goals, determine regulatory priorities, and allocate regulatory resources. Advocates of the precautionary principle have argued that, in the face of deep uncertainty, risk-based regulation immobilizes regulators and renders them impotent to address known hazards and prevent harm before it occurs.[436]

Advocates of the precautionary principle argue that, according to one well known articulation of the principle, "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[437] In some versions of the principle, it shifts the burden of establishing the need for regulation from regulators to regulated entities.[438]

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expertise in formulating monetary policy in the Federal Reserve and how decisionmakers rely on improvisation, political considerations, and cultural cues).

435. *Id.* at 7 ("The Fed's opacity and the esoteric nature of its operations facilitates a mythic representation of its technical rationality.").

436. *E.g.*, Wendy E. Wagner, *The Triumph of Technology-Based Standards*, 2000 U. ILL. L. REV. 83, 93 [hereinafter Wagner, *Triumph of Technology*] (advocating a precautionary approach when "whatever inefficiencies occur are expected to be less than the costs entailed in identifying and implementing a more 'efficient' control strategy"); Howard Latin, *Ideal Versus Real Regulatory Efficiency: Implementation of Uniform Standards and "Fine-Tuning" Regulatory Reforms*, 37 STAN. L. REV. 1267, 1283, 1313-14 (1985) (criticizing insistence on cost-benefit analysis in the face of significant uncertainty as costly and leading to under regulation).

437. U.N. Conference on Environment and Development, *Rio Declaration on Environment and Development*, ¶ 15 U.N. Doc. A/CONF.151/26/(Vol.1), annex I (Aug. 12, 1992); *see also* Majone, *supra* note 4, at 106-13 (analyzing various versions of the precautionary principle); Sunstein, *supra* note 5, at 1 (listing four versions of the precautionary principle).

438. *E.g.*, Wagner, *Triumph of Technology*, *supra* note 436, at 92.

Proponents of risk-based regulation have derided the principle as vague, inefficient, and, in many instances, counterproductive.[439] They argue that the precautionary principle provides no guidance to policymakers regarding the stringency of regulatory standards.[440] They point out that, notwithstanding its apparent adherence to cost-effectiveness, it betrays that commitment insofar as it departs from risk-based regulatory approaches.[441] They suggest that, in some cases, it may suppress incentives for further scientific research or generate substitution effects that are worse than the hazard it seeks to suppress.[442]

Amid this ongoing pitched battle, there are signs of compromise. For example, Cass Sunstein, a leading proponent of risk-based regulation, has suggested that the precautionary principle may provide a useful approach to the regulation of potentially catastrophic, irreversible harms under conditions of deep uncertainty.[443] For their part, advocates of precaution agree that "soft" cost-benefit analysis—by which policymakers "compare of costs and benefits without attempting to quantify every factor"—can help identify important tradeoffs associated with different types and levels of precaution.[444] Mindful that there are different degrees of uncertainty, the Office of Management and Budget recognizes the need for agencies to grapple openly with nonquantifiable uncertainty in regulatory impact analysis[445]—although as this Article and others have demonstrated, the science charade leads agencies to fall short of this advice.[446]

Thus, the tension between cost-benefit analysis and the precautionary principle might be more accurately characterized as a spectrum of options, many of which include a mixture of both arrayed according to the degree and type of uncertainty that characterizes a hazard.[447] Figure 4 illustrates this spectrum.

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439. *E.g.*, Majone, *supra* note 4, at 106-13.

440. *Id.*

441. *Id.*

442. *Id.*

443. Sunstein, *supra* note 5, at 11.

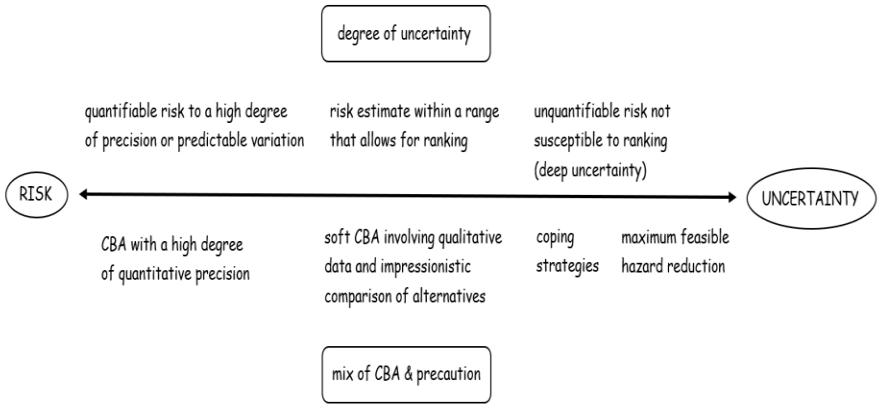
444. *E.g.*, DANIEL A. FARBER, ECO-PRAGMATISM: MAKING SENSIBLE ENVIRONMENTAL DECISIONS IN AN UNCERTAIN WORLD 39 (1999).

445. Farber, *supra* note 5, at 1, 6-7 (discussing 2003 guidance and a proposed reform).

446. *E.g.*, Wagner, *The Science Charade*, *supra* note 10.

447. *See* Amy Sinden, *Formality and Informality in Cost-Benefit Analysis*, 2015 UTAH L. REV. 93, 93 (developing an analysis that arrays the precision of CBA along multiple dimensions); *see also* Walker et al., *supra* note 5, at 2-5 (distinguishing different levels of uncertainty); Sunstein, *supra* note 5, 20 (discussing bounded uncertainty).

Figure 4.



This spectrum reflects that hazards can be characterized by diverse levels of uncertainty regarding the risk of harm. Moreover, as scientific knowledge regarding a hazard increases, a hazard may become less or more uncertain, depending upon whether additional information makes it easier to predict outcomes or, alternatively, identifies new data gaps, risk factors, or complexities.[448]

The spectrum also highlights that the coping strategies advanced in this Article constitute a moderate precautionary approach to regulating known unknowns. These coping strategies are less aggressive than precautionary approaches that advocate maximum feasible reduction of a hazard (for example, through technology-based regulation).[449] Although this Article takes a moderate approach to precaution, it simultaneously justifies the expansion of that approach beyond merely catastrophic harms to routine, small scale harms such as food safety.

B. Public Regulation and Private Standards

This Article recommends reliance on state-of-the-art private governance standards endorsed by stakeholders. This coping strategy raises important questions about the rigor of private standards and how to incentivize advances in science and technology that can improve regulatory outcomes.[450]

448. Kasperson, *supra* note 5, at 338-39, 342.

449. *See* Wagner, *Triumph of Technology*, *supra* note 436, at 84-85.

450. *See* Timothy D. Lytton, *Competitive Third-Party Regulation: How Private Certification Can Overcome Constraints that Frustrate Government Regulation*, 15

Indeed, critics of this kind of heavy reliance on private governance sometimes refer to it dismissively as the fox guarding the hen house.[451]

The case of agricultural water standards demonstrates that economic, legal, and political pressures can strongly incentivize stakeholders to do their best to establish rigorous private standards and to pursue high quality policy-relevant research. The combination of high-profile foodborne-illness outbreaks and brand sensitivity in the early 2000s mobilized industry leaders to organize technical committees consisting of the leading experts from industry, government, and academia to design rigorous, feasible standards. The FDA essentially copied those standards, relying on input from these same stakeholders during the notice-and-comment process. In response to additional outbreaks in the 2010s, the LGMA quickly increased the stringency of its metrics, while the FDA continued to delay implementation of its agricultural water quality standards.[452]

All major produce handlers, responsible for more than 99% of California greens production, have endorsed the LGMA's standards.[453] The LGMA harnesses California Department of Food and Agriculture inspectors to perform mandatory compliance audits of each member every sixty days during the harvest season.[454] It publishes annual reports that detail the type and number of citations for noncompliance by farmers. These reports boast a compliance rate over 99%.[455]

Both the USDA and the industry fund research to expand scientific knowledge and new technology to measurably improve agricultural water quality and to better understand the link between agricultural water quality and human health. The USDA's Agricultural and Food Research Initiative funds competitive grants for scientific research in this area.[456] The industry's Center for Produce Safety provides funding and serves as a pass-through

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THEORETICAL INQUIRIES L. 539, 556-62 (2014) [hereinafter Lytton, *Competitive Third-Party Regulation*] (analyzing the conditions that promote rigorous private standards).

451. *E.g.*, Ashton W. Merck, *The Fox Guarding the Henhouse: Coregulation and Consumer Protection in Food Safety, 1946-2002*, 22 ENTER. & SOC'Y 921, 921-22 (2021) (criticizing reliance on private governance in poultry production).

452. *See supra* Sections I.B.1.-.2.

453. LYTTON, *supra* note 27, at 137.

454. CAL. LEAFY GREENS HANDLER MKTG. AGREEMENT (LGMA), ANNUAL REPORT: APRIL 2018 – MARCH 2019, at 1 (n.d.), https://perma.cc/KCA8-MYVF.

455. *Id.* at 4.

456. *See Food Safety Research Projects Database Search*, *supra* note 416.

organization for federal funding.[457] The Center's board includes representatives from federal government agencies and academia.[458]

The regulation of agricultural water quality involves the integration of private governance and public regulation.[459] It is a collaborative effort among stakeholders in private industry, government, and academia. All of the leading experts are involved in industry technical committees, engaged in the notice-and-comment process, or participating in academic conferences. Economic, legal, and political incentives are aligned to favor rigorous standards. As Part II.C. demonstrated, excessive stringency is as much or more of a problem as insufficient rigor. These same incentives have motivated ongoing research and technology development. Moreover, the LGMA's inspection and compliance rates compare very favorably with the FDA's performance.[460]

To be sure, the foregoing discussion should not suggest that current efforts have verifiably reduced the risk of human illness. The danger posed by agricultural water quality remains a known unknown, characterized by deep uncertainty and a considerable science-policy gap. Nor is it the case that industry stakeholders are always as highly motivated to develop rigorous standards to address other examples of known unknowns.[461] Nevertheless, this case study of agricultural water quality regulation demonstrates that, under the right conditions, private governance can play a vital role in advancing public welfare.[462]

Aligning economic, legal, and political incentives to motivate private stakeholders to establish rigorous regulatory standards and achieve high rates of compliance requires that private standard-setters suffer the cost of failure. This can be achieved through market pressure, government enforcement actions, and civil liability—all three of which played a part in motivating the California leafy greens industry to develop the LGMA.[463] These tools can also be marshalled in other contexts to create conditions that favor rigorous

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457. *See About CPS*, CTR. FOR PRODUCE SAFETY, https://perma.cc/6ERD-FJB7 (last visited Mar. 3, 2024).

458. *Board of Directors*, CTR. FOR PRODUCE SAFETY, https://perma.cc/MK3H-DSM9 (last visited Mar. 3, 2024).

459. Lytton, *Technical Standards*, *supra* note 107.

460. *See supra* notes 231-233, 402-406 and accompanying text.

461. *See, e.g.*, Tom Lyon, *How Corporations Use Greenwashing to Convince You They Are Battling Climate Change*, THE CONVERSATION (May 15, 2023, 8:33 AM), https://perma.cc/7RB9-GJRH;

462. For an extended study of the conditions that favor successful private governance, see Lytton, *Competitive Third-Party Regulation*, *supra* note 450, at 556-62.

463. *See supra* Section I.B.2.

private governance.[464] The suggestion that reliance on state-of-the-art standards endorsed by stakeholders is little more than industry capture, as the fox-guarding-the-hen-house characterization implies, misrepresents the potential of private governance to help public regulators cope with known unknowns.

Conclusion

This case study of efforts to regulate the risk of foodborne illness from contaminated leafy greens illustrates the phenomenon of known unknowns—identifiable hazards that pose an unquantifiable risk of harm. In the face of known unknowns, regulators must confront deep uncertainty, characterized by unobtainable data, extreme heterogeneity of risk factors, and complex causal chains. I have argued that deep uncertainty triggers anxiety that results in reflexive, unrealistic demands for science-based reforms, which in turn, results in more stringent and detailed regulations unjustified by science and accompanied by efforts to conceal the professional judgments, policy values, speculation, and political calculations that regulators must use to bridge the science-policy gap.

I have proposed a set of five principles to help regulators and stakeholders cope with known unknowns without engaging in the science charade. These principles reflect a novel perspective on regulatory reform. By adopting a precautionary approach informed by hazard-control principles that reduce harm while generating policy-relevant information, regulators can improve the prospects for reliable risk-based regulation in the future. Thus, strategic reliance on precaution can advance rather than replace risk-based regulation.

Moreover, the analysis presented here challenges the unproductive framing and stale terms of the long-running and shrill public debate over regulatory policy between advocates of robust government intervention and champions of unregulated free markets. Such highly polarized discourse does little to address the country's most trenchant social and economic problems. In recommending that government invest more in localized state-of-the-art industry standards endorsed by a broad representation of stakeholders, this Article suggests that the most effective way to maintain the integrity of public regulation is greater reliance on effective private governance.

As it turns out, the lettuce fields of California are fertile ground not only for fresh produce but also for regulatory reform.

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464. *See* Lytton, *Competitive Third-Party Regulation*, *supra* note 450, at 557, 562-63.