

# OVERSIGHT IN PRIVATE FOOD SAFETY AUDITING: ADDRESSING AUDITOR CONFLICT OF INTEREST

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Private auditing is a significant component of food safety regulation. Typically, manufacturers, retail sellers, and food-service operators require their suppliers to obtain food safety certification from a private third-party auditor paid by the supplier. Auditors' financial interest in acquiring accounts from suppliers who want the cheapest certification that they can obtain gives auditors incentive to reduce the rigor of audits. This constitutes a conflict of interest between the auditor's private financial interest and its professional obligation to protect the public from food safety risks. Audit industry insiders and outside observers are well aware of this problem, and various institutional actors—both public and private—have developed oversight mechanisms to address it.

We analyze the nature and sources of this conflict of interest in food safety auditing, efforts to prevent it, and responses when it occurs. Our focus is on institutional design—organizational structures, administrative routines, and professional norms. Part I of the Article describes how conflicts of interest lead some auditors to be less probing in their inspection of suppliers' operations and to skew their risk evaluations in favor of suppliers' desire for cheap certification. Part II of the Article surveys the different oversight mechanisms currently in place or under development that aim to counteract auditors' incentive to reduce the rigor of audits.

Conflict of interest is a structural feature of any system of private standards compliance in which the auditor is paid by the entity being audited. Other prominent examples include securities rating and environmental audits. Our analysis of food safety auditing aims to offer general insights into the comparative strengths and weaknesses of different responses to this problem.

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## INTRODUCTION

Private food safety auditing is a large and rapidly growing global industry.<sup>1</sup> Although no one has comprehensive data on the size of the industry, there are indications that it operates on a scale comparable to that of government food safety regulation. In 2011, the U.S. Food and Drug Administration (FDA) inspected 19,073 domestic food facilities and 995 foreign food facilities.<sup>2</sup> In addition, the U.S. Department of Agriculture (USDA) maintains inspectors in 6,000 domestic facilities that produce meat, poultry, and processed egg products.<sup>3</sup> State governments also conduct tens of thousands of food safety inspections each year under state programs that regulate agricultural production and food processing facilities.<sup>4</sup> By comparison, private food safety

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1. Ronald Doering, former president of the Canadian Food Inspection Agency, asserts that “the extraordinary growth” of private food safety auditing is the “most significant food safety development in the last decade.” Ronald Doering, *Third-Party Audits & Food Safety*, FOOD IN CANADA, Feb. 24, 2012, <http://www.foodincanada.com/opinions/third-party-audits-and-food-safety>.

2. This figure includes state inspections under contract with the FDA. U.S. FOOD & DRUG ADMIN., ANNUAL REPORT TO CONGRESS ON FOOD FACILITIES, FOOD IMPORTS, AND FDA FOREIGN OFFICERS (2012) [hereinafter FDA 2012 ANNUAL REPORT], available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm>. The FDA is responsible for most federal government food safety regulation outside of meat and poultry production. The USDA is responsible for federal food safety regulation of meat, poultry, and processed egg products. For a summary of FDA and USDA food safety jurisdictions, see RENEE JOHNSON, CONG. RESEARCH SERV., RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER (2012), available at <https://www.fas.org/sgp/crs/misc/RS22600.pdf>. See also INST. OF MED. & NAT’L RESEARCH COUNCIL, ENSURING SAFE FOOD: FROM PRODUCTION TO CONSUMPTION 26–27 (1998); MARION NESTLE, SAFE FOOD: THE POLITICS OF FOOD SAFETY 55–58 (2d ed. 2010).

3. U.S. DEP’T OF AGRIC., FISCAL YEAR 2012 SUMMARY OF PERFORMANCE AND FINANCIAL INFORMATION, at v (2012), available at [http://www.ocfo.usda.gov/docs/USDA\\_SPF\\_508\\_FINAL.pdf](http://www.ocfo.usda.gov/docs/USDA_SPF_508_FINAL.pdf).

4. For example, the California Department of Food and Agriculture conducts 500 inspections of leafy green producers each year under the California Leafy Greens Products Handler Marketing Agreement, and the New York State Department of

inspections are conducted by over 500 audit firms, many of which have global operations.<sup>5</sup> The Food Safety Service Providers, an industry association representing nine leading private food safety audit firms, asserts that its members conduct more than 200,000 audits and inspections in over 100 countries each year.<sup>6</sup> Based on these figures, the scale of private food safety auditing activity appears to be at least ten times larger than that of federal government inspection, and it may exceed that of all federal and state efforts combined.

Government regulation alone cannot meet the demand for food safety. Many factors, including the size and complexity of the task, inhibit comprehensive government regulation. The food industry is the world's largest industry, with a diverse array of sectors and global production chains, which generate an estimated \$7 trillion in annual revenues.<sup>7</sup> The FDA lacks sufficient resources to inspect more than a small fraction of the domestic facilities under its jurisdiction or to ensure inspection of the many foreign facilities outside of its jurisdiction.<sup>8</sup>

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Agriculture and Markets inspects 2,800 food-processing facilities annually. CAL. LEAFY GREEN PRODS. HANDLER MARKETING AGREEMENT, 2011/2012 ANNUAL REPORT 1 (2012), available at [http://www.lgma.ca.gov/sites/default/files/11.12%20CALGMA%20Annual%20Report%20sml\\_0.pdf](http://www.lgma.ca.gov/sites/default/files/11.12%20CALGMA%20Annual%20Report%20sml_0.pdf); N.Y. DEP'T OF AGRIC. & MKTS., INSPECTION, <http://www.agriculture.ny.gov/FS/inspection.html> (last visited Jan. 8, 2014).

5. See Scott Rafferty, *FDA Moving Too Slowly to Promote Private Inspections*, FOOD SAFETY NEWS (Sept. 6, 2013), <http://www.foodsafetynews.com/2013/09/the-fda-is-moving-too-slowly-to-promote-private-inspections/#.Us2HcImA1i4> (asserting that there are 568 private food safety auditing firms). A *New York Times* article puts the total at 200. Michael Moss & Andrew Martin, *Food Problems Elude Private Inspectors*, N.Y. TIMES, Mar. 5, 2009, <http://www.nytimes.com/2009/03/06/business/06food.html?pagewanted=all>.

6. FOOD SAFETY SERV. PROVIDERS, COMMENTS ON FSMA PROPOSED RULES ON ACCREDITATION OF THIRD-PARTY AUDITORS/CERTIFICATION BODIES (2013), available at <http://www.noticeandcomment.com/FDA-2011-N-0146-0031-fcod-344195.aspx> (stating that "FSSP members conduct more than 200,000 audits and inspections in over 100 countries each year"); see also U.S. HOUSE OF REPRESENTATIVES, COMM. ON ENERGY AND COMMERCE, REPORT ON THE INVESTIGATION OF THE OUTBREAK OF *LISTERIA MONOCYTOGENES* IN CANTALOUPE AT JENSEN FARMS (Jan. 10, 2012) [hereinafter JENSEN FARMS REPORT], available at <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/analysis/20120110Listeria.pdf> (stating that Primus Labs "conducts approximately 15,000 audits per year . . . for over 3,000 clients worldwide").

7. IMAP, FOOD AND BEVERAGE INDUSTRY GLOBAL REPORT—2010, 4 (2010), available at [www.imap.com/imap/media/resources/IMAP\\_Food\\_Beverage\\_Report\\_WEB\\_AD6498A02CAF4.pdf](http://www.imap.com/imap/media/resources/IMAP_Food_Beverage_Report_WEB_AD6498A02CAF4.pdf).

8. In 2011, FDA inspected approximately 11 percent of the 167,000 registered domestic food facilities under its jurisdiction and 0.4 percent of the 254,088 registered foreign food facilities. See FDA 2012 ANNUAL REPORT, *supra* note 2. The Food Safety Modernization Act (FSMA), signed by President Obama in 2011, mandates an increase in the number of inspections, but most domestic food facilities will still be inspected only once every five years, with designated, high-risk facilities inspected once every three years. FDA Food Safety Modernization Act, 21 U.S.C. § 350j(2)(A), (D)(i)–(ii) (2012). With respect to foreign food facilities, FSMA requires that the FDA double its annual

Government regulation of food safety is also hindered by incomplete information about the risks posed by foodborne pathogens,<sup>9</sup> industry resistance to detailed mandates,<sup>10</sup> and policy implications for agriculture, environment, health, economy, labor, trade, public assistance, energy, and foreign affairs.<sup>11</sup> These factors and others have led the FDA to prefer producing voluntary standards over binding regulations.<sup>12</sup>

Private food safety auditors are free from many constraints that hamper government regulation. They do not operate on fixed budgets but

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inspection rate of foreign food facilities each year through 2017, but this rate will still reach only 3.2 percent. *See id.* Moreover, attaining even this limited enforcement goal depends upon adequate funding of these FSMA provisions, which is not assured. *See* U.S. FOOD & DRUG ADMIN., ENSURING A SAFE FOOD SUPPLY: A REPORT TO CONGRESS UNDER THE FDA FOOD SAFETY MODERNIZATION ACT SECTION 110(a)(1), 10, 60–62 (2013), available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM351876.pdf>; RENEE JOHNSON, CONG. RESEARCH SERV., R42885, FOOD SAFETY ISSUES FOR THE 113TH CONGRESS 12 (2013), available at [http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/R42885\\_01092013.pdf](http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/R42885_01092013.pdf).

9. Risk analysis in regulating foodborne illness is especially complex given the remote nature of many of the risks involved, variability of conditions within food production, insufficient scientific knowledge about the nature and migration of rare pathogens, lack of consensus about metrics and testing protocols, and incomplete understanding of the environmental implications of risk reduction measures. *See* Jim Prevor, *How to Improve Food Safety: Aggrandizing the FDA Only Distracts from Real Solutions*, NEW ATLANTIS, May 21, 2010, <http://www.thenewatlantis.com/publications/how-to-improve-food-safety>. For similar concerns regarding food safety investigations, see Ronald Doering, *Uncertainty and Food Safety Investigations—Part II*, FOOD IN CANADA, Nov.–Dec. 2011, at 20, available at <http://www.gowlings.com/knowledgeCentre/publicationPDFs/Uncertainty-and-food-safety-Investigations-Part-II.pdf>.

10. *See, e.g.*, NESTLE, *supra* note 2, at 86–112 (detailing industry resistance to FDA attempts to mandate HACCP requirements); Dan Flynn, *Pushback Begins against FSMA On-the-Farm Rules*, FOOD SAFETY NEWS (Nov. 15, 2013), <http://www.foodsafetynews.com/2013/11/pushback-begins-against-fsma-on-the-farm-rules/#.Us6AromA1i5> (describing industry resistance to proposed regulations for fresh produce under FSMA); Moss & Martin, *supra* note 5 (noting industry resistance to FDA guidance on food safety certification). *But see* Prevor, *supra* note 9 (arguing that FDA rather than the produce industry is the source of resistance to detailed food safety regulations).

11. On regulatory delays based on interagency concerns, see Cass R. Sunstein, *What OIRA Really Does*, REG BLOG (Sept. 10, 2013), [www.law.upenn.edu/blogs/regblog/2013/09/10-sunstein-what-oira-does.html](http://www.law.upenn.edu/blogs/regblog/2013/09/10-sunstein-what-oira-does.html).

12. *See, e.g.*, JENSEN FARMS REPORT, *supra* note 6 (finding that in the case of cantaloupe processing, the “FDA has no specific regulations, only guidance”); *Guidance for Industry - Voluntary Third-Party Certification Programs for Foods and Feeds*, U.S. FOOD & DRUG ADMIN. (Jan. 2009), <http://www.fda.gov/regulatoryinformation/guidances/ucm125431.htm> (providing voluntary guidance for the conduct of third-party food safety audits). *See also* Prevor, *supra* note 9 (arguing that the FDA avoids promulgating detailed standards so that, in the event of an outbreak, it can avoid responsibility by blaming the producer for having an inadequate food safety plan).

instead generate fees for their services.<sup>13</sup> They are not limited by jurisdictional boundaries.<sup>14</sup> They typically have specialized technical knowledge of particular production processes and associated risks.<sup>15</sup> They are unburdened by the competing policy concerns and political resistance that government regulators must confront. Consequently, private auditing of industrial food production has, over the course of the past two decades, become a pervasive and fast-growing industry.<sup>16</sup>

Given the significant role played by private auditors, it is important to scrutinize the nature and sources of error in private food safety auditing. The news media has increasingly focused on the shortcomings of private food safety auditing in coverage of foodborne illness outbreaks.<sup>17</sup> In reporting on high-profile *Salmonella* outbreaks in 2009

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13. The FDA charges fees for the permitting and licensing of prescription drugs and for grading seafood products, but FDA proposals to charge fees for inspection and monitoring of food safety typically face stiff political resistance. See, e.g., JOHNSON, *supra* note 8, at 13; Helena Bottemiller, *Hamburg: FDA Needs More Resources for Food Safety*, FOOD SAFETY NEWS (Mar. 1, 2012), <http://www.foodsafetynews.com/2012/03/commissioner-hamburg-fda-needs-more-resources-for-food-safety/#.UxU60c3SOEA>; Hank Schultz, *Strapped by FSMA, FDA Seeks Authority for New User Fees in Budget Request*, FOOD NAVIGATOR-USA.COM (Apr. 11, 2013), <http://www.foodnavigator-usa.com/Regulation/Strapped-by-FSMA-FDA-seeks-authority-for-new-user-fees-in-budget-request>.

On FDA fees for permitting and licensing prescription drugs, see *Prescription Drug User Fee Act (PDUFA)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm> (last visited Mar. 10, 2014). On FDA fees for grading seafood products, see JOHNSON, *supra* note 2, at 5. On USDA fees for grading agricultural products, see Ken Petersen, *USDA 3rd Party Audit Verification Programs*, [http://www.gaps.cornell.edu/documents/USDA\\_3rd\\_Party\\_Audit.pdf](http://www.gaps.cornell.edu/documents/USDA_3rd_Party_Audit.pdf) (last visited Mar. 26, 2014). California charges fees for food safety inspection of leafy greens. See Jessica Mulholland, *Food Safety Audits Keep Leafy Greens Clean*, GOVERNING: THE STATES AND LOCALITIES (May 2012), <http://www.governing.com/topics/health-human-services/gov-food-safety-audits-keep-leafy-greens-clean.html>.

Even when government charges fees for its services, these fees are typically designed merely to cover costs. See Timothy D. Lytton, *Competitive Third-Party Regulation: How Private Certification Can Overcome Constraints That Frustrate Government Regulation*, 15 THEORETICAL INQUIRIES L. (forthcoming 2014), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2313109](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2313109). By contrast, private fees typically cover more than costs, and this revenue is used to raise salaries, hire more staff, invest in business development, and support special projects. *Id.* Thus, government fees do not offer the same level of incentive as private fees to expand inspection and monitoring. *Id.*

14. Elena Fagotto, *Private Roles in Food Safety Provision: The Law and Economics of Private Food Safety*, 37 EUR. J.L. & ECON. 83, 92, 106 (2014), available at <http://link.springer.com/article/10.1007%2Fs10657-013-9414-z>.

15. *Id.* at 100.

16. See Tetty Havinga, *Food Retailers as Drivers for Food Safety Standards* (Nijmegen Sociology of Law, Working Paper No. 3, 2013), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2331869](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2331869) (describing the rise of private food safety regulation).

17. See, e.g., Moss & Martin, *supra* note 5.

and 2010 traced to the Peanut Corporation of America and Wright County Egg, the *Washington Post* quoted Mansour Samadpour, president of IEH Laboratories & Consulting Group, a leading firm that specializes in lab testing for food contamination, who issued a harsh indictment: “I have not seen a single company that has had an outbreak or recall that didn’t have a series of audits with really high scores.”<sup>18</sup> In coverage of a 2011 *Listeria* outbreak traced to Jensen Farms cantaloupes, CNN also quoted Samadpour, who asserted that “[t]hese so-called food safety audits are not worth *anything*.”<sup>19</sup>

One should be careful, however, not to assume that high-profile outbreaks are an indication of system failure. Even the most successful regulatory systems have error rates.<sup>20</sup> Evaluating the overall performance of private food safety auditing requires analyzing errors within the context of the total amount of auditing activity, the controls in place for preventing mistakes, the response to mistakes when they happen, and the system’s capacity for generating feedback and using it to improve. Moreover, private food safety auditing, like all regulatory instruments, has strengths and weaknesses. Instead of asking how it measures up to some ideal of food safety, it may be more useful to evaluate how it compares to other options. Food safety, like other areas of regulation, involves a choice among imperfect alternatives.<sup>21</sup>

This Article focuses on one particular problem that undermines public confidence in private food safety auditing: the conflict of interest that arises when auditors are paid by the entities that they audit.<sup>22</sup> Industry insiders and outside observers are well aware of this problem,

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18. Lena H. Sun, *Food Inspection Is Often Flawed*, WASH. POST, Oct. 22, 2010, A1, available at [http://www.washingtonpost.com/wp-dyn/content/article/2010/10/21/AR2010102106909\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2010/10/21/AR2010102106909_pf.html).

19. Scott Bronstein & Drew Griffin, *Third-Deadliest U.S. Food Outbreak Was Preventable, Experts Say*, CNN (May 3, 2010), available at <http://www.cnn.com/2012/05/03/health/listeria-outbreak-investigation/>.

20. Prevor, *supra* note 9.

21. On comparative institutional analysis, see ROSS E. CHEIT, SETTING SAFETY STANDARDS: REGULATION IN THE PUBLIC AND PRIVATE SECTORS 17, 193 (1990); NEIL KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY 3–13 (1994); PETER SCHUCK, THE LIMITS OF LAW: ESSAYS ON DEMOCRATIC GOVERNANCE 424 (2000); David Vogel, *Taming Globalization?: Civil Regulation and Corporate Capitalism*, in THE OXFORD HANDBOOK OF BUSINESS AND GOVERNMENT 473 (David Coen et al. eds., 2010); see generally Philip Harter & George Eads, *Policy Instruments, Institutions, and Objectives: An Analytical Framework for Assessing “Alternatives” to Regulation*, 37 ADMIN. L. REV. 221 (1985). For a recent comparative institutional analysis of public and private food safety regulation, see Fagotto, *supra* note 14.

22. Other problems that undermine the reliability of private food safety auditing include insufficiently rigorous standards, auditor incompetence, and the quality and consistency of audits. See Douglas Powell et al., *Audits and Inspections Are Never Enough: A Critique to Enhance Food Safety*, 30 FOOD CONTROL 686, 686–90 (2013).

and various institutional actors—both public and private—have developed oversight mechanisms to address it.<sup>23</sup> We analyze the nature and sources of this conflict of interest, efforts to prevent it, and responses when it occurs. Our focus is on institutional design—organizational structures, administrative routines, and professional norms.<sup>24</sup> Part I of the Article defines the problem. Part II examines the oversight mechanisms currently in place or under development that aim to address it.

Our focus on institutional design highlights that oversight can be provided by a variety of sources, and it can take different forms. We use the term “oversight” in a very broad sense to cover any ongoing effort to ensure or improve quality. This includes promulgating norms and encouraging administrative routines as well as monitoring performance and imposing sanctions. These forms of oversight can come from personnel within organizations (such as trainers and managers), from external private sources (such as audit firms and trade associations), or from the government (such as agencies and courts). Oversight mechanisms thus involve different combinations of regulatory techniques and institutional actors, each of which has comparative strengths and weaknesses. They may provide alternatives to each other or coexist; they may be redundant or complementary.<sup>25</sup> The effectiveness of oversight may depend upon an ultimate overseer, or it may depend upon a network of overseers and oversight mechanisms.

Conflict of interest is a structural feature of any private system of standards compliance in which the auditor is paid by the entity being audited.<sup>26</sup> Other examples include securities rating and environmental audits.<sup>27</sup> Our analysis of food safety auditing aims to offer general insights into the comparative strengths and weaknesses of different responses to this problem.

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23. See, e.g., GLOBAL FOOD SAFETY INITIATIVE, ENHANCING FOOD SAFETY THROUGH THIRD PARTY CERTIFICATION 22–23 (2011), available at [http://www.mygfsi.com/gfsifiles/GFSI\\_White\\_Paper\\_-\\_Enhancing\\_Food\\_Safety\\_Through\\_Third\\_Party\\_Certification.pdf](http://www.mygfsi.com/gfsifiles/GFSI_White_Paper_-_Enhancing_Food_Safety_Through_Third_Party_Certification.pdf); Doering, *supra* note 1; Moss & Martin, *supra* note 5; Powell et al., *supra* note 22; Richard Stier, *Third-Party Audits: What the Food Industry Really Needs*, FOOD SAFETY MAG., Oct.–Nov. 2009, available at <http://www.foodsafetymagazine.com/magazine-archive1/october-november-2009/third-party-audits-what-the-food-industry-really-needs/> (all discussing the problem of auditor conflict of interest).

24. On institutional design, see generally ELINOR OSTROM, GOVERNING THE COMMONS: THE EVOLUTION OF INSTITUTIONS OF COLLECTIVE ACTION (1990).

25. Harter & Eads, *supra* note 21, at 223.

26. See Lesley K. McAllister, *Regulation by Third-Party Verification*, 53 B.C. L. REV. 1, 28–44 (2012).

27. See generally BENJAMIN CASHORE, GRAEME AULD & DEANNA NEWSOM, GOVERNING THROUGH MARKETS: FOREST CERTIFICATION AND THE EMERGENCE OF NON-STATE AUTHORITY (2004); TIMOTHY J. SINCLAIR, THE NEW MASTERS OF CAPITAL: AMERICAN BOND RATING AGENCIES AND THE POLITICS OF CREDITWORTHINESS (2005).

Before proceeding, we wish to emphasize two caveats regarding the nature and limits of our claims. First, although our analysis is relevant to evaluating the performance of private food safety audits, *we offer no judgment concerning the overall performance of either government regulation or private auditing in the area of food safety*. Such judgments would require analysis of the optimal level of risk reduction, the amount of risk reduction achieved, and the costs of this risk reduction—all of which are beyond the scope of this Article. Instead, we begin with the premise that government regulation alone cannot satisfy the demand for food safety and that private auditing plays a significant and growing role in the current food safety system, and we analyze different oversight mechanisms designed to improve the quality of private food safety audits. This Article analyzes the integrity of private audits, not their efficacy. Our focus on institutional design provides a better understanding of how private food safety auditing works, but it does not offer a general assessment of how well it works.

Second, *our analysis does not support a general preference for private over public regulatory instruments or vice versa*.<sup>28</sup> We claim only that, in the area of food safety, there is demand for both, and they are likely to coexist in the future. Nor do we believe that private and public regulatory instruments are mutually exclusive. In contrast to the highly polarized discourse over regulatory policy that prevails in American political culture—which pits defenders of command-and-control government regulation against advocates of unregulated markets—policy makers, industry participants, and scholars have long recognized that many areas of regulation are characterized by a diverse mix of

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28. The concept of “private regulation” may strike some readers as odd, especially in the context of contemporary political debate, which presents a stark choice between government regulation and unregulated private markets. For at least two decades, however, scholars within the “new governance” movement have emphasized that between these two extremes lies a spectrum of regulatory options, such as public-private partnerships, tradable permits, and private standard setting. There is a growing consciousness that economic and social regulation have never really been the exclusive domain of government authorities and that private entities can perform regulatory functions. For an introduction to this literature, see TIM BUTHE & WALTER MATTLI, *THE NEW GLOBAL RULERS: THE PRIVATIZATION OF REGULATION IN THE WORLD ECONOMY* (2011); Julia Black, *Critical Reflections on Regulation*, 27 *AUSTL. J. LEGAL PHIL.* 1 (2002); Fabrizio Cafaggi, *New Foundations of Transnational Private Regulation*, 38 *J.L. & SOC’Y* 20 (2011); Jody Freeman, *The Private Role in Public Governance*, 75 *N.Y.U. L. REV.* 543 (2000); Vogel, *supra* note 21, at 473–94; Daniel Diermeier, *Private Politics-A Research Agenda*, *POL. ECONOMIST* (Am. Political Sci. Ass’n), Summer 2007, at 1. For a recent collection of essays on private regulation of the food industry, see *PRIVATE FOOD LAW: GOVERNING FOOD CHAINS THROUGH CONTRACT LAW, SELF-REGULATION, PRIVATE STANDARDS, AUDITS AND CERTIFICATION SCHEMES* (Bernd M.J. van der Meulen ed., 2011) [hereinafter *PRIVATE FOOD LAW*]. See also TIMOTHY D. LYTTON, *KOSHER: PRIVATE REGULATION IN THE AGE OF INDUSTRIAL FOOD* (2013).

overlapping—and frequently complementary—public and private regulatory instruments.<sup>29</sup> Popular political discourse about the size of government and increasingly rigid battle lines between “progressive” liberals and “libertarian” conservatives is long on rhetoric and short on the kind of technical detail that is needed to support pragmatic efforts to evaluate and improve the performance of the imperfect institutional alternatives that comprise the food safety system.

#### I. AUDITOR CONFLICT OF INTEREST IN PRIVATE FOOD SAFETY AUDITING

The term “private food safety auditing” encompasses a number of distinct practices. We use the term to denote both inspection and auditing. “Inspection” generally refers to direct observation of production operations that provides a “snapshot” of activities and practices at a particular time.<sup>30</sup> By contrast, “auditing” refers to review of written records that document events at various times as well as ongoing policies and procedures.<sup>31</sup> Auditors commonly distinguish between conducting “factory floor inspections,” which involve walking the production line, and doing “paper audits,” which entail going through files in the office.<sup>32</sup> The term “food safety audit” commonly refers to some combination of inspection and auditing, and we adopt this usage.<sup>33</sup>

An important distinction within private food safety auditing—especially from the perspective of institutional design—is the

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29. See, e.g., IAN AYRES & JOHN BRAITHWAITE, *RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE* (1992); NEIL GUNNINGHAM, PETER GRABOSKY & DARREN SINCLAIR, *SMART REGULATION: DESIGNING ENVIRONMENTAL POLICY* (1998); *THE TOOLS OF GOVERNMENT: A GUIDE TO THE NEW GOVERNANCE* (Lester Salamon ed., 2002). For more recent studies, see Tetty Havinga, *Conceptualizing Regulatory Arrangements: Complex Networks of Actors and Regulatory Roles* (Nijmegen Sociology of Law, Working Paper No. 1, 2012), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2189471](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2189471); Lesley K. McAllister, *Harnessing Private Regulation*, 3 MICH. J. ENVTL. & ADMIN. L. (forthcoming 2014).

30. Powell et al., *supra* note 22, at 686.

31. *Id.*

32. Interview with Roy Costa, long-time food safety consultant and Professor, Valencia Coll. (Aug. 12, 2013); Interview with Bill Pursley, former Vice President of Food Safety Educ., AIB Int'l (Aug. 8, 2013).

33. See, e.g., Kathy L. Gombas, *Auditing Mechanics 101: A Guide for Auditors and Auditees*, FOOD SAFETY MAG., Apr.–May 2005, available at <http://www.foodsafetymagazine.com/magazine-archive1/aprilmay-2005/auditing-mechanics-101-a-guide-for-auditors-and-auditees/>; Larry Keener, *The Total Plant Food Safety Audit: Rating Your Overall System*, FOOD SAFETY MAG., Dec. 2002–Jan. 2003, available at <http://www.foodsafetymagazine.com/magazine-archive1/december-2002january-2003/the-total-plant-food-safety-audit-rating-your-overall-system/>; John G. Surak & Tatiana A. Lorca, *Process Auditing for Food Safety*, FOOD SAFETY MAG., Aug.–Sept. 2007, available at <http://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2007/process-auditing-for-food-safety/>.

relationship between the auditor and the entity being audited. First-party audits, also referred to as self-audits, are conducted by an in-house auditor who works as a full-time employee for a company in its quality-assurance or food safety division and who audits that company's own production operations.<sup>34</sup> Second-party audits are conducted by an in-house auditor at a downstream company, referred to as a "buyer," who audits that company's upstream suppliers. Third-party audits of a company's operations are conducted by independent contractors. Some companies obtain third-party audits for internal reasons related to their own quality control or food safety concerns or both. More commonly, companies are audited because a third-party audit is required by a buyer as a condition of doing business.<sup>35</sup> Suppliers typically pay for such audits.<sup>36</sup> Our analysis focuses on third-party supplier audits required by buyers.

The three parties to a third-party supplier audit are the buyer, supplier, and auditor. The buyer is a downstream purchaser of the supplier's product—for example, a manufacturer, such as Kellogg or PepsiCo; a retail seller, such as Walmart or Costco; or a food-service operator, such as McDonald's or Sodexo. The supplier is the upstream source of raw materials, ingredients, or finished products—for example, a grower, such as a corn farmer; a processor, such as a corn oil producer; or a manufacturer, such as a corn chip maker. And finally, the auditor is an entity independent of the buyer and supplier, either an individual, such as a private food safety consultant, or a firm, such as the American Institute of Baking (AIB) or Primus Labs.

Buyers typically specify the standards used in third-party supplier audits. Buyers may require audits using their own standards or standards developed by third-party auditing firms, industry associations, or standard-setting organizations. Buyers may also customize external audit schemes to suit their own particular needs.<sup>37</sup> In most cases, audits include elements that assess compliance with government regulatory requirements.<sup>38</sup> Auditors are generally capable of performing audits to a

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34. Powell et al., *supra* note 22, at 687.

35. These definitions are drawn from Powell et al., *supra* note 22, at 687; *see also* Laurence Busch, *Quasi-States? The Unexpected Rise of Private Food Law*, in *PRIVATE FOOD LAW*, *supra* note 28, at 60–61.

36. Powell et al., *supra* note 22, at 688 (explaining that “[a]lmost all food producers/retailers require their suppliers to pay for their own audits”); *see also* Busch, *supra* note 35, at 61 (noting that “it is the firm that is to be certified that pays the certifier”).

37. Powell et al., *supra* note 22, at 687; Stier, *supra* note 23.

38. Powell et al., *supra* note 22, at 687; *see also* GLOBAL FOOD SAFETY INITIATIVE, *supra* note 23, at 23 (noting that GFSI-recognized schemes audit for regulatory compliance).

variety of standards, although as standards become more detailed and complex, auditors are increasingly specializing.<sup>39</sup> In addition to specifying audit standards, buyers typically require their suppliers to obtain audits from a list of approved auditors.<sup>40</sup> Suppliers must maintain ongoing certification that they are in compliance with standards specified by a buyer to do business with that buyer.

Audits may be announced or unannounced. Announced audits allow an audited company to prepare its operations and organize its records for review. This reduces the time, and consequently the cost, of the audit. Announced audits evaluate a company's best efforts and uncover what it does not know.<sup>41</sup> By contrast, unannounced audits offer insight into normal operating conditions.<sup>42</sup> Suppliers increasingly obtain their own preaudit audits to prepare for audits required by their buyers and increase their chances of obtaining certification.<sup>43</sup> Some auditing firms offer consulting services to assist companies with audit compliance.<sup>44</sup> Figure 1 illustrates the relationship between supplier, auditor, and buyer in a typical third-party supplier certification audit.

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39. Interview with Patricia Wester, Vice President of Regulatory Affairs, Food Safety Net Services, and board member, Food Safety Services Providers (Aug. 13, 2013).

40. Michael Garry, *Food Safety Conundrum: Third-Party Audits*, SUPERMARKET NEWS (Feb. 2, 2012), <http://supermarketnews.com/food-safety/food-safety-conundrum-third-party-audits> (noting that Costco only accepts audits from approved auditing firms); Elizabeth Weise, *Food Safety Auditors Are Often Paid by the Firms They Audit*, USA TODAY, Oct. 4, 2010, [http://usatoday30.usatoday.com/money/industries/food/2010-10-01-foodaudits01\\_ST\\_N.htm](http://usatoday30.usatoday.com/money/industries/food/2010-10-01-foodaudits01_ST_N.htm) (describing how some buyers maintain a list of authorized auditors).

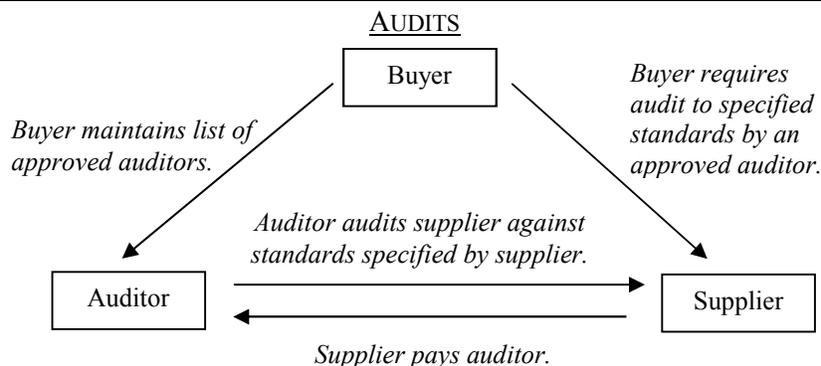
41. For discussion of the benefits of careful company preparation for an audit, see Gombas, *supra* note 33; Rena M. Pierami & John Williams, Jr., *Guaranteeing a Great Audit*, FOOD SAFETY MAG., Oct.–Nov. 2007, available at <http://www.foodsafetymagazine.com/magazine-archive1/october-november-2007/guaranteeing-a-great-audit/>; George Howlett, *Unannounced Audits*, SAFEFOOD 360° (July 27, 2013), <http://safefood360.com/unannounced-audits/>.

42. Fagotto, *supra* note 14, at 106 (describing the disadvantages of announced audits); Howlett, *supra* note 41; Powell et al., *supra* note 22, at 689 (arguing that “[m]ore effective audit systems incorporate unannounced visits”).

43. Stier, *supra* note 23. See, e.g., *Pre Audits*, MICRON2, [http://micron2.com/?page\\_id=149](http://micron2.com/?page_id=149) (last visited Jan. 10, 2014) (describing pre-audit services of Micron2, a British food safety auditing firm).

44. See Interview with Bill Pursley, *supra* note 32. See, e.g., *Food Safety Modernization Act (FSMA) Services*, NSF INT'L, <http://www.nsf.org/services/by-industry/food-safety-quality/food-safety-modernization-act/> (last visited Jan. 10, 2014) (describing “analysis/consultation” services of NSF International, a U.S. food safety auditing firm).

FIGURE 1. THE STRUCTURE OF THIRD-PARTY SUPPLIER CERTIFICATION



The typical fee arrangement in third-party supplier audits—whereby the supplier pays the auditor—creates a conflict of interest for the auditor.<sup>45</sup> Since certification is a condition of market access, some suppliers are more interested in satisfactory audit scores than in rigorous evaluation of their operations.<sup>46</sup> Some suppliers “will hunt down the fastest, cheapest, easiest, and least-intrusive third-party audit that will provide the certificate,” explains former FDA Associate Commissioner for Foods David Acheson.<sup>47</sup> Audits are expensive—fees range from \$1,000 to more than \$25,000.<sup>48</sup> Moreover, companies do not believe that audits enhance the value of their products to consumers.<sup>49</sup> According to one industry observer, marketing food safety “is like an airline saying ‘We haven’t had a crash in twelve years.’”<sup>50</sup> Consequently, auditors competing for accounts have incentive to reduce the cost and burden of audits by spending less time, downplaying food safety risks, and inflating audit scores.<sup>51</sup> “Some auditing firms are becoming known for their lower

45. Spencer Henson & James Northern, *Economic Determinants of Food Safety Controls in Supply of Retailer Own-Branded Products in United Kingdom*, 14 *AGRIBUSINESS* 113, 122 (1998) (explaining that buyers outsource food safety audits to third-party auditors paid by suppliers to increase the buyers’ operating margins).

46. Irwin Pronk, *Is Food Safety Auditing about Safety or Money? GFSI-Light?*, *BARFBLOG* (May 4, 2011), <http://barfblog.com/tags/irwin-pronk/> (describing how some suppliers “have been choosing certification bodies based on price alone, compromising the integrity of audits”).

47. Sun, *supra* note 18.

48. *Id.*

49. Interview with Michael Doyle, Regents Professor of Microbiology and Dir. of the Ctr. for Food Safety, Univ. of Ga. (Aug. 6, 2013) (asserting that food safety is a “non-competitive issue”).

50. Interview with Keith Schneider, Professor of Food Sci., Univ. of Fla. (Aug. 2, 2013).

51. Pronk, *supra* note 46; Irwin Pronk, *Third-Party Audits: Missing the Forest for the Trees*, *BARFBLOG* (Nov. 5, 2010) [hereinafter Pronk, *Third-Party Audits*], <http://barfblog.com/tags/irwin-pronk/>. Individual auditors may reduce the rigor of their

cost quotes, and the result is an inadequate audit,” asserts Irwin Pronk, a prominent food safety consultant.<sup>52</sup>

Before examining oversight mechanisms that address this conflict of interest, it may be helpful to further specify the nature of the conflict involved and its influence on audit quality. Auditors have a financial interest in getting hired and rehired by suppliers, some of whom want the cheapest certification that they can obtain. This financial interest gives auditors an incentive to reduce the rigor of audits by cutting corners and skewing results.<sup>53</sup> Cutting corners means that the auditor is less diligent in the thoroughness and scope of an audit than a disinterested auditor of equal skill would be in similar circumstances. Skewing results means that an auditor exercises discretion in a way that favors a supplier’s financial interest more than would the professional judgment of a disinterested auditor of equal professional skill in similar circumstances.<sup>54</sup> Thus, there is a conflict between the auditor’s financial interest and his professional obligation to protect the public from food safety risks.

The professional obligations of food safety auditors are not as well defined as those of some other professions.<sup>55</sup> However, based on accreditation standards, audit schemes, professional literature, popular press accounts of auditing, and interviews with experienced auditors, we posit that food safety auditors have a professional obligation to perform audits as would a disinterested auditor.<sup>56</sup> By “disinterested auditor,” we

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audits on their own initiative or, if they work for an auditing firm, under the direction of a manager. *Id.*

52. Pronk, *supra* note 46.

53. *Id.*; Pronk, *Third-Party Audits*, *supra* note 51.

54. Cutting corners and skewing results may be conscious or unconscious on the part of the auditor. See McAllister, *supra* note 26, at 37–38 (discussing conscious and unconscious bias in financial accounting); see also Esther Duflo et al., *Truth-Telling by Third Party Auditors and the Response of Polluting Firms: Experimental Evidence from India*, 128 Q.J. ECON. 1499, 1504 (2013).

55. Many professions have detailed ethics codes. See, e.g., *AMA’s Code of Medical Ethics*, AM. MED. ASS’N, <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page> (last visited Jan. 20, 2014); *Code of Ethics*, SOC’Y PROF. JOURNALISTS, <http://www.spj.org/pdf/ethicscode.pdf> (last visited Mar. 10, 2014); *Model Rules of Professional Conduct*, AM. BAR. ASS’N, [http://www.americanbar.org/groups/professional\\_responsibility/publications/model\\_rules\\_of\\_professional\\_conduct.html](http://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct.html) (last visited Jan. 30, 2014).

56. See, e.g., INT’L ORG. FOR STANDARDIZATION (ISO) & INT’L ELECTROTECHNICAL COMM’N (IEC), ISO/IEC 17065 CONFORMITY ASSESSMENT—REQUIREMENTS FOR BODIES CERTIFYING PRODUCTS, PROCESSES AND SERVICES §§ 3.13, 4.2, 5.2, A.2 (2012) [hereinafter ISO/IEC 17065] (accreditation standard); *Criteria for SQF Certification Bodies*, SAFE QUALITY FOOD INST. (July 2012) [hereinafter *SQF Criteria*], <http://www.sqfi.com/wp-content/uploads/Criteria-for-Certification-Bodies-7-24-12.pdf> (audit scheme); T. Sikora, M. Niewczas & A. Prusak, *Ethics and Trust in Quality Assurance* (57th EOQ Congress, Quality Renaissance - Co-creating a Viable

mean an auditor whose diligence and judgment are based exclusively on a commitment to public welfare that balances risk reduction against social cost to determine the optimal level of audit rigor. We recognize that disinterested auditors lack the information and the capacity to calculate precisely the socially optimal level of audit rigor. We assume, however, that disinterested auditors are guided by their own rough sense of optimal rigor—what they might describe as their unbiased professional judgment about the appropriate level of scrutiny and skepticism in a particular set of circumstances. Moreover, independent audit schemes, which we discuss below, have developed specific provisions about the duration, frequency, and thoroughness of audits that aim to define the optimal level of audit rigor.<sup>57</sup>

We focus on conflict of interest as distinct from other sources of limited or reduced audit rigor. For example, auditors may limit audit rigor based on considerations of social cost (rigor beyond a certain level may generate costs to consumers that outweigh any additional reduction in food safety risk), or buyers and suppliers may specify undemanding audit standards. Our concern, however, is not the proper balance of risk reduction and social cost or the insufficient rigor of audit standards, but rather the conflict of interest between private financial interest and professional obligation which leads auditors to cut corners and skew results.<sup>58</sup>

Two features of food safety auditing make it difficult to detect when auditors cut corners or skew results. First, food safety audits involve highly technical judgments, and auditors must exercise considerable discretion in evaluating compliance and scoring audits.<sup>59</sup> Uncovering auditor bias requires specialized expertise and careful scrutiny. Second, many victims of foodborne illness never attribute it to food—and even if they do, they are unable to identify its source. Unreliable audits

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Future, 2013), available at <http://www.quality2013.eu/sites/www.quality2013.eu/files/webform/fullpapers/Sikora%20Niewczas%20Prusak.pdf> (professional literature); Weise, *supra* note 40 (popular press); Interview with Charles Cook, Founder, Cook & Thurber (Aug. 13, 2013).

57. See, e.g., SQF INST., SQF CODE § 2.5 (7.1 ed. 2013), available at <http://www.sqfi.com/wp-content/uploads/SQF-Code-Ed-7.1-4-3-13.pdf>.

58. Our focus on auditor conflict of interest leaves aside the question of whether suppliers also have a conflict of interest between their private financial interest and a duty to produce safe food. We also leave aside the problem of government officials taking bribes, which is a related but distinct problem. See, e.g., Benjamin Weiser, *Food Inspectors Facing Charges in Bribery Case*, N.Y. TIMES, Oct. 28, 1999, <http://www.nytimes.com/1999/10/28/nyregion/food-inspectors-facing-charges-in-bribery-case.html?pagewanted=print> (reporting a scandal involving USDA inspectors taking bribes).

59. On audit complexity and the need for professional judgment, see Stier, *supra* note 23.

undoubtedly cause harm, but the harm is rarely traced back to the auditor.<sup>60</sup> The difficulty of detecting when auditors cut corners or skew results reduces the risk of legal or reputational sanctions that would otherwise provide buyers and suppliers incentive to demand rigorous audits and auditors' incentive to provide them. This exacerbates the conflict of interest.

We do not know how widespread this problem is, nor do we know any way to measure it. Evidence of the problem remains entirely anecdotal. Moreover, the conflict of interest faced by auditors may not be entirely, or even primarily, financial. Some auditors have a desire to be liked by company personnel with whom they have ongoing and regular contact. This is especially true in small towns where local auditors may interact socially as well as professionally with company personnel. In some cases, auditors may downplay problems or skew results to avoid generating resentment or complaints to the firm that employs them that they are being unreasonably stringent. Auditors may also reduce the rigor of audits so as not to subject company food safety managers to the disapproval of senior management at the company.<sup>61</sup>

Nevertheless, personal interviews, professional commentary, and the popular press suggest that financial conflict of interest compromises the integrity of some audits and undermines public confidence in private food safety auditing more generally.<sup>62</sup> As we shall demonstrate below,

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60. On the difficulties of tracing foodborne illness to a particular food safety failure, see Doering, *supra* note 9. See also JEAN BUZBY ET AL., ECON. RESEARCH SERV., REPORT NO. 799, PRODUCT LIABILITY AND MICROBIAL FOODBORNE ILLNESS 24 (2001), available at <http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCgQFjAA&url=http%3A%2F%2Fwww.ers.usda.gov%2FersDownloadHandler.a shx%3Ffile%3D%2Fmedia%2F533488%2Faer799.pdf&ei=rKUuU-2lFqik2gXS8oHYC Q&usq=AFQjCNGs qcabGOSRAI4RhDK7LRJorlgePw&sig2=zU2A7mCx-ZFocewY2H hpUw&bvm=bv.62922401,d.b2I>; CAROLINE SMITH DEWAAL ET AL., CTR. FOR SCI. IN THE PUB. INTEREST, ALL OVER THE MAP: A 10-YEAR REVIEW OF STATE OUTBREAK REPORTING (2011), available at <http://cspinet.org/new/pdf/alloverthemap.pdf> (analyzing variability among states in surveillance and reporting of foodborne illness outbreaks); Dennis Stearns, *On (C)redibility: Why Food in the United States May Never Be Safe*, 21 STAN. L. & POL'Y REV. 245, 258 (2010); Moss & Martin, *supra* note 5 (comparing the frequency of having foodborne illness traced back to a particular supplier to a "meteor strike").

61. Telephone Interview with Jim Prevora, leading food safety commentator in the produce industry (Jan. 28, 2014).

62. See, e.g., Friederike Albersmeier et al., *The Reliability of Third-Party Certification in the Food Chain: From Checklists to Risk-Oriented Auditing*, 20 FOOD CONTROL 927 (2009); Busch, *supra* note 35, at 61, 65; Powell et al., *supra* note 22, at 689; *Editorial: Food Safety Auditors Too Tied to Industry*, USA TODAY, Dec. 24, 2012, <http://usatoday30.usatoday.com/news/opinion/editorials/story/2012-01-24/contaminated-cantaloupe-food-auditors/52780580/1>; Interview with Richard Stier, a leading food safety scientist and food safety commentator on auditing (Aug. 26, 2013). For empirical evidence of conflict of interest in third-party environmental audits as a result of auditors being paid by regulated entities, see Duflo et al., *supra* note 54.

audit firm management policies, audit scheme guidelines, accreditation standards, and industry association benchmarks all include provisions that specifically address the problem.<sup>63</sup> At the very least, it is safe to say that both industry insiders and outside commentators believe it to be a significant concern that merits attention.

## II. OVERSIGHT MECHANISMS

Multiple oversight mechanisms create incentives that counteract auditors' private financial incentive to reduce the rigor of audits. This oversight may be aimed at auditors or at others with direct or indirect influence over auditors. The system of oversight is extensive and complex, and there are significant variations in different sectors of the industry. We do not purport to offer a detailed or comprehensive account. Instead, our analysis is schematic, canvassing a number of oversight mechanisms that involve particular institutional actors and regulatory instruments and highlighting their comparative strengths and weaknesses. Table 1 presents an overview of these different institutional actors, regulatory instruments, and comparative criteria.

TABLE 1. OVERVIEW OF ANALYSIS

<b>Institutional Actors</b>	suppliers, audit firms, buyers, plaintiffs' attorneys, liability insurers, accreditation bodies, audit scheme owners, industry associations, government agencies, media, and consumer organizations
<b>Regulatory Instruments</b>	training, management oversight, supply chain pressure, tort liability, insurance, standard setting, third-party auditing, accreditation, licensing, public reporting
<b>Comparative Criteria</b>	access to information about the rigor of audits, ability to alter financial incentives, ability to alter the normative environment, susceptibility to conflict of interest, over-deterrence, administrative efficiency, capacity to generate feedback and learning, stakeholder participation, transparency, democratic accountability

Within this system, there is no one-to-one correspondence between institutional actors and regulatory instruments. Two different actors can use the same instrument and the same actor can use multiple instruments.

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63. See *infra* Part II.F.

Moreover, interrelations between the various combinations of institutional actors and regulatory instruments create a network of oversight and accountability with its own strengths and weaknesses.

### *A. Supplier Self-Regulation*

Many suppliers are motivated by personal morality or the brand value of their products to demand rigorous audits of their operations. Rigorous audits can help suppliers improve their operations, reduce risk to consumers, and increase their attractiveness to buyers. These suppliers train their staff to cooperate fully with auditors, and they provide management oversight to support thorough inspection and document review.<sup>64</sup>

Supplier self-regulation has several comparative advantages. Suppliers have easy access to information about the rigor of audits of their own operations at little to no cost. Because they pay for audits, suppliers can create financial incentive for auditors to avoid cutting corners or skewing results. And because they bear the cost of audits, suppliers are especially vigilant about avoiding administrative inefficiency and over-deterrence. In training and managing staff, suppliers can create an organizational culture that makes food safety a priority and supports rigorous audits.<sup>65</sup> When suppliers receive feedback from buyers and consumers, they are in a good position to use it to quickly improve their operations.

Supplier self-regulation also has several comparative shortcomings. Even if most suppliers are morally committed to consumer safety, unscrupulous suppliers who have lower audit costs can create pressure on competitors—who would otherwise be more diligent—to reduce the rigor of their audits.<sup>66</sup> Moreover, in practice, the difficulty of tracing

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64. Michael Cramer & Tammi Frederick, *Awesome Audit Attitudes: Jumping through Hoops without Grinding Gears*, FOOD SAFETY MAG., Apr.–May 2004, available at <http://www.foodsafetymagazine.com/magazine-archive1/aprilmay-2004/awesome-audit-attitudes-jumping-through-hoops-without-grinding-gears/> (describing best practices for supplier facilitation of rigorous audits); Erin Holleran et al., *Private Incentives for Adopting Food Safety and Quality Assurance*, 24 FOOD POL'Y 669, 679 (1999) (analyzing supplier incentives to obtain rigorous audits); Stier, *supra* note 23 (noting that some suppliers obtain audits out of a “genuine desire to improve”). For a general introduction to self-regulation, see Neil Gunningham & Joseph Rees, *Industrial Self-Regulation: An Institutional Perspective*, 19 L. & POL'Y 363, 363–66 (1997).

65. For a discussion of how to enhance food safety culture within a firm, see Douglas Powell et al., *Enhancing Food Safety Culture to Reduce Rates of Foodborne Illness*, 22 FOOD CONTROL 817, 818 (2011). For a discussion of industrial morality more generally, see Gunningham & Rees, *supra* note 64, at 376–80.

66. Pronk, *supra* note 46; Ching-Fu Lin, *Challenges to Third-Party Food Safety Audits and Certification*, BILL OF HEALTH (Dec. 5, 2013), <http://blogs.law.harvard.edu/billofhealth/2013/12/05/challenges-to-third-party-food-safety-audits-and-certification/>.

foodborne illness back to a particular supplier diminishes the risk of damage to a supplier's brand from less rigorous audits and reduces the feedback to suppliers that food safety failures provide. Finally, supplier self-regulation lacks the stakeholder participation and transparency that lend other oversight mechanisms greater legitimacy. Although consumer response to food safety failure could constitute a type of democratic accountability that supports legitimacy, traceability problems limit consumers' ability to hold companies accountable.

### *B. Audit Firm Quality Control*

Leading audit firms provide auditor training and management oversight to ensure the rigor of their audits. These firms are motivated by a sense of organizational mission and a desire to increase the brand value of their services in an increasingly competitive market.<sup>67</sup> For example, one leading food safety auditing firm recruits experienced food safety managers from private industry to conduct its audits and provides them with ongoing training in particular areas of food safety and general investigative techniques.<sup>68</sup> The firm's auditors are trained to place the burden on suppliers to demonstrate that they have adequate food safety controls and that these controls are verifiably effective.<sup>69</sup> The firm's middle managers conduct routine shadow audits of their own auditors to assure the quality of the auditors' work, and managers review every audit report for thoroughness and consistency.<sup>70</sup> After auditors generate audit reports with ratings and recommendations, certification decisions are made by a separate office within the firm which also carefully reviews audit reports.<sup>71</sup>

Audit firm quality control has several comparative advantages. Audit firms have access to information at little to no cost about the rigor of audits conducted by their auditors. Since the auditor is paid by the firm, not by the supplier, the audit firm can create financial incentives for the auditor to apply the level of rigor desired by the audit firm and to file an accurate written account of each audit with the firm. Audit firms whose mission includes a commitment to integrity have reason and leverage to cultivate that commitment among their employees. Audit firms are also especially sensitive to administrative inefficiency and over-deterrence because providing audits where the costs outweigh the

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67. Interview with Rena Pierami, Vice President of Auditing, Silliker (Sept. 9, 2013).

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

value makes firms less competitive. When audit firms receive feedback from suppliers and buyers, they are highly motivated and well-positioned to use it to improve their services.<sup>72</sup> Because they provide services to many different suppliers who produce many different products, audit firms have many opportunities for feedback, and they face a higher risk that an incidence of foodborne illness will eventually be traced back to them if they perform unreliable audits.

Audit firm quality control also has several shortcomings. Audit firms that maintain high standards of audit rigor risk losing market share and being driven out of the market altogether if their competitors are able to underbid them for accounts. Economic survival may trump organizational mission and require that firms build their brands not only on high standards, but also on competitive pricing. Moreover, a shortage of qualified auditors—who must possess the requisite technical knowledge and practical experience, be willing to travel to remote places to perform physically strenuous work, and put in long hours for moderate pay—has made it difficult for most firms to retain auditors and has led them to rely on independent subcontractors.<sup>73</sup> Audit firms have less influence over independent subcontractors than they do over their employees, and this diminishes the effectiveness of their efforts to maintain a consistently high level of rigor in their auditing services.<sup>74</sup> Audit firms also lack the stakeholder participation, transparency, and public accountability that lend legitimacy to other oversight mechanisms.

### *C. Buyer Vigilance*

Because retail buyers deal more directly with consumers, they are highly brand sensitive. Moreover, their name recognition and deep pockets make them especially vulnerable to tort liability in the case of a food safety failure. Consequently large buyers monitor the rigor of audits by reviewing audit reports and sending their own employees to conduct shadow audits.<sup>75</sup> Buyers also use supply chain pressure to promote

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72. For a discussion of the capacity for learning among forestry certification programs, see Errol Meidinger, *The Administrative Law of Global Private-Public Regulation: The Case of Forestry*, 17 EUR. J. INT'L L. 47, 78 (2006).

73. Interview with Bill Purlsey, *supra* note 32.

74. *Id.* (noting that AIB relies only on fulltime employees since this allows for greater control over the quality of audits). *But see* Jim Prevor, *When It Comes to Audits . . . Retailers Get What They Specify*, JIM PREVOR'S PERISHABLE PUNDIT (Oct. 23, 2011), <http://www.perishablepundit.com/index.php?date=10/23/2011&pundit=4> (suggesting that “some of the best auditors become contractors because they can make more money than as a salaried employee of any of the auditing companies”).

75. Some buyers contract consultants who specialize in food safety to oversee the auditing of their suppliers. Interview with Charles Cook, *supra* note 56; Interview with Dave Theno, leading food safety consultant (Sept. 12, 2013).

rigorous auditing by refusing to purchase the goods of suppliers who do not demand rigorous audits and by refusing to accept certification audits by auditors who cut corners and skew results.<sup>76</sup>

The market power of large buyers equips them to create strong financial incentives for suppliers to demand rigorous audits and auditors to provide them.<sup>77</sup> Market power also allows buyers relatively easy access to information about the rigor of audits through reviewing reports and shadow auditing.<sup>78</sup> In addition, because buyers sell products under their own brand names, they are more identifiable to consumers than suppliers and auditors, and so they are more likely to receive feedback from food safety failures. Buyers incorporate this information into their oversight of supplier certification audits, and they pass it on to suppliers and auditors. Their brand recognition also makes them more vulnerable to legal and reputational sanctions for food safety failures, which gives them incentive to exercise vigilant oversight of suppliers and auditors.<sup>79</sup>

Although buyers are well equipped to create financial incentives that favor rigorous audits, they have limited ability to shape a mission and a culture that prioritize food safety within supply operations and audit firms that make food safety a top priority. Mission and culture are arguably more effectively shaped by management within an organization rather than by pressure from outside.<sup>80</sup> The gap between overseeing and performing an audit makes buyers less well situated than suppliers and auditors to institute improvements based on feedback. Moreover, like suppliers and auditors, buyers also face competitive pressures to cut costs, which may lead them to be less vigilant in their oversight of supplier certification audits. While buyers' quality assurance departments may consider food safety a top priority, their marketing departments may not view it as a primary driver of brand value.<sup>81</sup> Also, the large number of audits that a major buyer has to deal with limits the extent of shadow auditing and the thoroughness of audit review.<sup>82</sup> Jim Prevor, a leading

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76. Interview with Bob Brown, Director of Nutrition, Frito-Lay (July 30, 2013); Interview with Craig Wilson, Vice President for Food Safety and Quality Assurance, Costco (Aug. 15, 2013).

77. Henson & Northern, *supra* note 45, at 117.

78. *Id.* at 120.

79. *Id.* at 118.

80. See JANICE KLEIN, TRUE CHANGE: HOW OUTSIDERS ON THE INSIDE GET THINGS DONE IN ORGANIZATIONS 2, 48 (2004) (arguing that true change comes from within an organization). We do not mean to imply, however, that external incentives cannot contribute to change within an organization. See Gunningham & Rees, *supra* note 64, at 389–96 (discussing the efficacy of external pressure in influencing industrial morality).

81. Interview with Keith Schneider, *supra* note 50.

82. Interview with Jim Prevor, leading food safety commentator in the produce industry (Aug. 13, 2013).

commentator on the fresh produce industry, explains that in a typical supermarket, the produce section alone stocks 900 items, with multiple vendors for each item and each vendor may purchase from hundreds of producers.<sup>83</sup> The one supermarket employee charged with audit review likely has little time to do more than merely affirm that each of the tens of thousands of suppliers is certified.<sup>84</sup> In addition, since they outsource the cost of audits to suppliers, buyers are less sensitive to over-deterrence.<sup>85</sup> According to Devon Zagory, the founder of a leading food safety auditing firm in the produce sector, retail buyers often unrealistically demand that their suppliers eliminate 100 percent of the risk of foodborne illness, regardless of the cost.<sup>86</sup> Like supplier self-regulation and auditor quality control, buyer oversight lacks the stakeholder participation and transparency that lends legitimacy to other regulatory oversight mechanisms, although buyers' brand sensitivity and liability exposure may make them relatively more accountable to consumers for food safety failures.

#### *D. Tort Litigation*

Motivated by injury compensation and contingency fees, tort plaintiffs and their attorneys can impose costly liability on buyers, suppliers, and auditors for their food safety failures. Suppliers and buyers are strictly liable for injuries caused by unsafe products that they sell, and this liability exposure gives them incentive to promote rigorous auditing.<sup>87</sup> Brad Sullivan, an attorney who represents produce suppliers, asserts that "liability exposure is a major driver of risk management among growers."<sup>88</sup> Plaintiffs have also recently begun to file claims against food safety auditors for negligence.<sup>89</sup> Tort doctrine defines

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83. *Id.*

84. *Id.*

85. Interview with Devon Zagory, Founder, Davis Fresh (Aug. 21, 2013).

86. *Id.*

87. For a general introduction to strict liability for product manufacturers and sellers, see DAN DOBBS, *THE LAW OF TORTS* 969–1045 (2000). For discussion of food sellers' liability for microbial illness, see BUZBY, *supra* note 60.

88. Interview with Brad Sullivan, an attorney who represents produce suppliers (Aug. 15, 2013).

89. See Press Release, Marler Clark, Marler Clark Sues Cantaloupe Distributor & Farm Auditor in Louisiana (Sept. 24, 2012), [http://www.marlerclark.com/press\\_releases/view/marler-clark-sues-cantaloupe-distributor-farm-auditor-in-louisiana](http://www.marlerclark.com/press_releases/view/marler-clark-sues-cantaloupe-distributor-farm-auditor-in-louisiana) (announcing the filing of a lawsuit against a leading food safety auditor). See also Ronen Avraham, *Private Regulation*, 34 HARV. J.L. & PUB. POL'Y 546, 552 (2011) (advocating tort liability for private medical standard setters to promote optimal patient safety); Rafferty, *supra* note 5 (arguing that requiring food safety auditors to indemnify other defendants in a tort claim would improve the quality of audits); Divya Anantharaman et al., *State Liability Regimes within the United States and Auditor Reporting* 38–39 (Dec.

negligence as the failure to exercise the care of an ordinary, prudent person acting in similar circumstances, which is often further defined in cases of professional negligence as the failure to exercise a level of care that is cost-effective or the level of care customarily exercised by other professionals in the same field.<sup>90</sup> This definition of negligence instantiates the professional standard of the disinterested auditor, and tort liability is a practical way to enforce compliance with it. Whereas suppliers, auditors, and buyers all have a financial incentive to cut costs by reducing the rigor of audits, plaintiffs and their attorneys have a financial incentive to identify the optimal level of rigor in food safety auditing and to bring claims against those who fall short of it.

As an oversight mechanism, tort law has a number of comparative advantages. Liability exposure creates a powerful incentive for buyers, suppliers, and auditors to assure an optimal level of rigor in food safety audits.<sup>91</sup> The litigation process itself offers additional regulatory benefits. In filing claims, tort plaintiffs may frame foodborne illness outbreaks in ways that highlight particular failures in the private food safety auditing system—for example, carelessness in the selection or supervision of auditors or in the execution of audits. The discovery process generates valuable performance feedback. During discovery, plaintiffs can compel suppliers, auditors, and buyers to disclose information about audit quality that might not otherwise come to light.<sup>92</sup> Discovery can also uncover information linking a foodborne illness outbreak to a particular buyer, supplier, and auditor. Each stage of the litigation, from filing to final outcome, can generate media coverage that magnifies the reputational effects of food safety failures and places and maintains food safety improvement on the top of corporate, government, and public agendas.<sup>93</sup>

Tort litigation also has shortcomings as a regulatory tool. The generation of useful feedback is limited in practice because tort claims against multiple strictly liable defendants are frequently settled without

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10, 2013) (unpublished manuscript), *available at* [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2372993](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2372993) (finding that financial auditors “are more likely to issue a modified going-concern (GC) report to financially distressed clients headquartered and/or incorporated in high litigation states” and that modified GC reporting has decreased significantly in states that passed laws reducing the liability exposure of auditors).

90. See DOBBS, *supra* note 87, at 277–80.

91. This is true regardless of whether the liability exposure is based on negligence or strict liability. See STEVEN SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 262 (2004) (explaining how strict liability in a tort, like negligence, provides incentive to take optimal care).

92. FED. R. CIV. P. 26.

93. See TIMOTHY D. LYTON, HOLDING BISHOPS ACCOUNTABLE: HOW LAWSUITS HELPED THE CATHOLIC CHURCH CONFRONT CLERGY SEXUAL ABUSE 81–162 (2008) (analyzing the framing, information disclosure, and agenda-setting effects of the tort litigation process).

identification of the precise cause of a plaintiff's illness within the supply chain.<sup>94</sup> Supply contracts typically require suppliers to indemnify buyers for any liability arising out of foodborne illness, simply pushing liability up the supply chain.<sup>95</sup> Moreover, critics assert that tort litigation is inefficient. They argue that attorneys' fees on both sides, court costs, and the extensive time and energy expended by parties in litigation are a high price for a modest regulatory benefit.<sup>96</sup> To be sure, these costs appear very high in comparison to those of supplier self-regulation, auditor quality control, and buyer oversight. A complete appraisal, however, would have to weigh these against the regulatory benefits, which are difficult to quantify. Similarly, in comparing the comparative efficiency of tort litigation to government regulation, a fair comparison would have to take into account the full cost of the legislative process, the notice-and-comment rule-making process, and enforcement costs. One would also need to compare their effectiveness.

Critics have also questioned the legitimacy of tort litigation as a regulatory tool.<sup>97</sup> Participation is limited to a very narrow range of stakeholders; private negotiations and settlements are generally not transparent; and plaintiffs' attorneys are not democratically accountable to either the electorate or consumers (nor, in many states, are judges). At the same time, tort litigation allows important stakeholders—victims of foodborne illness—to participate directly in investigating misconduct and enforcing standards in food safety auditing, and much of the process is a matter of public record.

### *E. Liability Insurance*

Liability insurance translates the uncertain prospect of getting sued into more immediate and specific financial incentives to optimize risk reduction.<sup>98</sup> Buyers, suppliers, and auditors all carry insurance that covers liability for foodborne illness and, in some cases, the cost of recalling products.<sup>99</sup> Some of these policies set premiums based on the

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94. On the difficulty of establishing causation, see *supra* note 60.

95. Interview with Brad Sullivan, *supra* note 88.

96. See, e.g., WALTER OLSEN, *THE RULE OF LAWYERS: HOW THE NEW LITIGATION ELITE THREATENS AMERICA'S RULE OF LAW* 1–24 (2003); W. Kip Viscusi, *Overview*, in *REGULATION THROUGH LITIGATION* 1–21 (W. Kip Viscusi ed., 2002).

97. Viscusi, *supra* note 96, at 1.

98. For an introduction to the mechanics of liability insurance underwriting, see Tom Baker & Thomas O. Farrish, *Liability Insurance and the Regulation of Firearms*, in *SUNG THE GUN INDUSTRY: A BATTLE AT THE CROSSROADS OF GUN CONTROL & MASS TORTS* 292–98 (Timothy D. Lytton ed., 2005).

99. This coverage comes in many forms, including primary commercial liability coverage, excess coverage, umbrella coverage, director's and officer's coverage, errors and omissions coverage, miscellaneous professional liability coverage, and product recall

insured's history of past claims—a practice known as experience rating—to encourage an optimal level of risk reduction in food safety practices, including auditing.<sup>100</sup>

In theory, liability insurance has a number of comparative strengths. When writing coverage, insurers have access to information about audit rigor, and they have a financial interest in determining the optimal level of risk reduction.<sup>101</sup> Liability insurers can then use underwriting techniques such as experience rating and coverage exclusions to give policyholders specific financial incentives to take cost-effective precautions. Insurers can also provide their policyholders with performance feedback to reduce risk. Like plaintiffs' attorneys, insurers' private financial interests are aligned with the public interest in optimal risk reduction. Insurers also have incentive to minimize their administrative costs, which motivates them to be more efficient.

In practice, however, liability insurance in the food industry currently falls short of this ideal. Accurately pricing risk is difficult. For example, in the produce industry, the risk of contamination by pathogens varies greatly from product to product, and even within a single product the risk varies based on season, region, and scale of production.<sup>102</sup> Moreover the science concerning how contamination occurs and the level of risk to human health that it imposes, as well as techniques and technology for tracing foodborne illness back to a particular source, are still emerging.<sup>103</sup> Pricing such risks is a challenge for even the most sophisticated and experienced underwriters.<sup>104</sup>

The difficulty of pricing risk may lead to problems of both over-deterrence and under-deterrence. According to Sullivan, in the wake of major outbreaks, some liability insurers “tend to overreact—they set impossible standards or simply stop writing policies.”<sup>105</sup> By contrast, Chuck Stauber, a former AIG employee who specializes in food industry liability insurance, worries that, in a competitive race to develop new product lines and increase their market share, underwriters are too quick to write coverage, which creates a moral hazard among suppliers and

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coverage. Interview with Charles Stauber, Vice President and Head of Casualty Claims, Torus Insurance USA, (Aug. 27, 2013). *See also* BUZBY, *supra* note 60.

100. *See* SHAVELL, *supra* note 91 (explaining how strict liability in tort provides incentive to take optimal care); Rafferty, *supra* note 5 (arguing that compelling auditors to indemnify other tort defendants would improve the quality of audits).

101. *See* Baker & Farrish, *supra* note 98, at 297–98 (discussing the incentives for liability insurers to conduct risk research).

102. *See* Prevor, *supra* note 9.

103. *See* Doering, *supra* note 9; Prevor, *supra* note 9.

104. Interview with Brad Sullivan, *supra* note 88; *see also* Doering, *supra* note 9.

105. Interview with Brad Sullivan, *supra* note 88.

buyers who see foodborne illness as simply “a cost of business” and liability insurance as a form of “balance sheet protection.”<sup>106</sup> If this is true, then liability insurance is likely to provide little incentive to promote optimal audit rigor, and it is likely to have limited influence on shaping a sense of mission and an industry culture that prioritizes food safety.

Feedback and learning from insurance are also limited in practice. As mentioned above, liability settlements involving multiple strictly liable defendants typically proceed without identifying the cause of the plaintiff’s injury and, based on indemnification clauses, simply begin with payouts by the grower’s primary insurance carrier. Once that line is exhausted, plaintiffs move on to primary coverage of distributors, processors, manufacturers, and retailers further down the supply chain, as well as to excess and umbrella coverage policies.<sup>107</sup> Attribution problems and indemnity agreements mean that liability insurance may generate more feedback and learning about litigation dynamics and structuring coverage than about food safety risks. Moreover, the typical tangle of overlapping primary and excess coverage all along the supply chain raises questions about the efficiency of liability insurance in the food industry.<sup>108</sup> And aside from efficacy and efficiency, insurance lacks stakeholder participation, transparency, and democratic accountability.

#### *F. Accreditation*

Accreditation bodies verify the reliability of private food safety auditors through a process of inspection, auditing, and ongoing surveillance, using widely accepted standards jointly developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).<sup>109</sup> Many buyers only accept supplier audits conducted by accredited auditors.<sup>110</sup> A peer-review system coordinated by the International Accreditation Forum (IAF) seeks

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106. Interview with Charles Stauber, *supra* note 99.

107. *Id.*; Interview with Brad Sullivan, *supra* note 88.

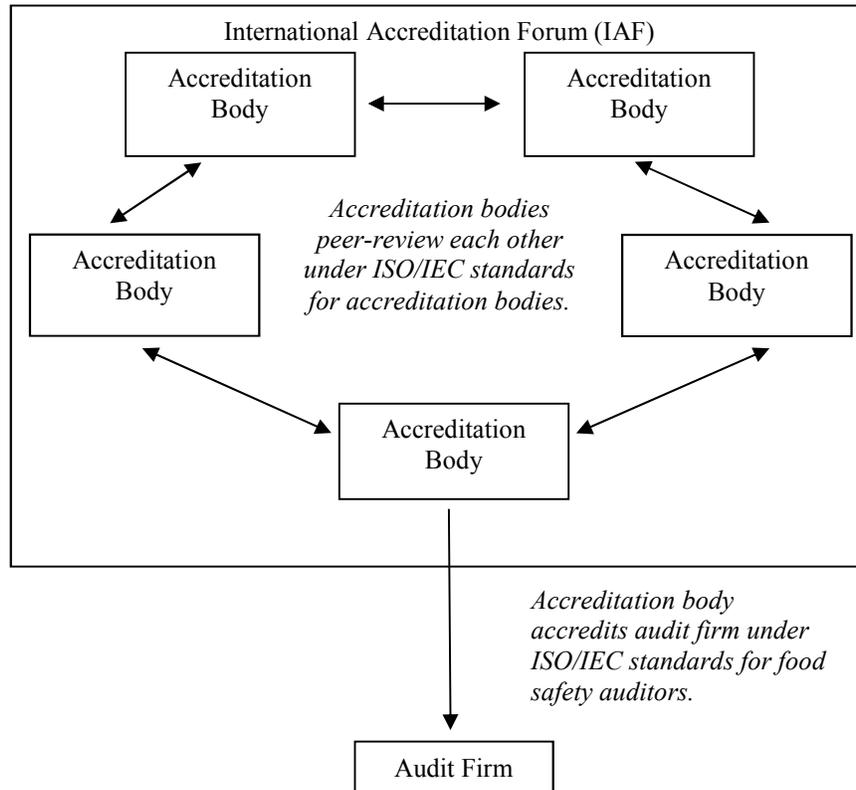
108. Interview with Brad Sullivan, *supra* note 88.

109. Private food safety auditing is just one example of a widespread industrial practice known as conformity assessment. For a general introduction to conformity assessment, accreditation, and the ISO/IEC standards governing them, see INT’L ORG. FOR STANDARDIZATION & U.N. INDUS. DEV. ORG. (UNIDO), BUILDING TRUST: THE CONFORMITY ASSESSMENT TOOLBOX, available at [http://www.iso.org/iso/casco\\_building-trust.pdf](http://www.iso.org/iso/casco_building-trust.pdf) (last visited Mar. 11, 2014).

110. Leading food safety schemes require suppliers to obtain accredited third-party audits. See NICOLAS CAVINET, FOOD & AGRIC. ORG., FOOD SAFETY CERTIFICATION 3 (2006), available at <http://webcache.googleusercontent.com/search?q=cache:zhOdIa0A8KkJ:ftp://ftp.fao.org/docrep./FAO/008/ag067e/ag067e00.pdf+&cd=1&hl=en&ct=clnk&gl=us>.

to ensure the reliability of accreditation bodies using ISO/IEC standards that apply to accreditation bodies themselves.<sup>111</sup> Figure 2 illustrates the organizational structure of accreditation.

FIGURE 2. ACCREDITATION



ISO/IEC standards use the concept of impartiality to define ethical norms, institutional structures, and administrative practices aimed at counteracting auditor conflict of interest.<sup>112</sup> According to ISO/IEC

111. See INT'L ORG. FOR STANDARDIZATION & U.N. INDUS. DEV. ORG. (UNIDO), *supra* note 109, at 86–90, 175–84. See also LAWRENCE BUSCH ET AL., UNITED STATES AGENCY INT'L DEV., THE RELATIONSHIP OF THIRD-PARTY CERTIFICATION (TPC) TO SANITARY/PHYTOSANITARY (SPS) MEASURES AND THE INTERNATIONAL AGRICULTURE TRADE: FINAL REPORT (2005).

112. ISO/IEC accreditation standards address the problem of auditor conflict of interest in a constellation of standards relevant to conformity assessment in general (ISO/IEC series 17000 standards) and food safety auditing in particular (ISO/IEC 22000 series). Our discussion focuses on standards in ISO/IEC 17065, *supra* note 56. ISO/IEC standards recognize "that the source of revenue for a certification body is its client paying for certification, and that this is a potential threat to impartiality." INT'L ORG. FOR STANDARDIZATION (ISO) & INT'L ELECTROTECHNICAL COMM'N (IEC), ISO/IEC 17021

standards, impartiality means that an auditor's judgment is unbiased, free from prejudice, neutral, fair, open-minded, even-handed, detached, and balanced.<sup>113</sup> Under the standards, the top management of an audit firm must commit itself to impartiality, and it must formalize this commitment in written principles and policies.<sup>114</sup> It must also have in place an oversight committee to advise it on the development of these principles and policies and to monitor its adherence to them.<sup>115</sup> The committee must include "a balanced representation of significantly interested parties" drawn from suppliers, buyers, trade associations, consumer organizations, auditing experts, and government agencies.<sup>116</sup> Personnel from the auditing firm on the committee "shall not predominate."<sup>117</sup>

An audit firm must "identify risks to its impartiality on an ongoing basis," report those risks to the committee, and demonstrate how the risks have been eliminated or minimized.<sup>118</sup> The committee must have the power to investigate any tendency by the audit firm "to allow commercial or other considerations to prevent the consistent impartial provision of certification activities," and "if the top management of the certification body [audit firm] does not follow the input" of the committee, it "shall have the right to take independent action," such as "informing authorities, accreditation bodies, [or other] stakeholders."<sup>119</sup> Additionally, under ISO/IEC standards, an audit firm must require auditors to sign a written agreement pledging that they will disclose any

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CONFORMITY ASSESSMENT—REQUIREMENTS FOR BODIES PROVIDING AUDIT AND CERTIFICATION OF MANAGEMENT SYSTEMS § 4.2.2 (2006). ISO/IEC standards identify several specific threats to impartiality, including "self-interest (e.g. overdependence on a contract for service or the fees, or fear of losing the customer or fear of becoming unemployed, to an extent that adversely affects objectivity in carrying out conformity assessment activities)." INT'L ORG. FOR STANDARDIZATION (ISO), IS/ISO/PAS 17001 CONFORMITY ASSESSMENT—IMPARTIALITY—PRINCIPLES AND REQUIREMENTS § 5.3 (2005); *see also* ISO/IEC 17065, *supra* note 56, § A.2.2. ISO/IEC standards also address the problem of conflict of interest in accreditation bodies in INT'L ORG. FOR STANDARDIZATION (ISO) & INT'L ELECTROTECHNICAL COMM'N (IEC), ISO/IEC 17011 CONFORMITY ASSESSMENT—GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING CONFORMITY ASSESSMENT BODIES (2004) [hereinafter ISO/IEC 17011] and INT'L ORG. FOR STANDARDIZATION (ISO) & INT'L ELECTROTECHNICAL COMM'N (IEC), ISO/IEC 17040 CONFORMITY ASSESSMENT—GENERAL REQUIREMENTS FOR PEER ASSESSMENT OF CONFORMITY ASSESSMENT BODIES AND ACCREDITATION BODIES (2005).

113. ISO/IEC 17065, *supra* note 56, § 3.13. ISO/IEC standards generally use the term "certification bodies." *Id.* We use the terms "auditor" and "auditing firm" for stylistic consistency with the rest of our analysis.

114. *Id.* § 4.2.5.

115. *Id.* § 4.2.7.

116. *Id.* § 5.2.2.

117. *Id.*

118. *Id.* § 4.2.3.

119. *Id.* § 5.2.

current or potential conflicts of interest and comply with rules governing conflicts of interest.<sup>120</sup> An audit firm must conduct an annual internal review of its compliance with these and other ISO/IEC standards, and it must submit itself to ongoing surveillance and periodic reassessment by an accreditation body to maintain its accreditation.<sup>121</sup>

As an oversight mechanism to address auditor conflict of interest, accreditation has several comparative strengths. It offers auditors a valuable credential that increases the marketability of their services. This creates a financial incentive to be impartial that counteracts the financial incentive to cut corners and skew results. The IAF peer-review system provides a similar incentive to accreditation bodies to be impartial in accrediting auditors, thereby counteracting the conflict of interest at the accreditation level. Oversight committees that include stakeholder representatives from industry, government, and public interest advocacy groups with the power to report wrongdoing to public authorities increase participation, transparency, and accountability in both the certification and accreditation processes. Internal management reviews within auditing firms and ongoing surveillance by accreditation bodies provide auditors with opportunities for feedback and learning.

Accreditation also has comparative weaknesses. Accreditation bodies have less direct access to information concerning the quality of audits than do suppliers and audit firms, and the frequency of their oversight is likely to be less than that of buyers (although it may be more probing). Accreditation bodies also lack the coercive power of civil discovery to uncover information that auditors wish to conceal. Accreditation constitutes another level of administration with its own independent institutions and personnel, which imposes additional administrative costs on the auditing process and may reduce its efficiency. Moreover, ISO/IEC standards are not publicly available. They must be purchased, and fees for a single standard can reach into the hundreds of dollars.<sup>122</sup> The results of audits and ongoing surveillance of

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120. *Id.* § 6.1. These standards also apply to subcontractors. *Id.* § 6.2.2.

121. *Id.* § 8.5 (internal review); ISO/IEC 17011, *supra* note 112, § 7.11 (accreditation surveillance and reassessment).

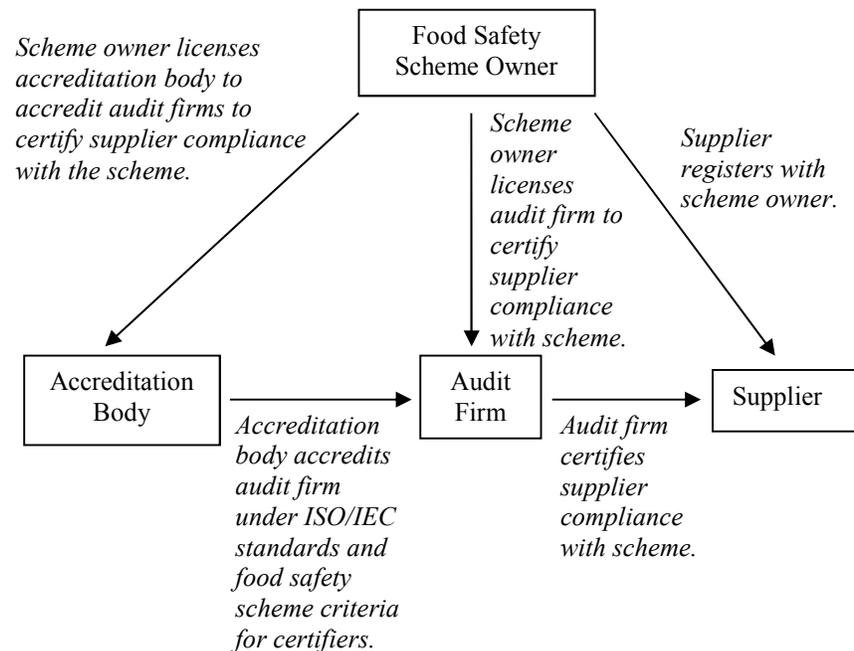
122. *See* Busch, *supra* note 35, at 66. Some unauthorized copies of standards can be found on the web. *See, e.g.*, PUBLIC.RESOURCE.ORG, <https://law.resource.org/pub/in/bis/S01/is.iso.pas.17001.2005.pdf> (last visited Mar. 29, 2014). Scholars have recently raised concerns about the accessibility of private standards that are incorporated into public regulations. *See, e.g.*, Emily S. Bremer, *Incorporation by Reference in an Open Government Age*, 36 HARV. J.L. & PUB. POL. 131, 133–39 (2013); Nina Mendelson, *Private Control over Access to Public Law: The Puzzling Federal Regulatory Use of Private Standards*, 112 MICH. L. REV. (forthcoming 2014); Peter L. Strauss, *Private Standards Organizations and Public Law* (Columbia Pub. Law Research, Working Paper No. 13-334, 2013), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2194210](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2194210).

auditors by accreditation bodies are also confidential.<sup>123</sup> Access restrictions to standards and confidentiality reduce transparency, participation, and public accountability in the accreditation process.

### G. Food Safety Scheme Licensing

Industry groups and non-governmental organizations have developed a number of schemes—consisting of principles, policies, and practices—designed to improve and standardize food safety. Major buyers increasingly demand that their suppliers implement one of these schemes and obtain independent certification that they have done so. Scheme owners license private food safety auditors to certify that suppliers are properly implementing the requirements of their schemes. The schemes require suppliers to adopt ethical norms, institutional structures, and administrative practices to reduce conflicts of interest, and they contain similar provisions for audit firms as a condition of obtaining a license to certify compliance with the scheme. Schemes also require audit firms to be accredited under ISO/IEC standards. Figure 3 illustrates the structure of food safety scheme licensing.

FIGURE 3. FOOD SAFETY SCHEME LICENSING



123. ISO/IEC recognizes a duty of auditors to keep information obtained in audits confidential. ISO/IEC 17065, *supra* note 56, § 4.5. Moreover, the Food Safety Service Providers have objected to proposed federal rules that would require auditors to report regulatory violations. FOOD SAFETY SERV. PROVIDERS, *supra* note 6.

For example, the Safe Quality Foods Institute (SQFI)—which is a division of the Food Marketing Institute, a leading industry association for food retailers and wholesalers—administers the Safe Quality Food (SQF) scheme.<sup>124</sup> The scheme requires suppliers to register with SQFI and commit themselves to ongoing improvement of their food safety systems.<sup>125</sup> Suppliers must establish detailed written food safety policies in accordance with SQF product-specific standards, train staff in the implementation of these policies, and regularly review the policies and their implementation through internal inspections and self-audits.<sup>126</sup> They must maintain written records of all reviews and violations and submit to third-party certification audits.<sup>127</sup>

Auditing firms must obtain a license from SQFI to certify suppliers as SQF compliant.<sup>128</sup> To obtain a license, an auditing firm must be accredited under ISO/IEC standards for certification bodies and additional SQF criteria.<sup>129</sup> Accreditation bodies must be IAF-approved under ISO/IEC standards for accreditation bodies and licensed by SQF to accredit auditors to provide SQF certification.<sup>130</sup>

SQF licensing criteria require auditing firms to ensure that anyone involved in conducting audits, making certification decisions, or supervising auditors is “free from any commercial, financial or other pressure that might influence the results of Certification.”<sup>131</sup> Specifically, audit firms must have policies that require individual auditors to disclose any relationship to suppliers that might constitute a conflict of interest.<sup>132</sup> Audit firms must establish a quality-control system in which managers review all SQF certification audit reports and conduct annual internal audits of the quality-control system.<sup>133</sup> Firms must also maintain written records of these reviews and internal audits and make them available to SQFI or third-party auditors.<sup>134</sup> Certification decisions must be made by a person or persons other than the person who performed the audit.<sup>135</sup> Audit firms may not offer both consulting services related to helping suppliers implement the SQF scheme and audit services designed to

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124. The SQF scheme was first developed in Australia and was acquired by the Food Marketing Institute in 2003. SQF INST., *supra* note 57, at 1.

125. *Id.* at 30, 44–45.

126. *Id.* at 44–48, 62.

127. *Id.* at 32, 45–69, 175.

128. *SQF Criteria*, *supra* note 56, at i.

129. *Id.* at i, iii.

130. *Id.* at i, iii, § 4.1.2.

131. *Id.* § 4.2.2.

132. *Id.* § 5.2.2.2.

133. *Id.* §§ 4.7, 11.4.

134. *Id.* § 4.9.

135. *Id.* § 4.2.3.

evaluate compliance.<sup>136</sup> Auditors must appoint an independent committee—consisting of representatives from the primary production, processing, food service, and retail sectors of the food industry—to oversee the development of these requirements.<sup>137</sup> SQFI also surveys suppliers and buyers about the quality of certification audits.<sup>138</sup>

Food safety scheme licensing has a number of comparative strengths. A license to certify compliance with a popular scheme enables auditors to offer a valuable service to suppliers. The license creates a significant financial incentive for auditors to conduct audits that meet the conflict-of-interest standards of scheme owners. Moreover, schemes require initial and ongoing training, which gives scheme owners opportunities to influence the food safety culture within supplier operations, audit firms, and consulting services, all of which are likely to be mutually reinforcing.<sup>139</sup> In addition, the various oversight mechanisms that schemes require auditors to establish and scheme owners' surveys of suppliers and buyers generate feedback concerning the quality of audits. Scheme owners share this feedback with auditors, and they take it into account in their frequent revisions of scheme requirements.<sup>140</sup>

Whether food safety scheme licensing has comparative advantages in terms of access to information regarding the rigor of audits and schemes' own susceptibility to conflict of interest is less clear. Oversight mechanisms and surveys provide scheme owners access to information about the rigor of audits. This access is dependent, however, upon the thoroughness of surveillance by accreditation bodies and oversight committees, the willingness of suppliers and auditors to share information, and the quality of information that buyers have. Presumably, scheme owners have a financial interest in providing rigorous and verifiable food safety standards that buyers can rely upon and have a mission to reduce the risk of foodborne illness. However, scheme owners might be tempted to relax their standards if they feel

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136. *Id.* § 5.2.2.1.

137. *Id.* § 4.2.1.

138. *SQF Certified Supplier Survey*, SURVEYMONKEY, [https://www.surveymonkey.com/s/supplierfeedback\\_survey](https://www.surveymonkey.com/s/supplierfeedback_survey) (last visited Jan. 13, 2014); *SQF Buyer Survey*, <http://www.surveymonkey.com/s/DCXRJYT> (last visited Jan. 13, 2014).

139. See *Licensed SQF Training Centers*, SQF INST., <http://www.sqfi.com/training-centers/> (last visited Jan. 13, 2014) (describing SQF training programs for suppliers and consultants); *Professional Training*, SQF INST., <http://www.sqfi.com/sqf-professional/sqf-professional-training/> (last visited Jan. 13, 2014) (describing SQF training and ongoing education for auditors and consultants).

140. See, e.g., *The SQF Technical Advisory Council*, SQF INST., <http://www.sqfi.com/about-sqf/technical-committees/> (last visited Jan. 13, 2014) (describing the process of routine updates of SQF standards).

competitive pressure to reduce the burdens on suppliers using the scheme or on auditors seeking a license.

Food safety scheme licensing also has a number of clear disadvantages. Schemes generate additional administrative costs for suppliers and auditors. Moreover, not all schemes make their standards available free of charge, and none make information concerning individual auditors and certifiers publicly available.<sup>141</sup> Consequently, audit-scheme licensing is relatively deficient in terms of broad stakeholder participation, transparency, and public accountability.

#### *H. Benchmarking*

In 2000, the Consumer Good Forum, a global trade association of over 400 leading manufacturers, retailers, and service providers, founded the Global Food Safety Initiative (GFSI) to establish benchmarks that would set minimum standards for food safety schemes and encourage buyers to accept certification under different schemes as equivalent.<sup>142</sup> Suppliers must frequently maintain multiple food safety certifications to sell their products to different buyers, each with its own preferred audit criteria.<sup>143</sup> GFSI recognizes a number of food safety schemes that meet its benchmarks—published in a guidance document—with the aim that buyers will accept certification under any of them and thereby reduce the inefficiency of suppliers needing to obtain multiple audits to satisfy different buyers.<sup>144</sup> This goal is summed up in the GFSI slogan: “once certified, accepted everywhere.”<sup>145</sup> Dozens of leading food manufacturers, retailers, and service providers—including Walmart, Coca-Cola, McDonald’s, Delhaize, and Sodexo—have agreed to accept certification based on any GFSI-recognized food safety scheme.<sup>146</sup> Figure 4 illustrates the relationship between GFSI, scheme owners, auditors, and suppliers.<sup>147</sup>

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141. See, e.g., *BRC Global Standards*, BRC BOOKSHOP, <http://www.tsoshop.co.uk/brcbookshop/bookstore.asp?FO=1235945> (last visited Jan. 15, 2014) (selling British Retail Consortium’s food safety standards); *SQF Criteria*, *supra* note 56, § 4.10 (requiring auditors to keep information regarding supplier performance confidential).

142. GLOBAL FOOD SAFETY INITIATIVE, *supra* note 23, at 2, 4.

143. *Id.* at 26.

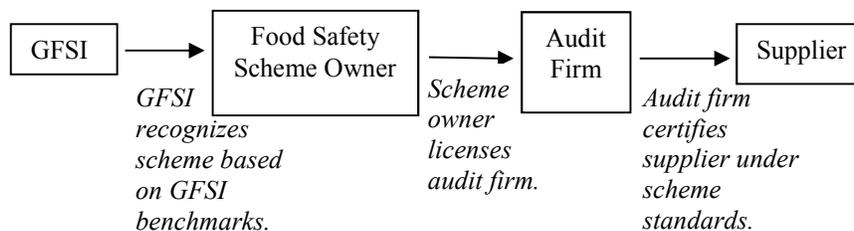
144. *Id.* at 8.

145. *Id.* at 26.

146. *GFSI and Benchmarking*, GLOBAL FOOD SAFETY INITIATIVE, <http://www.mygfsi.com/gfsi-benchmarking-general.html> (last visited Feb. 24, 2014).

147. For the sake of simplicity, Figure 4 omits accreditation bodies and buyers, which both play a role in the GFSI recognition of schemes. For a more complete illustration, see Figure 6, *infra*.

FIGURE 4: GFSI BENCHMARKING



GFSI benchmarking addresses the problem of auditor conflict of interest by prescribing several different types of standards. First, GFSI prescribes standards for food safety schemes' relationship with individual auditors. For example, according to GFSI benchmarks, schemes must require auditors to possess specific minimum qualifications in terms of training, experience, and ongoing professional development, and scheme owners must enforce these requirements through an auditor registration system.<sup>148</sup>

Second, GFSI prescribes standards for food safety schemes' relationship with auditing firms. For example, GFSI benchmarks prescribe that schemes require audit firms to have written policies regarding conflict of interest and to make all staff involved in the certification process sign an agreement that commits them to disclosing any actual or potential conflict and to performing their jobs unbiased by commercial or personal interests.<sup>149</sup> In addition, schemes seeking GFSI recognition must define criteria for audit firms—specified in detailed GFSI benchmarks—concerning the frequency and duration of audits, the contents of audit reports, management review of audit reports and auditor performance, documentation of these reviews, and quality improvement based on the reviews.<sup>150</sup> GFSI benchmarks further prescribe that schemes require auditing firms to be accredited to ISO/IEC standards and that they have a well-developed performance system that includes methods for obtaining feedback and for addressing complaints.<sup>151</sup>

Third, GFSI prescribes standards for food safety schemes' structure and governance. For example, GFSI benchmarks require that schemes not be developed, managed, or owned by audit firms and that schemes ensure that none of their employees or committee members has a conflict

148. GLOBAL FOOD SAFETY INITIATIVE, GFSI GUIDANCE DOCUMENT, §§ 3.4.1–10, 3.3.8 (6th ed. 2013), available at [http://www.mygfsi.com/gfsifiles/GFSI\\_Guidance\\_Document\\_Sixth\\_Edition\\_Version\\_6.3.pdf](http://www.mygfsi.com/gfsifiles/GFSI_Guidance_Document_Sixth_Edition_Version_6.3.pdf).

149. *Id.* § 3.3.13.6.

150. *Id.* §§ 3.3.13.1–7, 3.5–7.

151. *Id.* §§ 2.3.4, 2.5, 3.2–3, 7.5.

of interest that might influence decisions related to granting certification under the scheme.<sup>152</sup> Additionally, GFSI benchmarks require scheme operation and governance to be open and transparent and standards to be publicly available.<sup>153</sup>

Fourth, GFSI prescribes standards for food safety schemes' relationship with GFSI. For example, following recognition, GFSI requires schemes to submit annual self-assessments of compliance with GFSI benchmarks carried out by a committee of scheme stakeholders and accompanied by supporting documentation.<sup>154</sup> Schemes must reapply for GFSI recognition every four years.<sup>155</sup> The GFSI guidance document also contains detailed qualifications for members of GFSI committees that review scheme applications for recognition as well as detailed procedures for application, evaluation, and appeals.<sup>156</sup>

The examples cited here are intended merely to provide a sense of the nature and scope of the GFSI benchmarking system. They do not provide a detailed or comprehensive overview of the many GFSI benchmarks. The current edition of the guidance document is more than 166 pages of detailed standards and procedures.<sup>157</sup>

GFSI benchmarking is an attempt to strengthen the regulatory capacity of audit schemes to counteract auditor conflicts of interest. GFSI recognition increases the attractiveness of schemes to buyers and suppliers, which creates demand among audit firms for licenses to certify compliance with those schemes. In this way, GFSI recognition creates a financial incentive for scheme owners to set rigorous standards for audits and audit oversight, to verify compliance, and to discipline audit firms that fall short. In addition, GFSI benchmarks that prescribe quality assurance oversight at many levels—for example: audit firm review of audits, scheme owner surveillance of audit firms, and GFSI assessments of schemes—increase performance feedback and opportunities for learning. GFSI has also aimed to increase participation, transparency, and public accountability by establishing an Advisory Council of representatives from academia and non-governmental organizations and sponsoring an annual conference which attracts retailers, manufacturers, audit firms, accreditation bodies, scheme owners, food safety experts, and consultants that is open to anyone interested in participating.<sup>158</sup> GFSI also makes its guidance document and related materials publicly

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152. *Id.* § 2.4.

153. *Id.* §§ 2.3.5, 2.4.5.

154. *Id.* §§ 2.3.7–8, 2.5.3.

155. *Id.* §§ 1.2–3, 2.6.1–5.

156. *Id.* at 42, 46–49.

157. GLOBAL FOOD SAFETY INITIATIVE, *supra* note 148.

158. GLOBAL FOOD SAFETY INITIATIVE, *supra* note 23, at 3.

available for free on its website.<sup>159</sup> GFSI's mission to encourage widespread acceptance of uniformly high standards of food safety among buyers and suppliers is aligned with the public interest in optimal food safety.<sup>160</sup>

There are also comparative disadvantages to GFSI benchmarking. Except for its annual conference, GFSI has no direct relationship with auditors, so it has no firsthand access to information about the rigor of audits. This distance also limits GFSI's influence on audit firms' sense of mission and commitment to food safety. Moreover, all of the additional oversight prescribed by GFSI, as well as its own operations, generate additional administrative costs in the food safety system. To be fair, however, these costs must be weighed against the efficiency gains from reducing the need for multiple audits and reductions in the number of product recalls due to food safety concerns.<sup>161</sup>

### *I. Government Recognition of Accreditation Bodies*

The FDA is currently developing regulations under the Food Safety Modernization Act (FSMA), which requires the agency to establish a "system for the recognition of accreditation bodies."<sup>162</sup> According to the FDA's proposed regulations, the agency will recognize accreditation bodies to accredit auditors that provide regulatory compliance certification to food production facilities.<sup>163</sup> Figure 5 illustrates the structure of this regulatory approach.

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159. See GLOBAL FOOD SAFETY INITIATIVE, *supra* note 148.

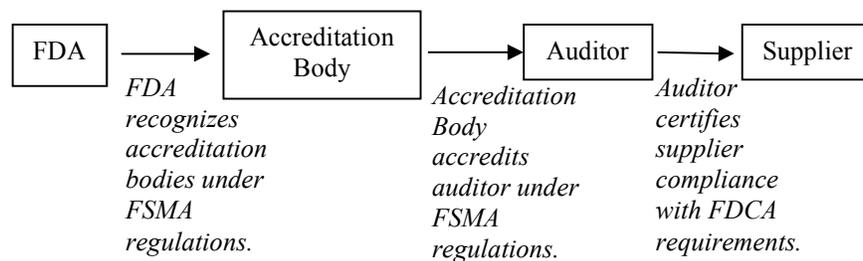
160. Critics have suggested, however, that the large manufacturers, retailers, and service providers that back GFSI see ratcheting up industry standards for food safety as a way to gain a competitive advantage over their smaller rivals. Thomas Bernauer & Lanida Caduff, *Food Safety and the Structure of the European Food Industry*, in WHAT'S THE BEEF: THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY 81, 92 (Christopher Ansell & David Vogel eds., 2006).

161. See *GFSI General Presentation*, GLOBAL FOOD SAFETY INITIATIVE, <http://www.mygfsi.com/communication/gfsi-general-presentation.html> (last visited Jan. 13, 2014) (citing food safety gains and cost reductions as a result of GFSI benchmarking).

162. FDA Food Safety Modernization Act (FSMA), 21 U.S.C. § 185(a) (2012); Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45,781–839 (proposed July 29, 2013) (to be codified at 21 C.F.R. pt. 1 and 16).

163. Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. at 45,782. FSMA provides that, in the event that the FDA has not identified and recognized an accreditation body within two years of establishing its recognition program, the agency may itself directly accredit auditors. 21 U.S.C. § 307(b)(1)(A)(ii); Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. at 45,820. Under the statute, a third-party auditor refers to a "foreign government, agency of a foreign government, foreign cooperative, or any other third

FIGURE 5. FDA RECOGNITION OF ACCREDITATION BODIES



The FDA's recognition program under FSMA applies only to certification of imported foods for compliance with federal food safety regulations under the Food, Drug, and Cosmetics Act (FDCA).<sup>164</sup> It aims to “ensure the competence and independence of third-party auditors/certification bodies who conduct foreign food safety audits” and to expedite approval of foods for importation.<sup>165</sup> All imported food under the FDA's jurisdiction is subject to inspection at the point of entry, and importers who voluntarily obtain certification of their facilities under the program are eligible for expedited review.<sup>166</sup> Additionally, under FSMA, the FDA may require importers of high-risk foods to provide certification by a foreign government agency or an accredited auditor that the food

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party” as deemed appropriate by the FDA in its regulations. 21 U.S.C. § 384d(a)(3). Private third-party auditors can be single individuals but are more likely to be companies that employ “audit agents.” 21 U.S.C. § 384d(a)(3) (stating that a third-party auditor may be a single individual and third-party auditors may employ an “audit agent,” defined at § 384d(a)(1) as “an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party auditor”).

164. *Imports*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm257980.htm> (last visited Mar. 11, 2014). In 2009, the FDA issued a guidance document endorsing broad standards for private food safety certification of both domestic goods and imports. *Guidance for Industry – Voluntary Third-Party Certification Programs for Foods and Feeds*, *supra* note 12. The FDA's proposed FSMA regulations state that the agency intends “to withdraw the 2009 Guidance upon publication of a final rule for accredited third-party certification.” Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. at 45,796 n.20. The European Community has also issued guidance on private food safety auditing. *See PRIVATE FOOD LAW*, *supra* note 28, at 391.

165. Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. at 45,796 n.20.

166. 21 U.S.C. § 302(a); *Importing Food Products into the United States*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/> (last visited Feb. 20, 2014).

complies with federal food safety standards as a condition of permitting its importation.<sup>167</sup>

The proposed regulations prescribe standards for FDA recognition of accreditation bodies and standards for these bodies' accreditation of auditors. Both sets of standards cover personnel training, qualifications, and ongoing professional development; auditing, documentation, and quality assurance; firm governance, conflict of interest, and periodic self-assessment; and evaluation procedures, monitoring, and sanctions for noncompliance.<sup>168</sup> The proposed regulations cover much the same ground as, and refer frequently to, ISO/IEC standards for accreditation bodies and food safety auditors.<sup>169</sup>

Government recognition of accreditation bodies has a number of comparative advantages. Under the FDA's recognition program, the agency will provide expedited review for imports certified by auditors accredited by accreditation bodies recognized by the FDA.<sup>170</sup> For high-risk foods, such certification (or certification by a foreign government) will be a condition of entry.<sup>171</sup> The program thus provides financial incentive to suppliers to obtain audits that conform to the FDA's standards. The proposed regulations also provide incentive to auditors to conduct rigorous audits, since the FDA may withdraw an auditor's accreditation if a supplier that it certifies is linked to a serious outbreak of foodborne illness, if it refuses to grant the FDA access to its records, if it demonstrates "bias or lack of objectivity," or if its "performance . . . [calls] into question the validity or reliability of its food safety audits."<sup>172</sup>

The proposed regulations additionally create incentives for accreditation bodies to ensure the rigor of audits performed by auditors that they accredit. The FDA can revoke recognition of an accreditation body that fails to conduct an adequate self-assessment and take necessary corrective action following FDA withdrawal of accreditation from an

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167. 21 U.S.C. § 303(b); *see also* Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. at 45,785.

168. *See* Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. at 45,796–97, 45,803–06 (proposed rules governing the FDA's recognition of accreditation bodies); *Id.* at 45,798 (proposed rules governing accreditation bodies' accreditation of food safety auditors). The proposed regulations emphasize that the rules presented are merely "a framework" for model accreditation standards that will be further specified in the subsequent promulgation of "Model Accreditation Standards." *Id.* at 45,785.

169. *Id.* at 45,782–88 (discussing the FDA's use of ISO/IEC standards for conformity assessment in the development of its regulations).

170. *Id.* at 45,784.

171. *Id.*

172. *Id.* at 45,819, 45,836.

auditor accredited by the accreditation body.<sup>173</sup> The FDA can also revoke recognition if an accreditation body refuses to grant the FDA access to its records, misleads the agency, demonstrates bias or lack of objectivity, or fails to adequately support a decision to grant accreditation.<sup>174</sup> In addition, accreditation bodies must maintain records on any denial, withdrawal, suspension, or limitation in the scope of auditor accreditation so that the agency can detect attempts by poorly performing auditors to “shop for favorable accreditation decisions.”<sup>175</sup> These record-keeping and disclosure requirements give the FDA access to information about the rigor of audits. Moreover, FDA oversight and self-assessments by auditors and accreditation bodies generate valuable feedback, and the threat of exclusion from the program creates incentives for them to take corrective action to improve the quality of audits and oversight.<sup>176</sup>

The FDA’s recognition program may have additional benefits in terms of participation, transparency, and public accountability. Notice-and-comment rule making offers stakeholders an opportunity to participate in shaping the regulations governing audits and makes much of the process transparent. Under the program, the FDA will publish on its website a registry of recognized accreditation bodies and accredited auditors and will post notices when it revokes the recognition of any accreditation body or withdraws the accreditation of any auditor.<sup>177</sup> The proposed regulations would require auditors to post on their websites a list of suppliers whom they have certified, the scope and duration of the certification, and the dates on which the supplier paid the auditor any fees associated with the audit.<sup>178</sup> The proposed regulations would also require auditors and accreditation bodies to file with the FDA reports of all certification and accreditation decisions, ongoing surveillance, and periodic self-assessments.<sup>179</sup> All of this disclosure would make the agency

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173. *Id.* at 45,804–05.

174. *Id.* at 45,804, 45,830, 45,837.

175. *Id.* at 45,783.

176. The proposed regulations also allow for reinstatement. *Id.* at 45,806.

177. *Id.* at 45,805, 45,819, 45,821.

178. *Id.* at 45,835.

179. *Id.* at 45,828–29, 45,835–36. Some have criticized these reporting provisions as overly broad, suggesting that they could lead to public disclosure of proprietary information which would discourage suppliers from participating in or seeking certification from accredited auditors. FOOD SAFETY SERV. PROVIDERS, *supra* note 6, at 2–3; SCOTT RAFFERTY, COMMENTS ON FDA-2011-N-1046 (RIN 0910-AG66) THIRD-PARTY CERTIFICATION OF FOOD IMPORTS 1, 7–9 (2013), available at <http://www.noticeandcomment.com/FDA-2011-N-0146-0029-fcod-325758.aspx>.

and, by extension, the administration, publicly accountable for the success or failure of the program.<sup>180</sup>

Several aspects of the FDA's recognition program may blunt its comparative advantages. First, the scope of the program is not comprehensive—it covers only certification of imports, which constitute 15 percent of the food consumed within the United States (although the percentage of imports may be much higher in particular sectors).<sup>181</sup> Whether the federal government will eventually extend this approach to domestic food production remains to be seen. Additionally, the program's ability to encourage rigorous auditing and oversight, provide the FDA access to information about the quality of audits, and generate feedback and learning rests entirely upon the strength of the incentives it creates. Scott Rafferty, an expert on third-party certification, warns that the expedited review afforded by voluntary certification under the program “may not be much of an incentive.”<sup>182</sup> He points out that expedited review for food imports has been widely available under “established programs that already streamline customs clearance for food importers.”<sup>183</sup> Rafferty predicts that, “[g]iven fiscal constraints, the FDA is unlikely significantly to increase its own presence at ports of entry. So importers know that the overwhelming majority of shipments will not be refused, held, or even inspected at the port,” thereby undermining the incentive of expedited review.<sup>184</sup> Presumably, limited FDA inspection would also decrease the incentive under the program to obtain certification for high-risk foods.

Moreover, one should not assume that government regulation is always more participatory, transparent, or accountable than private alternatives. Notice-and-comment rule making by government agencies can be heavily influenced behind the scenes by industry stakeholders. For example, a recent study by Wendy Wagner, Katherine Barnes, and Lisa Peters examined rule making by the U.S. Environmental Protection Agency involving standards for the release of air toxins from major sources.<sup>185</sup> They found that, prior to publication of proposed rules for

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180. For discussion of the democratic accountability of the administration for agency regulation, see Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245 (2001).

181. Michael Patoka, *Three Food Safety Rules Grow Moldy at OIRA as Import-Related Outbreaks Continue*, FOOD SAFETY NEWS (June 26, 2013), <http://www.foodsafetynews.com/2013/06/three-food-safety-rules-grow-moldy-at-oira-as-import-related-outbreaks-continue/#.UtQZ8ImA1i4>.

182. Rafferty, *supra* note 5.

183. RAFFERTY, *supra* note 179, at 5.

184. *Id.*

185. Wendy Wagner et al., *Rulemaking in the Shade: An Empirical Study of EPA's Air Toxic Regulations*, 63 ADMIN. L. REV. 99 (2011).

public comment, agency contacts with affected parties were “extensive” and were “dominated by regulated parties.”<sup>186</sup> During the notice-and-comment period, formal comments came “predominantly from regulated industry,” and changes to the proposed rules reflected this imbalance and generally favored industry.<sup>187</sup> After rules were promulgated as final, regulated parties frequently brought legal challenges and obtained additional revisions in nonpublic settlement negotiations.<sup>188</sup> The breadth of public participation and its impact in rule making for the FDA’s recognition program merits a similarly careful study.<sup>189</sup>

There are also clear disadvantages to the FDA’s recognition program. Rule making has so far proceeded at a slower pace than anticipated. FSMA mandated that the FDA promulgate final regulations for the recognition program by July 2013, but the agency had not even published proposed regulations by that date.<sup>190</sup> Pursuant to litigation against the FDA for the delay, a court ordered the agency to produce a final rule by June 30, 2015.<sup>191</sup> Whether delay is caused by insufficient FDA resources, technical complexity, the need for input from other agencies, political considerations, or some combination of these factors, the slow pace of administrative rule making suggests that the FDA’s recognition program may not be as capable of incorporating feedback in a timely manner to improve regulatory performance compared to private entities like auditing schemes and GFSI, which regularly revise their standards.<sup>192</sup>

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186. *Id.* at 124.

187. *Id.* at 128.

188. *Id.* at 113–14.

189. For a suggestion that private standard-setting bodies may in some instances be more independent of industry influence than government agencies, see Robert W. Hamilton, *The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health*, 56 TEX. L. REV. 1329, 1416 (1978).

190. Patoka, *supra* note 181.

191. *Id.*

192. For example, the SQF scheme has undergone many minor and major revisions since its inception in 1994. The most recent version is numbered Edition 7.1. See *The SQF Technical Advisory Council*, *supra* note 140 (describing how the SQF Technical Advisory Council engages in ongoing revision of the SQF scheme). Similarly, GFSI’s most recent version is Edition 6.3. GLOBAL FOOD SAFETY INITIATIVE, *supra* note 23, at 8–9 (describing GFSI’s ongoing revision process). See also Busch, *supra* note 35, at 63 (praising the flexibility of private standards regimes); *id.* at 66 (noting that they can also sometimes hinder innovation).

*J. Media Coverage*

Media and consumer organizations uncover and disseminate information about audit failures. In doing so, they generate reputational information and enhance its influence. For example, media reports of the 2008 *Salmonella* outbreak linked to the Peanut Corporation of America (PCA) focused on an audit by a leading audit firm that awarded PCA's production operations a "superior" rating.<sup>193</sup> Several articles specifically highlighted the conflict of interest inherent in private food safety auditing paid for by suppliers.<sup>194</sup> Media coverage contributed to public outrage that resulted in FDA enforcement action, a congressional inquiry, and criminal prosecution.<sup>195</sup> The resulting reputational damage to the auditing firm, the peanut-processing industry, peanut product buyers (manufacturers and retail sellers), and the FDA is frequently cited—along with media coverage of similar outbreaks—as contributing to a variety of food safety reforms, including the development of enhanced quality control within auditing firms, demand among suppliers and buyers for more rigorous audits, stricter audit scheme standards, GFSI benchmarking, and passage of FSMA.<sup>196</sup>

Media coverage has a number of comparative advantages. The tenacity of journalists and consumer advocates in uncovering information

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193. Moss & Martin, *supra* note 5.

194. See, e.g., *id.*; Sun, *supra* note 18; Weise, *supra* note 40.

195. Gretchen Goetz, *Peanut Corporation of America from Inception to Indictment: A Timeline*, FOOD SAFETY NEWS (Feb. 22, 2013), <http://www.foodsafetynews.com/2013/02/peanut-corporation-of-america-from-inception-to-indictment-a-timeline/#.UtUKI4mA1i4>. In fairness to the firm in this case, it should be mentioned that the audit took place six months before the outbreak occurred, and conditions at the production facility in question may have subsequently deteriorated. Brian Hatman & Kate Barrett, *Timeline of the Salmonella Outbreak*, ABCNEWS (Feb. 10, 2009), <http://abcnews.go.com/Health/story?id=6837291&page=1&singlePage=true>. These details of the story were not examined closely in media accounts. Since our concern here is with the media coverage, and not the underlying events, we will not delve further into these details.

196. See, e.g., Garry, *supra* note 40 (citing widely publicized foodborne illness outbreaks attributed to lax auditing practices as spurring the development of auditor reforms, higher scheme standards, GFSI benchmarking, and FSMA); see also Linda Fulponi, *Private Voluntary Standards in the Food System: The Perspective of Major Food Retailers in OECD Countries*, 31 FOOD POL'Y 1, 6 (2006) (attributing the rise of private food safety standards to the reputational effects of food safety failures); Tetty Havinga, *Private Regulation of Food Safety by Supermarkets*, 28 L. & POL'Y 517–18 (2006) (attributing the rise of new food regulations in Europe to food safety scares); Henson & Northern, *supra* note 45 (analyzing reputational and liability incentives for brand-name companies to obtain rigorous audits); Diana Stuart, *Science, Standards, and Power: New Food Safety Governance in California*, 25 J. RURAL SOC. SCIS. 111, 118–23 (2010) (attributing the development of the California Leafy Greens Marketing Agreement to reputational damage in the wake of a foodborne illness outbreak caused by tainted spinach).

about the rigor of audits in the wake of a foodborne illness outbreak and their eagerness to publicize their findings are motivated by a mix of mission and financial reward. The potential negative media coverage that could accompany a food safety failure creates financial incentive for food manufacturers and retail sellers to demand rigorous audits of their suppliers, for suppliers to obtain them, and for auditors to provide them. Moreover, media reports can generate feedback that is useful for informing and motivating improvements in food safety auditing.

Media coverage also has disadvantages. Although journalists and consumer advocates are highly motivated to obtain information about the rigor of audits, they do not necessarily have easy or reliable access to it or the expertise to carefully assess it. Fear of negative press makes many industry insiders loathe to speak to journalists and consumer advocates. And when journalists and consumer advocates do obtain information, it may be incomplete.<sup>197</sup> Moreover, these two professions have incentives to emphasize egregious wrongdoing and large-scale system failure—both of which make for more newsworthy stories that validate the self-images of both professions as protectors of the broad public interest—and this may produce incomplete or insufficiently nuanced analyses of the private food safety auditing system.<sup>198</sup> Nor is either of these groups publicly accountable in any meaningful way for inaccuracies in their coverage of the industry. Indeed, they may even reap additional benefits from sensational stories regardless of their completeness or accuracy.<sup>199</sup> Fear of such accounts may, in the end, make industry actors less willing to share information about failures that could spur and inform improvement.

#### *K. Network Configuration*

The different oversight mechanisms that address conflict of interest in private food safety auditing do not operate in isolation from one another. Instead, they comprise a network of institutional actors

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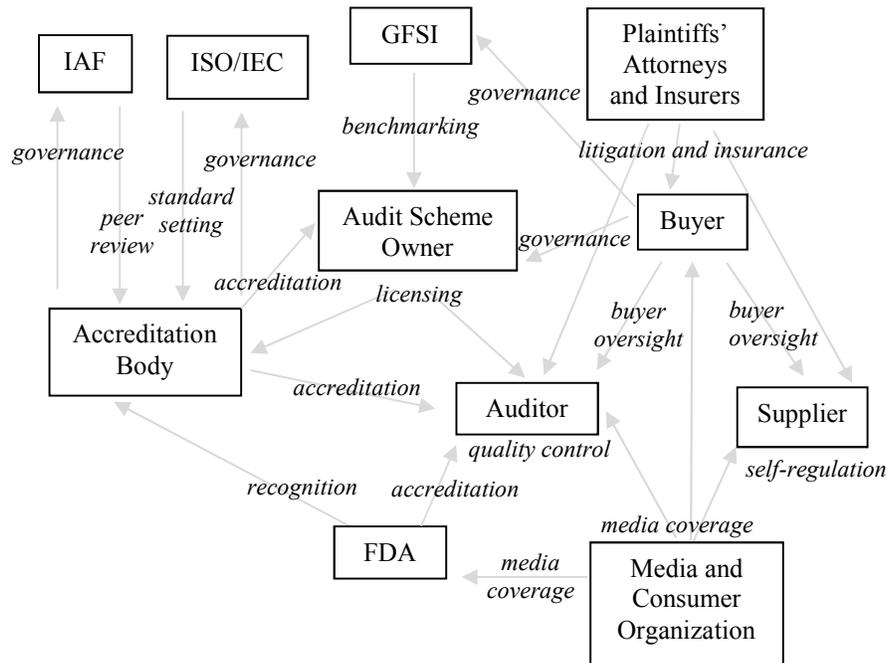
197. For example, industry insiders complain that media coverage of the Peanut Corporation of America (PCA) scandal mischaracterized the role of auditing in assuring food safety in general and sensationalized the limitations of the audit of PCA's facilities in particular. Interview with Bill Pursley, *supra* note 32.

198. For an introduction to the sociology of news making and the concept of newsworthiness, see HERBERT GANS, *DECIDING WHAT'S NEWS: A STUDY OF THE CBS EVENING NEWS, NBC NIGHTLY NEWS, NEWSWEEK, AND TIME* (1979); MICHAEL SCHUDSON, *THE SOCIOLOGY OF NEWS* (2003); Graham Murdoch, *Political Deviance: The Press Presentation of a Militant Mass Demonstration*, in *THE MANUFACTURE OF NEWS: SOCIAL PROBLEMS, DEVIANCE, AND THE MASS MEDIA* 206, 214 (Stanley Cohen & Jock Young eds., rev. ed. 1981).

199. See *supra* note 198. (analyzing incentives to sensationalize media coverage).

employing interrelated regulatory instruments.<sup>200</sup> Figure 6 illustrates the structure of this network.

FIGURE 6. THE NETWORK OF OVERSIGHT & ACCOUNTABILITY



This network structure itself is part of the institutional architecture of oversight, and—like its component parts—it can be analyzed in terms of its strengths and weaknesses relative to other configurations.<sup>201</sup>

We will focus on three particular structural attributes of this network: multiplicity, nesting, and outsourcing. First, the network includes multiple oversight mechanisms. All eleven of the mechanisms that we have surveyed counteract auditor conflict of interest. Second, some parts of the network have a nested structure. For example, GFSI benchmarks audit schemes that license auditors that conduct quality control. Third, some institutional actors outsource credentialing and

200. See generally Harter & Eads, *supra* note 21. See also Abraham L. Newman & David Zaring, *Regulatory Networks: Power, Legitimacy, and Compliance*, in *INTERDISCIPLINARY PERSPECTIVES ON INTERNATIONAL LAW AND INTERNATIONAL RELATIONS: THE STATE OF THE ART 244* (Jeffrey Dunoff & Mark Pollack eds., 2013).

201. For a robust analysis of private food safety regulatory networks, see Fabrizio Cafaggi, *Transnational Governance by Contract: Private Regulation and Contractual Networks in Food Safety*, in *PRIVATE STANDARDS AND GLOBAL GOVERNANCE* (Axel Marx et al. eds., 2012).

oversight tasks to others. For instance, audit scheme owners rely on accreditation bodies to accredit auditors.

Each of these network attributes has comparative advantages. Multiplicity allows some oversight mechanisms to fill gaps left by others.<sup>202</sup> Consider, for example, a buyer that did not require its domestic suppliers to obtain audits using benchmarked schemes or accredited auditors. Such audits would fall outside the purview of the FDA's regulation of import audits and the oversight provided by GFSI benchmarking, accreditation, and scheme owner licensing. Tort litigation and liability insurance might fill this gap. If potential food safety failures were too small to support tort claims worth bringing, fear of exposure by media and consumer organizations might still provide incentive to conduct rigorous audits.

Multiple oversight mechanisms may also overlap. This can increase financial incentives that favor rigorous auditing. For example, a supplier weighing the risk of an audit failure that gives rise to foodborne illness must consider the cost of tort liability, increased insurance premiums, reduction in brand value, and loss of business with buyers. Overlap may also reinforce professional norms and organizational commitment to food safety throughout the network. For example, professionalism among auditors is reinforced by audit firm policies, buyer specifications, food safety scheme criteria, accreditation standards, benchmarks, tort doctrine, and government regulations. Overlapping oversight mechanisms that generate similar information may increase the salience of the information, its framing, or its importance within an organization.<sup>203</sup> For example, performance feedback from an accreditation inspection may include information already known to audit firm personnel, but an accreditation report may validate internal findings, highlight their importance, present them in a way that more clearly identifies the causes of shortcomings, or attract the attention of top managers more effectively than the same information when generated by internal reviews. Finally, multiplicity also increases opportunities for stakeholder participation in the regulatory network.<sup>204</sup>

Nesting also has comparative advantages. By creating layers of oversight, nesting addresses the problem of conflict of interest at

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202. See SPENCER HENSON & JOHN HUMPHREY, *FOOD & AGRIC. ORG., THE IMPACTS OF PRIVATE FOOD SAFETY STANDARDS ON THE FOOD CHAIN AND ON PUBLIC STANDARD-SETTING PROCESSES* 7 (2009), available at [http://ec.europa.eu/food/international/organisations/sps/docs/private\\_standards\\_codex\\_en.pdf](http://ec.europa.eu/food/international/organisations/sps/docs/private_standards_codex_en.pdf) (discussing how private food safety standards "fill voids" in the regulatory system).

203. See Joanna Schwartz, *Introspection through Litigation*, (forthcoming 2014) (manuscript at 30–31 n.148), available at <http://ssrn.com/abstract=2383605>.

204. See Meidinger, *supra* note 72, at 83.

different levels of private regulation.<sup>205</sup> For example, just as audit fees give auditors incentive to reduce the rigor of audits, licensing fees give food safety scheme owners incentive to reduce the rigor of their oversight of auditors. GFSI benchmarking creates an additional layer of oversight that creates a financial incentive and cultivates norms to counteract the conflict of interest faced by scheme owners which, in turn, strengthens the effectiveness of their efforts to counteract the conflict of interest faced by auditors. The FDA's recognition program similarly addresses the conflict of interest faced by accreditation bodies in their oversight of auditors. Nesting also broadens participation by involving additional stakeholders in oversight, increases transparency through disclosure requirements, and adds a layer or layers of accountability to institutional actors that grant recognition, accreditation, or a license.

Outsourcing assigns specific oversight tasks, such as information collection, monitoring, and sanctioning, to other institutional actors. Separating functions among different institutional actors may reduce the susceptibility of either actor to conflict of interest. For example, by relying on accreditation bodies to accredit auditors, an audit scheme limits its own ability to lower standards for licensing auditors, which it might be tempted to do in order to increase its income from licensing fees. Simultaneously, the accreditation body's desire to maintain its license from the audit scheme creates an incentive to apply rigorous accreditation standards to auditors, which counteracts the incentive to go easy on auditors in order to increase revenues from accreditation fees.<sup>206</sup> Outsourcing may also increase efficiency by assigning specific tasks to institutional actors best equipped to perform them. Finally, outsourcing increases opportunities for feedback and learning.

These network attributes also have disadvantages. Most notably, overlap and nested layers of oversight may produce inefficient duplication of effort.<sup>207</sup> Additionally, by contrast to a more linear and hierarchical system, a network diffuses responsibility and thereby reduces each institutional actor's accountability for its regulatory performance.<sup>208</sup> The buck does not stop anywhere. Instead, oversight and accountability are distributed throughout the system.

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205. For a discussion of how nesting multiplies agency problems, see Susan Shapiro, *The Social Control of Impersonal Trust*, 93 AM. J. SOC. 623 (1987).

206. See LYTTON, *supra* note 28, at 127, 133 (discussing similar incentives that result from "triangulation" between certifiers, food companies, and consumers).

207. See NAT'L RESEARCH COUNCIL, STANDARDS, CONFORMITY, ASSESSMENT, AND TRADE: INTO THE 21ST CENTURY 87-97 (1995) (discussing the costs of redundancy in the U.S. standards setting system).

208. For discussions of lack of accountability in networks of private regulation, see ANNE METTE KJÆR, GOVERNANCE 14 (2004); Busch, *supra* note 35, at 64; McAllister, *supra* note 26, at 32.

## CONCLUSION

We have surveyed a variety of distinct oversight mechanisms that address auditor conflict of interest in private food safety certification audits. Our analysis identifies the institutional actors involved, describes the regulatory instruments that they use, and maps the network that connects their efforts. Our analysis also summarizes relative strengths and weaknesses of each mechanism.

Any evaluation of the effectiveness of the food safety system and its constituent parts would require analysis of performance goals, metrics, and outcomes—all of which are beyond the scope of this Article. We have, however, disaggregated some of the complexity of the system in a way that can inform efforts to undertake such an evaluation. Moreover, we believe that this analysis can be helpful in thinking about regulatory design in other arenas where a multiplicity of institutional actors and regulatory instruments can be combined and configured in different ways to reduce conflict of interest in private auditing and, ultimately, improve regulatory outcomes.<sup>209</sup>

We see our task in this Article as primarily descriptive, and we have refrained from offering suggestions for improvement. Tentatively, however, we believe our analysis supports at least one prescription. The system of oversight and accountability that we have described relies on linking foodborne illness to particular food safety failures. Only when outbreaks are traced back to food safety failures does lax auditing carry the risk of adverse consequences, such as damage to brand value, loss of market access, reduced income, and tort liability. Without the prospect of these consequences, institutional actors—suppliers, auditors, buyers, plaintiffs' attorneys, liability insurers, food safety scheme owners, accreditation bodies, and GFSI—lack financial incentive to assure rigorous auditing. Historically, oversight and accountability in food safety auditing have developed only as advances in microbiology, epidemiology, and public reporting have made it possible to link consumer illness to industrial production.<sup>210</sup> Improvements in attributing illness to food safety failures and associated audit failures are likely to improve regulatory performance throughout the network.<sup>211</sup> These improvements might be realized through additional private or public investment in scientific research on the causes of foodborne illness,

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209. For an empirical analysis of specific reforms aimed at reducing auditor conflict of interest in environmental auditing, see Duflo et al., *supra* note 54.

210. Tanya Roberts, *Economics of Private Strategies to Control Foodborne Pathogens*, 20 CHOICES 117, 117–21 (2005).

211. See Graeme Auld et al., *Can Technological Innovations Improve Private Regulation in the Global Economy?*, 12 BUS. & POL., Oct. 2010, at 26 (discussing the importance of supply chain tracking for reliable private regulation).

public education about how to recognize foodborne illness when it occurs, and public health reporting systems to identify outbreaks and trace them back to their sources.<sup>212</sup>

Finally, we hope to help move the debate over food safety regulation beyond the highly polarized and public discourse that presents a simple choice between government regulation and unregulated private markets. In a weekly address in 2009, President Obama asserted, “There are certain things only a government can do. And one of those things is ensuring that the foods we eat, and the medicines we take, are safe and don’t cause us harm.”<sup>213</sup> By contrast, Larry Keener, a prominent private food safety consultant, voiced a common industry sentiment in a *Food Safety Magazine* interview that “the government is not responsible for food safety; rather, food safety is the responsibility of those involved in its manufacturing and marketing.”<sup>214</sup> Regulatory scholars, policy makers, and industry insiders have openly acknowledged for over two decades that regulation typically involves a mix of public and private actors employing multiple instruments.<sup>215</sup> We hope that public discourse will soon catch up and that it will contribute to greater appreciation of the complex issues of institutional design that must be addressed in efforts to improve food safety.

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212. *Id.* at 27 (advocating government investment in technology to improve supply chain tracking).

213. President Barack Obama, Weekly Address (Mar. 14, 2009), *available at* [http://www.whitehouse.gov/the\\_press\\_office/weekly-address-president-barack-obama-announces-key-fda-appointments-and-tougher-f](http://www.whitehouse.gov/the_press_office/weekly-address-president-barack-obama-announces-key-fda-appointments-and-tougher-f). This kind of rhetoric does not match even the administration’s own policy. Just three months earlier, the FDA issued guidance on third-party food safety certification stating that:

Ensuring the safety and security of food products is shared responsibility between the public and private sectors. FDA has the authority to establish regulatory standards, inspection facilities, and take action if there are violations, but industry has the primary responsibility to ensure that food products intended for human and animal consumption in the United States are safe and meet applicable FDA requirements.

*Guidance for Industry – Voluntary Third-Party Certification Programs for Foods and Feeds*, *supra* note 12.

214. *Industry Perceptions of Proposed FSMA Rule on Preventive Controls*, *FOOD SAFETY MAG.*, Apr.–May 2013, <http://www.foodsafetymagazine.com/magazine-archive1/aprilmay-2013/industry-perceptions-of-proposed-fsma-rule-on-preventive-controls/>.

215. *See supra* note 29.