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BLOCKCHAIN MEETS GENOMICS: GOVERNANCE CONSIDERATIONS FOR PROMOTING FOOD SAFETY AND PUBLIC HEALTH

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I. Introduction

Foodborne illness remains an ongoing public health challenge in both the developing and industrialized worlds.[1] In the United States, almost 50 million reported cases of infectious disease occur every year from a food product, resulting in substantial morbidity and mortality with economic burdens to health care and productivity.[2] Despite recognition as a leader in food safety, the U.S. experiences longstanding and novel issues in food safety.[3] Advances in whole genome sequencing (WGS) promise to bolster food safety regulators' capabilities to identify pathogens and determine their source.[4] However, inefficiencies in tracing food products through the supply chain remain.[5]

Simultaneously, practical applications are beginning to emerge for new distributed ledger technologies, including blockchain.[6] First popularized by the Bitcoin cryptocurrency, blockchain has been hailed as a transformative technology for any industry engaged in recordkeeping.[7] Blockchain has attracted

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[1] Diane G. Newell et al., *Food-Borne Diseases — The Challenges of 20 Years Ago Still Persist While New Ones Continue to Emerge*, 139 INT'L J. FOOD MICROBIOLOGY S3, S4 (2010).

[2] Robert L. Scharff, *Economic burden from health losses due to foodborne illness in the United States*, 75 J. FOOD PROT. 123, 123 (2012).

[3] RENÉE JOHNSON, CONGRESSIONAL RESEARCH SERVICE, THE FDA FOOD SAFETY MODERNIZATION ACT (P.L. 111-353) 1 (Feb. 18, 2011).

[4] Jennifer L. Gardy & Nicholas J. Loman, *Towards A Genomics-Informed, Real-Time, Global Pathogen Surveillance System*, 19 NATURE REV. GENETICS 9 (2018).

[5] Thea King et al., *Food Safety for Food Security: Relationship Between Global Megatrends and Developments in Food Safety*, 68 TRENDS FOOD SCI. & TECH. 160, 170 (2017).

[6] DYLAN YAGA ET AL., U.S. NAT'L INST. STANDARDS & TECH., NISTIR 8202, BLOCKCHAIN TECHNOLOGY OVERVIEW 1 (2018), https://nvlpubs.nist.gov/nistpubs/ir/2018/NIST.IR.8202.pdf [hereinafter NIST REPORT].

[7] Marco Iansiti & Karim R. Lakhani, *The Truth About Blockchain*, Jan.–Feb. 2017 HARV. BUS. REV. 1, 3–4 (2017), https://enterprisersproject.com/sites/default/files/the_truth_about_blockchain.pdf.

massive investments for its broad applications in finance.[8] Meanwhile, academic and industry research on blockchain has exploded since 2012.[9] Though blockchain applications have only begun to surface, other sectors including healthcare, energy, and government services stand to benefit from this technological revolution.[10]

New pilot projects suggest blockchain may also serve a public health function as applied to food safety,[11] potentially overlapping with WGS advances. Blockchain in the food industry promises increased traceability of food products through the supply chain, as well as reduced fraud and counterfeiting of food products.[12] In 2017, Walmart and IBM began a collaboration to pilot blockchain in the food supply chain to hasten responses and reduce waste during an outbreak of foodborne illness.[13] Federal regulators in the U.S. have gained interest in exploring this application of blockchain technologies in the wake of two lettuce E. coli outbreaks during 2018 which suffered from traceability issues.[14] Given their complementary

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[8] Andrew Ross Sorkin, *Demystifying the Blockchain*, N.Y. TIMES (July 16, 2018), https://www.nytimes.com/2018/06/27/business/dealbook/blockchain-technology.html.

[9] Jesse Yli-Huumo et al., *Where Is Current Research on Blockchain Technology?—A Systematic Review*, 11 PLOS ONE 10.1371, 9–10 (2016).

[10] U.K. GOV'T OFFICE SCI., DISTRIBUTED LEDGER TECHNOLOGY: BEYOND BLOCK CHAIN 64–71 (2016), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/492972/gs-16-1-distributed-ledger-technology.pdf; Katharine Gammon, *Experimenting with Blockchain: Can One Technology Boost Both Data Integrity and Patients' Pocketbooks?*, 24 NATURE MED. 378, 381 (2018); Mike Orcutt, *How Blockchain Could Give Us a Smarter Energy Grid*, MIT TECH. REV. (Oct. 16, 2017), https://www.technologyreview.com/s/609077/how-blockchain-could-give-us-a-smarter-energy-grid/.

[11] *See generally* Frank Yiannas, *A New Era of Food Transparency Powered by Blockchain*, 12 INNOVATIONS: TECH., GOVERNANCE, GLOBALIZATION 46 (2018).

[12] Sylvian Charlebois, *How Blockchain Technology Could Transform the Food Industry*, CONVERSATION (Dec. 19, 2017), https://theconversation.com/how-blockchain-technology-could-transform-the-food-industry-89348.

[13] *See IBM Announces Major Blockchain Collaboration with Dole, Driscoll's, Golden State Foods, Kroger, McCormick and Company, McLane Company, Nestlé, Tyson Foods, Unilever and Walmart to Address Food Safety Worldwide*, IBM (Aug. 22, 2017), https://www-03.ibm.com/press/us/en/pressrelease/53013.wss (detailing IBM's announcement in 2017 that it would begin a major blockchain collaboration with various companies, including Walmart as well as blockchain's suitability to combat food waste problems) [hereinafter IBM Press Release].

[14] Maggie Fox, *The FDA Thinks Walmart May Have One Solution to Romaine Lettuce Recalls*, NBC NEWS (Nov. 28, 2018), https://www.nbcnews.com/health/health-news/fda-thinks-walmart-may-have-one-solution-romaine-lettuce-recalls-n940826.

nature, industry-driven blockchain projects could soon converge with government-based WGS infrastructure to provide a more comprehensive approach to responding to foodborne illness. Accomplishing this goal will require addressing regulatory and technical hurdles.

This article illustrates opportunities and obstacles arising from combining blockchain and WGS in food safety. Part I reviews food safety regulatory infrastructure in the U.S. and recent advances in WGS. Part II describes the rise of blockchain and its application in the food supply chain. Part III presents the promise of successfully combining blockchain and WGS tools alongside governance challenges and opportunities, pointing to soft law approaches including voluntary regulatory programs and technical standards as a potential path forward.

II. Food Safety Oversight and Whole Genome Sequencing

Ensuring food safety and preventing foodborne illness represent common, pervasive public health challenges for every nation and state.[15] Nearly 50 million individuals in the U.S. become ill after exposure to contaminated food products in a single year.[16] Food poisoning may produce more mild symptoms of gastric distress but can also yield potentially fatal liver, kidney, and neurological complications.[17] In turn, foodborne illnesses in the U.S. result in 128,000 hospitalizations and 3,000 mortalities annually.[18] Globally, food poisoning strikes 600 million individuals, resulting in 420,000

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[15] *See* INST. MED., ADDRESSING FOODBORNE THREATS TO HEALTH: POLICIES, PRACTICES, AND GLOBAL COORDINATION 3 (2006) ("Ensuring the safety of food is a long-standing and critical objective of public health. The estimate that millions of Americans—whose food is among the safest on earth—are sickened by tainted food each year attests to the need to further safeguard our food supply, while the mounting threat of terrorism lends this mission a particular urgency.").

[16] *See* L. Hannah Gould et al., *Surveillance for Foodborne Disease Outbreaks --- United States, 2008*, 60 MORBIDITY & MORTALITY WKLY. REP. 1197, 1197 (2011) ("Foodborne agents cause an estimated 48 million illnesses annually in the United States.").

[17] *See* Paul S. Mead et al., *Food-Related Illness and Death in the United States.*, 5 EMERGING INFECTIOUS DIS. 607, 607 (1999) ("[S]ymptoms of foodborne illness range from mild gastroenteritis.").

[18] *Foodborne Illness and Germs*, U.S. CTR. DIS. CONTROL & PREVENTION (Feb. 16, 2018), https://www.cdc.gov/foodsafety/foodborne-germs.html.

fatalities.[19] Foodborne illness may have disparate impacts on vulnerable groups, including minorities and people of lower socioeconomic status,[20] suggesting health justice as a needed lens for this public health hazard.[21] Consumers consistently rate food poisoning among top food-related concerns, ahead of pesticides, antibiotics, or allergens.[22] The economic burden of foodborne illness from common pathogens on the American healthcare system may approach $78 billion per year.[23]

The expansive scope of pathogens and food products contributing to foodborne illness complicates oversight for prevention and response.[24] Myriad species of microorganisms and toxic metabolites lead to illness every year. Prominent pathogens are

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19 *Food Safety: Key Facts*, WORLD HEALTH ORG. (Oct. 31, 2017), http://www.who.int/news-room/fact-sheets/detail/food-safety.

20 *See* Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 FOOD & DRUG L.J. 681, 686 (1998) ("Foodborne illness is particularly dangerous for those without access to health care, including the homeless, migrant workers, and others of low socioeconomic status."); Jennifer J. Quinlan, *Foodborne Illness Incidence Rates and Food Safety Risks for Populations of Low Socioeconomic Status and Minority Race/Ethnicity: A Review of the Literature*, 10 INT'L J. ENVTL. RES. & PUB. HEALTH 3634, 3645–46 (2013) (discussing the impact of "greater access to small, independently operated food markets and fast-food/take-out restaurants" on minorities' increased food poisoning rates). *Cf.* K. L. Newman et al., *The Impact of Socioeconomic Status on Foodborne Illness in High-Income Countries: A Systematic Review*, 143 EPIDEMIOL. & INFECT. 2473, 2473 (2015) (finding that the effect of socio-economic status, or SES, varies depending on the pathogen, but "the majority of identified studies for *Campylobacter*, salmonellosis, and *E. coli* infection showed an association between high SES and illness.").

21 *See generally* Lindsay F. Wiley, *Health Law as Social Justice*, 24 CORNELL J. LAW & PUB. POL'Y 47 (2014) (arguing that health law should be used as a tool for social justice).

22 *See, e.g.*, INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION, 2018 FOOD & HEALTH SURVEY 49 (2018) (finding "[f]oodborne illness from bacteria" was ranked as the most important food safety issue in 2018 more often than any other choice); INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION, 2014 FOOD & HEALTH SURVEY 75 (2014).

23 *See* Scharff, *supra* note 2, at 123 (finding that the aggregated annual cost of foodborne illness was $77.7 billion under its enhanced model). *Cf.* Sandra Hoffmann et al., *Annual Cost of Illness and Quality-Adjusted Life Year Losses in the United States Due to 14 Foodborne Pathogens*, 75 J. FOOD PROTECTION 1292, 1292 (2012) (reporting an average of $14 billion annually as a result of only common pathogens).

24 *See generally* U.S. FOOD & DRUG ADMIN., BAD BUG BOOK: HANDBOOK OF FOODBORNE PATHOGENIC MICROORGANISMS AND NATURAL TOXINS (2d ed. 2012) (providing information about major food pathogens and discussing the related oversight challenges) [hereinafter BAD BUG BOOK].

bacterial or viral, including salmonella, E. coli, and norovirus.[25] Parasites, protozoa, prions, and chemical toxins can also contaminate food and cause illness.[26] Every year, multiple outbreaks in meat, produce, and other types of consumables are investigated by federal regulators.[27] Illness arising from all food types can give rise to infection, hospitalization, and mortality.[28] Moreover, contamination vulnerabilities exist at all stages of the food supply chain, "from farm to table."[29] Identifying the pathogen responsible and the origin of contamination is a critical part of the response to an outbreak and preventing future outbreaks, and thus promoting food safety more broadly.[30] Difficulties in characterizing pathogens can arise from food contaminated by multiple microorganisms.[31] Unfortunately, determining the origin of an outbreak with current tools can require a substantial amount of time, potentially enabling the outbreak to propagate.[32]

Federal law divides regulatory authority over food safety between multiple agencies.[33] Recently boosted by the Food Safety Modernization Act, the Food and Drug Administration (FDA) has primary responsibility for preventing and responding to food

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[25] *Foodborne Illnesses and Germs*, U.S. CTR. DIS. CONTROL & PREVENTION (Feb. 16, 2018), https://www.cdc.gov/foodsafety/foodborne-germs.html.

[26] *See* BAD BUG BOOK, *supra* note 24 (discussing the impact of each of these categories of contaminants on food safety).

[27] *List of Multistate Foodborne Outbreak Investigations,* U.S. CTR. DIS. CONTROL & PREVENTION (Oct. 17, 2018), https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html.

[28] John A. Painter et al., *Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by using Outbreak Data, United States, 1998–2008*, 19 EMERGING INFECTIOUS DIS. 407, 410–13 (2013).

[29] FED. FOOD SAFETY WORKING GROUP, PROGRESS REPORT 1 (2011), https://obamawhitehouse.archives.gov/sites/default/files/fswg_report_final.pdf.

[30] *Steps in a Foodborne Outbreak Investigation*, U.S. CTR. DIS. CONTROL & PREVENTION (June 20, 2018), https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/investigations/detection.html. *See also* Sébastien Pouliot & Daniel A. Sumner, *Traceability, Liability, and Incentives for Food Safety and Quality*, 90 AM. J. AGRIC. ECON. 15, 24–25 (2008).

[31] Marion Koopmans, *Food-Borne Viruses from a Global Perspective*, *in* INSTITUTE OF MEDICINE, IMPROVING FOOD SAFETY THROUGH A ONE HEALTH APPROACH: WORKSHOP SUMMARY 225, 225 (2012).

[32] Il-Hoon Cho & Seockmo Ku, *Current Technical Approaches for the Early Detection of Foodborne Pathogens: Challenges and Opportunities*, 18 INT'L J. MOLECULAR SCI. 2078, 2079 (2017); *IBM Food Trust: Trust and Transparency in Our Food*, IBM (2018), https://www.ibm.com/blockchain/solutions/food-trust (last visited Apr. 11, 2019).

[33] GOV'T ACCOUNTABILITY OFFICE, FOOD SAFETY: A NATIONAL STRATEGY IS NEEDED TO ADDRESS FRAGMENTATION IN FEDERAL OVERSIGHT 6–7 (2017).

contamination.[34] FDA wields various tools for ensuring food safety including inspection, recalls, sampling, and voluntary destruction.[35] Complementing FDA jurisdiction, the Department of Agriculture's Food Safety Inspection Service (FSIS) has similar authority over meat, poultry, and processed eggs.[36] The Centers for Disease Control and Prevention (CDC) conducts food safety surveillance, investigates multistate outbreaks, and coordinates state and local public health actions.[37] These three federal agencies established the Interagency Food Safety Analytics Collaboration (IFSAC) in 2011 to promote coordination and cooperation in identifying culpable pathogens and contaminated food products.[38]

Despite its multi-agency scheme, gaps in U.S. food safety oversight remain. For example, of the nearly 50 million cases of foodborne illness in the U.S. each year, the responsible pathogen has historically only been identified in one fifth of the cases.[39] In 2011, the FDA launched the "Whole Genome Sequencing (WGS) Program" to enhance its food safety operations.[40] WGS methods comprehensively decode the full genome of an organism, identifying

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[34] FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399i (2018)); *see* Debra M. Strauss, *An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business*, 66 FOOD & DRUG L. J. 353, 354–55 (2011) (analyzing the new duties as well as the enhanced scope of FDA's authority created by FSMA).

[35] *See* Deliganis, *supra* note 20, at 702–05 (considering the many tools available in FDA's arsenal); *Food: Compliance & Enforcement*, U.S. FOOD & DRUG ADMIN. (Sept. 18, 2018), https://www.fda.gov/Food/ComplianceEnforcement/default.htm (discussing FDA's authority to take action against "adulterated" or "misbranded" foods); *see also* 21 U.S.C. §§ 321(f), 393(b)(2)(A) (2018).

[36] 21 U.S.C. §§ 451–72 (2019); 21 U.S.C. §§ 601–26 (2019); 21 U.S.C. §§ 1031–56 (2019).

[37] 21 U.S.C. § 2224; *CDC and Food Safety*, U.S. CTR. DIS. CONTROL & PREVENTION (Apr. 4, 2018), https://www.cdc.gov/foodsafety/cdc-and-food-safety.html. *See generally* U.S. CTR. DISEASE CONTROL & PREVENTION, SURVEILLANCE FOR FOODBORNE DISEASE OUTBREAKS, UNITED STATES: 2016 ANNUAL REPORT (2016).

[38] INTERAGENCY FOOD SAFETY ANALYTICS COLLABORATION, STRATEGIC PLAN: CALENDAR YEAR 2017-2021 2–3 (2017).

[39] *See* Elaine Scallan et al., *Foodborne Illness Acquired in the United States—Major Pathogens*, 17 EMERGING INFECTIOUS DIS. 7, 7 (2001) (finding 9.4 million cases of foodborne illness caused by known, common pathogens); *see also* Elaine Scallan et al, *Foodborne Illness Acquired in the United States—Unspecified Agents*, 17 EMERGING INFECTIOUS DIS. 16, 16 (2011) (finding 38.4 million cases of foodborne illness caused by unknown pathogens).

[40] Eric L. Stevens et al., *The Public Health Impact of a Publicly Available, Environmental Database of Microbial Genomes*, 8 FRONTIERS MICROBIOLOGY 1, 2 (2017).

the organism by comparing the data produced through sequencing to reference genomic datasets.[41] With the costs of WGS technology falling,[42] the FDA program calls on laboratories to characterize the full genome of microbes obtained from food, environmental, and clinical samples in their local areas.[43] The GenomeTrakr platform serves as a key tool in the FDA Whole Genome Sequencing Project by providing an international reference database of pathogen genomes.[44] GenomeTrakr enables public health officials to infer the origin of contamination in food products by comparing the genomes of new outbreak pathogens, obtained from WGS, to references in the database from various geographical locations.[45] In 2013, CDC announced its existing PulseNet network of genomic food safety laboratories would begin collecting WGS data.[46] PulseNet aims to recognize outbreaks earlier by finding common strains of specific pathogens in different clinical cases and whole genome data should augment these efforts.[47] FSIS contributes to both CDC's PulseNet and FDA's GenomeTrakr, and, in 2017, indicated interest in conducting its own analyses of pathogen genomic data.[48] An overview of the efforts of IFSAC agencies to implement WGS techniques in food safety are described in Figure 1.

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[41] Jenny C. Taylor et al., *Factors Influencing Success of Clinical Genome Sequencing Across a Broad Spectrum of Disorders*, 47 NATURE GENETICS 717, 717 (2015).
[42] Xavier Didelot et al., *Transforming Clinical Microbiology with Bacterial Genome Sequencing*, 13 NATURE REV. GENETICS 601, 610 (2012).
[43] *Whole Genome Sequencing (WGS) Program*, U.S. FOOD & DRUG ADMIN. (Feb. 15, 2018), https://www.fda.gov/food/foodscienceresearch/wholegenomesequencingprogramwgs/.
[44] *GenomeTrakr Fast Facts*, U.S. FOOD & DRUG ADMIN. (Oct. 30, 2018), https://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/ucm403550.htm.
[45] *Id.*
[46] *PulseNet: Whole Genome Sequencing (WGS)*, U.S. CTR. DISEASE CONTROL & PREVENTION (Feb. 11, 2016), https://www.cdc.gov/pulsenet/pathogens/wgs.html.
[47] *Id.*; *Fast Facts About PulseNet*, U.S. CTR. DISEASE CONTROL & PREVENTION (Feb. 16, 2016), https://www.cdc.gov/pulsenet/about/fast-facts.html.
[48] Use of Whole Genome Sequence Analysis to Improve Food Safety and Public Health, 82 Fed. Reg. 44378 (Sept. 22, 2017).

Figure 1. IFSAC Agencies and WGS Initiatives

FDA	CDC	FSIS
Uses GenomeTrakr to determine foodborne pathogen identity and location of origin	Uses PulseNet to recognize related pathogens in different cases, identifying outbreaks	Contributes to other efforts and has announced interest in analyzing pathogen whole genomes

Early evidence suggests these WGS methods for pathogen characterization may improve the response capacity of food safety regulators.[49] FDA reports cases showing WGS affords the ability to identify and distinguish between problematic pathogens in the food system, even in products with ingredients from diverse geographic locations.[50] In 2013, CDC launched a pilot project to detect food contaminated with listeria using WGS techniques.[51] Initial results demonstrate that WGS methods enabled public health officials to identify as many as 50% more related cases of foodborne listeria in a year and reduced the average number of cases reported per outbreak by up to 50%.[52] The listeria project points to significant possible public health and economic savings by reducing the burden of foodborne illness.[53] The expanding international adoption of PulseNet and GenomeTrakr should allow for further improved results.[54] Moreover, WGS systems may offer a platform for public health officials to monitor the food supply chain and intervene earlier

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[49] *See* E. Kurt Lienau et al., *Identification of a Salmonellosis Outbreak by Means of Molecular Sequencing*, 364 NEW ENG. J. MED. 981, 981 (2011) (discussing how genome sequencing methods were used in identifying a salmonella outbreak in 2009-2010).

[50] *Examples of How FDA Has Used Whole Genome Sequencing of Foodborne Pathogens for Regulatory Purposes*, U.S. FOOD & DRUG ADMIN. (Nov. 16, 2017), https://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/ucm422075.htm.

[51] Brendan R. Jackson et al., *Implementation of Nationwide Real-time Whole-genome Sequencing to Enhance Listeriosis Outbreak Detection and Investigation*, 63 CLINICAL INFECTIOUS DIS. 380, 380–81 (2016).

[52] *Id.* at 382 (comparing data from the year prior to WGS implementation to year 2 of WGS use).

[53] Robert L. Scharff et al., *An Economic Evaluation of PulseNet: A Network for Foodborne Disease Surveillance*, 50 AM. J. PREVENTIVE MED. S66, S66 (2016).

[54] *See* Marc W. Allard et al., *Practical Value of Food Pathogen Traceability through Building a Whole-Genome Sequencing Network and Database*, 54 J. CLINICAL MICROBIOLOGY 1975, 1975 (2016); Celine Nadon et al., *PulseNet International: Vision for the Implementation of Whole Genome Sequencing (WGS) for Global Food-Borne Disease Surveillance*, 22 EUR. SURVEILLANCE 1.

than otherwise possible to mitigate the spread of detected pathogens.[55]

Despite advances in WGS food regulation, gaps exist in industry and regulatory entities' abilities to trace food through the supply chain.[56] Paper documentation in the food supply chain continues to be used despite inefficiency.[57] No comprehensive digital system exists to track food products through the supply chain, slowing down regulatory responses to outbreaks of foodborne illnesses.[58] The summer 2018 regulatory investigation of an E. coli outbreak in lettuce from Arizona lasted for weeks,[59] illustrating long response times despite access to CDC and FDA genomic databases. Challenges in traceability can lead to significant waste as well. For example, after struggling to identify the source of an E. coli outbreak in November 2018, CDC and FDA warned consumers and distributors to discard all romaine lettuce from all producers.[60] This extensive response to the uncertain source of contamination further raised objections from farmers feeling they were unfairly forced to

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[55] *Proactive Approaches of Whole Genome Sequencing Technology*, U.S. FOOD & DRUG ADMIN. (Nov. 16, 2017), https://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/ucm422077.htm.

[56] *See* King et al., *supra* note 5 at 160, 170.

[57] Myo Min Aung & Yoon Seok Chang, *Traceability in a Food Supply Chain: Safety and Quality Perspectives*, 39 FOOD CONTROL 172, 181 (2014).

[58] Sylvain Charlebois et al., *Comparison of Global Food Traceability Regulations and Requirements*, 13 COMPREHENSIVE REV. FOOD SCI. & FOOD SAFETY 1104, 1108 (2014).

[59] *Statement from FDA Commissioner Scott Gottlieb, M.D., on Developments in the Romaine Outbreak Investigation* U.S. FOOD & DRUG ADMIN. (June 28, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm612187.htm.

[60] *CDC Food Safety Alert: E. coli Outbreak Linked to Romaine Lettuce*, U.S. CTR. DISEASE CONTROL & PREVENTION (Nov. 20, 2018), https://www.cdc.gov/media/releases/2018/s1120-ecoli-romain-lettuce.html; *Statement from FDA Commissioner Scott Gottlieb, M.D., On the Current Romaine Lettuce E. coli Outbreak Investigation*, U.S. FOOD & DRUG ADMIN (Nov. 26, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626716.htm [hereinafter FDA Update]. CDC even recommended consumers discard lettuce when unsure if lettuce was romaine. *Id.* FDA Commissioner Gottlieb expressed frustration that the contaminated food could not be well identified or traced to specific producers. *See* Susan Scutti, *Don't Eat Romaine Lettuce, CDC Urges Amid E. coli Concerns*, CNN (Nov. 21, 2018), https://www.cnn.com/2018/11/20/health/romaine-lettuce-e-coli-cdc/index.html. Some commentators were wry in their description of the regulatory inefficiency. *See, e.g.*, Tom McKay, *CDC: Do Not Eat Any Romaine Lettuce Until We Can Figure Out What the Hell Is Going On*, GIZMODO (Nov. 20, 2018), https://gizmodo.com/cdc-do-not-eat-any-romaine-lettuce-until-we-can-figure-1830580265.

carry the costs of traceability issues.[61] New approaches for digitally managing food safety data and tracing food products will be needed to complement other advances in preventing and responding to foodborne illness.

III. Blockchain and Applications in the Food Supply Chain

Improving traceability in the food supply chain may require novel tools. Opportunities to optimize and streamline the food safety infrastructure and to trace contaminated foods identified by WGS through the supply chain may arise with new technological approaches offered by blockchain.[62] These approaches offer platforms for a host of participants to collectively build a record of data while ensuring that only one, authoritative version exists at any time.[63]

Blockchain represents a large category of upcoming technologies anchored in the larger umbrella of distributed ledger technologies.[64] Blockchain systems have gained substantial attention by stakeholders from myriad industries due to several key elements

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[61] *See* Martin Finucane & Katie Camero, *Farmer Worries CDC Has Gone Too Far With Its Lettuce Warning*, BOSTON GLOBE (Nov. 23, 2018), https://www.bostonglobe.com/metro/2018/11/23/has-cdc-gone-too-far-with-its-lettuce-warning/F6WaKxSWQ81AsZtg8lLjuO/story.html. Some groups began labeling lettuce by its location and date of harvesting in response. Jesse Newman, *Lettuce Producers Prepare Labeling Changes in Response to New E. coli Outbreak*, WALL ST. J. (Nov. 26, 2018), https://www.wsj.com/articles/lettuce-producersprepare-labeling-changes-in-response-to-newe-coli-outbreak-1543255194?mod=hp_lead_pos10.

[62] *See generally* Massimo Di Pierro, *What Is the Blockchain?*, 19 COMPUTING SCI. & ENGINEERING 92 (2017); *Explainer: What Is a blockchain?*, MIT TECH. REV. (Apr. 23, 2018), https://www.technologyreview.com/s/610833/explainer-what-is-a-blockchain/.

[63] *See, e.g.*, Ryan Surujnath, *Off the Chain: A Guide to Blockchain Derivatives Markets and the Implications on Systemic Risk Notes*, 22 FORDHAM J. CORP. & FIN. L. 257, 262 (2017) (discussing the efficiency of blockchains compared to a centralized system); *see* Sorkin, *supra* note 8 (comparing blockchains to the use of Google Docs).

[64] WORLD BANK GROUP, DISTRIBUTED LEDGER TECHNOLOGY (DLT) AND BLOCKCHAIN 1 (2017), http://documents.worldbank.org/curated/en/177911513714062215/pdf/122140-WP-PUBLIC-Distributed-Ledger-Technology-and-Blockchain-Fintech-Notes.pdf; R3, BLOCKCHAIN BYTE: WHAT IS THE DISTINCTION BETWEEN A BLOCKCHAIN AND A DISTRIBUTED LEDGER? 2–3 (2017), https://www.finra.org/sites/default/files/2017_BC_Byte.pdf.

of the technology.[65] First, blockchain acts as a ledger or recording system for data or transactions.[66] Data are loaded onto the ledger in discrete "blocks" and coupled to the prior block, forming a "chain" with a timeline.[67] Second, blocks are placed on the ledger chronologically and users can view all blocks dating back to the original.[68] Third, that ledger is distributed across all nodes in the system, signifying that all users have a copy of the record.[69] Finally, verified blocks become immunized from changes by individual users, because altering an old block requires a majority of nodes to agree on the change.[70]

Classifying blockchains can occur in multiple manners, though a useful lens comes from viewing systems as permissioned or permissionless, public or private (as in Figure 2).[71] Permissionless blockchains enable any party to add a block to the chain, where permissioned systems require users to first obtain prior authorization from an administrator.[72] The public-private dimension instead distinguishes whether anyone can access and review data stored on the ledger, or if only authorized entities can access the information.[73] While Bitcoin functions as a public, permissionless system without a central authority, businesses looking for more top-down

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[65] The National Academies describes blockchain as "a technology meant to achieve and unalterable, decentralized, public, append-only log of transactions, without any single authority in a position to change the log." NAT'L ACAD. SCI., ENG'G, & MED., SECURING THE VOTE: PROTECTING AMERICAN DEMOCRACY 103 (2018).

[66] *See* NIST REPORT, *supra* note 6, at 13–1717 (explaining the ways blockchain can track data); Konstantinos Christidis & Michael Devetsikiotis, *Blockchains and Smart Contracts for the Internet of Things*, 4 IEEE ACCESS 2292, 2293 (2016).

[67] NIST REPORT, *supra* note 6, at 13–17; Christidis & Devetsikiotis, *supra* note 66, at 2293; *see also* Wessel Reijers, Fiachra O'Brolcháin & Paul Haynes, *Governance in Blockchain Technologies & Social Contract Theories*, 1 LEDGER 134, 136 (2016).

[68] X. Xu et al., *A Taxonomy of Blockchain-Based Systems for Architecture Design*, *in* 2017 IEEE INTERNATIONAL CONFERENCE ON SOFTWARE ARCHITECTURE (ICSA) 243, 244 (2017).

[69] WORLD BANK GROUP, *supra* note 64, at 5–6; *see also* R3, *supra* note 64, at 2 (noting that while blockchains are distributed, they can be built as both centralized or decentralized systems).

[70] Nir Kshetri, *Blockchain's Roles in Strengthening Cybersecurity and Protecting Privacy*, 41 TELECOMM. POL'Y 1027, 1027–28 (2017); *see* Yli-Huumo et al., *supra* note 9, at 3 (discussing the process of forming blockchain).

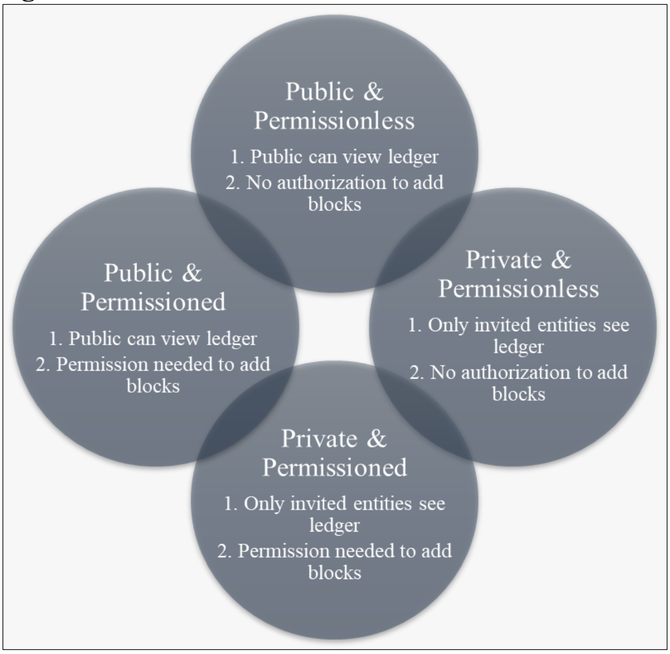
[71] Weizhi Meng et al., *When Intrusion Detection Meets Blockchain Technology: A Review*, 6 IEEE ACCESS 10179, 10183 (2018).

[72] *See* NIST REPORT, *supra* note 6, at 5–6.

[73] *See* Meng et al., *supra* note 71, at 10183.

approaches generally select private and permissioned schemes.[74] These characteristics may change the method of verifying blocks before being added to the immutable chain, called consensus models.[75] Proof of work consensus models have become commonplace in permissionless blockchains such as Bitcoin, which competitively reward the first participating node to verify blocks by solving algorithmic "puzzles."[76] However, consensus protocols better suited for permissioned systems may provide useful alternatives to proof of work models and their high fiscal and energy costs.[77] For greater flexibility, data recorded on the distributed ledger and associated applications can be stored on- or off-chain.[78]

Figure 2. Basic Blockchain Structural Classifications[79]



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[74] Praveen Jayachandran, *The Difference Between Public and Private Blockchain*, IBM BLOG (May 31, 2017), https://www.ibm.com/blogs/blockchain/2017/05/the-difference-between-public-and-private-blockchain/.

[75] For a comprehensive review of consensus mechanisms, *see* NIST REPORT, *supra* note 6, at 18–24.

[76] *Id.* at 19–20.

[77] *See id.* at 21–24; CATHERINE MULLIGAN ET. AL. BLOCKCHAIN BEYOND THE HYPE 5, WORLD ECON. F. (2018), http://www3.weforum.org/docs/48423_Whether_Blockchain_WP.pdf.

[78] *See* Jose Luis Bellod Cisneros et al., *Public Health Surveillance using Decentralized Technologies*, 1 BLOCKCHAIN HEALTHCARE TODAY 1, 7 (2018).

[79] Adapted from information in NIST Report, *supra* note 6, at 5–6; Meng et al., *supra* note 71, at 10183.

Blockchain has gained a reputation as a financial technology, with its popularization through Bitcoin and the oscillating market value of cryptocurrencies since then.[80] However, blockchain applications also offer substantial promise in the health care and public health sectors.[81] Perhaps best documented is the anticipated application of blockchain to power electronic health records to enhance privacy and portability.[82] But various other opportunities to advance public health through blockchain exist, including tracing medical products through the supply chain.[83] Converging with the interest in blockchain for logistics,[84] blockchain has been proposed as a system to track prescription opioids through the drug supply chain.[85]

The intersection of blockchain, supply chain logistics, and public health has recently sparked attention for its applications in food safety. In August 2017, IBM and food industry giants including Walmart announced a partnership to pilot a blockchain-based food surveillance system.[86] The permissioned IBM platform aims to record data throughout the supply chain for individual food batches including location of origin, identification numbers, expiration dates, shipping records, and other processing information.[87] Notably, the Walmart-IBM collaboration promises to identify the source of an

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[80] *See* JERRY BRITO & ANDREA CASTILLO, BITCOIN: A PRIMER FOR POLICYMAKERS, MERCATUS CTR. 1–2, 6 (2016), https://www.mercatus.org/system/files/gmu_bitcoin_042516_webv3_0.pdf.

[81] Ron Ribitzky et al., *Pragmatic, Interdisciplinary Perspectives on Blockchain and Distributed Ledger Technology: Paving the Future for Healthcare*, 1 BLOCKCHAIN HEALTHCARE TODAY 1, 5–9 (2018), https://blockchainhealthcaretoday.com/index.php/journal/article/view/24/21.

[82] *See* Gammon, *supra* note 10, at 378–79.

[83] Liam Bell et al., *Applications of Blockchain Within Healthcare*, 1 BLOCKCHAIN HEALTHCARE TODAY 1, 2 (2018), https://blockchainhealthcaretoday.com/index.php/journal/article/view/8/29.

[84] *See* WORLD ECON. FORUM, TRADE TECH – A NEW AGE FOR TRADE AND SUPPLY CHAIN FINANCE 11 (2018), http://www3.weforum.org/docs/White_Paper_Trade_Tech_report_2018.pdf.

[85] Susan Galer, *Betting on Blockchain as a Miracle Cure for the $78 Billion Opioid Crisis*, FORBES (Sept. 12, 2017), https://www.forbes.com/sites/sap/2017/09/12/betting-on-blockchain-as-a-miracle-cure-for-the-78b-opioid-crisis/.

[86] IBM Press Release, *supra* note 13.

[87] Brigid McDermott, *Improving Confidence in Food Safety with IBM Blockchain*, IBM BLOCKCHAIN BLOG (Sept. 5, 2017), https://www.ibm.com/blogs/blockchain/2017/09/improving-confidence-in-food-safety-with-ibm-blockchain/. (In general, relevant supply chain data loaded on the blockchain may include "time, location, price, parties involved, and other relevant information when an item changes ownership."); *See* Kshetri, *supra* note 70, at 1034.

outbreak "in seconds rather than days or weeks."[88] The blockchain application could give retailers the confidence to only discard food products from the affected farms, rather than wasting considerably more food.[89] By September 2018, Walmart announced it would retain the program permanently to trace lettuce products.[90] Walmart will require direct suppliers and over 100 upstream farms to comply over the course of 2019.[91]

Though no public data on the project have been released, the Walmart-IBM pilot offers a valuable case study in leveraging distributed ledger technology to promote public health.[92] The preliminary reports of success for blockchain in the food supply chain will likely draw further interest from industry competitors and regulators alike for uses beyond leafy greens.[93] In November 2018, the French distributor Auchan SA announced its own blockchain

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[88] *See* IBM Press Release, *supra* note 13.

[89] *IBM Food Trust Expands Blockchain Network to Foster a Safer, More Transparent and Efficient Global Food System*, IBM (Oct. 8, 2018), https://newsroom.ibm.com/2018-10-08-IBM-Food-Trust-Expands-Blockchain-Network-to-Foster-a-Safer-More-Transparent-and-Efficient-Global-Food-System; *see supra* note 60 and accompanying text.

[90] Matt Smith, *In Wake of Romaine E. coli Scare, Walmart Deploys Blockchain to Track Leafy Greens*, WALMART , https://news.walmart.com/_news_/2018/09/24/in-wake-of-romaine-e-coli-scare-walmart-deploys-blockchain-to-track-leafy-greens (last accessed Apr. 8, 2019).

[91] Michael Corkery & Nathaniel Popper, *From Farm to Blockchain: Walmart Tracks Its Lettuce*, N.Y. TIMES (Sept. 24, 2018), https://www.nytimes.com/2018/09/24/business/walmart-blockchain-lettuce.html; Kim S. Nash, *Walmart Requires Lettuce, Spinach Suppliers to Join Blockchain*, WSJ BLOG (Sept. 24, 2018), https://blogs.wsj.com/cio/2018/09/24/walmart-requires-lettuce-spinach-suppliers-to-join-blockchain/.

[92] The late 2018 expansion of the pilot to include European food distributor Carrefour may open more opportunities for evaluation. *See Food Traceability: Carrefour, a Blockchain Pioneer in Europe, Has Joined the IBM Food Trust Platform to Take Action on a Global Scale* (Oct. 8, 2018), http://www.carrefour.com/current-news/food-traceability-carrefour-a-blockchain-pioneer-in-europe-has-joined-the-ibm-food. However, should the pilot fail and these industry leaders abandon a blockchain approach, this may ripple into the food supply chain industry. *See* Christian Catalini & Catherine Tucker, *When Early Adopters Don't Adopt*, 357 SCIENCE 135, 135–36 (2017).

[93] *See From Shore to Plate: Tracking Tuna on the Blockchain*, PROVENANCE (July 15, 2016), https://www.provenance.org/tracking-tuna-on-the-blockchain. Contamination in other common food products also cause public health burdens, as the 2018 FSIS recalls on raw beef indicate. *See* News Release, U.S. Food Safety & Inspection Serv., JBS Tolleson, Inc. Recalls Raw Beef Products Due to Possible Salmonella Newport Contamination (Dec. 4, 2018), https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive/archive/2018/recall-085-2018-EXP-release.

pilot to trace meat and vegetables through the supply chain.[94] The World Wildlife Fund has launched a blockchain project to trace tuna through the supply chain in Australia, New Zealand, and Fiji.[95] Insurers may support the drive towards blockchain, given the potential for lowering fiscal risk in the food supply chain.[96] Publicized foodborne illness outbreaks may add pressure to adopt blockchain, with some coverage casting blockchain as a potential solution to traceability issues arising from the November 2018 E. coli outbreak.[97] CDC and FDA already collaborate with IBM on blockchain applications in public health,[98] and may take new steps to infuse their food safety operations with blockchain.[99] While vital to acknowledge that blockchain technology cannot solve all problems,[100] its potential to reduce foodborne illness will likely drive further experimentation and implementation.

IV. Governance Considerations for Combining Blockchain and Genomics

Two rising trends in food safety may soon converge. On one side, food regulators have begun to implement WGS methods and databases to enhance responses to foodborne illness, aiming also to

[94] *Globalized blockchain: Auchan implements food traceability technology on international scale*, FOODINGREDIENTSFIRST (Nov. 28, 2018), https://www.foodingredientsfirst.com/news/globalized-blockchain-auchan-implements-food-traceability-technology-on-international-scale.html

[95] *New Blockchain Project Has Potential to Revolutionize Seafood Industry*, WORLD WILDLIFE FUND (Jan 8, 2018), https://www.wwf.org.nz/what_we_do/marine/blockchain_tuna_project/.

[96] *See* David Hundeyin, *Australian Insurer Announces Blockchain Trial for Beef Export Supply Chain*, CCN (Dec. 11, 2018), https://www.ccn.com/australian-insurer-announces-blockchain-trial-for-beef-export-supply-chain/.

[97] *See* Bruce Y. Lee, *What Blockchain Has to Do with Turkey, Romaine Lettuce, and Food Safety*, FORBES (Nov. 28, 2018), https://www.forbes.com/sites/brucelee/2018/11/28/what-does-blockchain-have-to-do-with-turkey-lettuce-and-food-safety/#41fb5c7b7399.

[98] Steven Melendez, *How IBM and the CDC Are Testing Blockchain to Track Health Issues Like the Opioid Crisis*, FAST COMPANY (Sept. 4, 2018), https://www.fastcompany.com/90231255/how-ibm-and-the-cdc-are-testing-blockchain-to-track-health-issues-like-the-opioid-crisis; *IBM Watson Health Announces Collaboration to Study the Use of Blockchain Technology for Secure Exchange of Healthcare Data*, IBM (Jan. 11, 2017), https://www-03.ibm.com/press/us/en/pressrelease/51394.wss.

[99] *See* Fox, *supra* note 14.

[100] R. JESSE MCWATERS, THE FUTURE OF FINANCIAL INFRASTRUCTURE 18, WORLD ECON. FORUM (2016), http://www3.weforum.org/docs/WEF_The_future_of_financial_infrastructure.pdf.

augment prevention efforts.[101] On the other, private industry is developing blockchain capabilities for data recording to streamline regulatory compliance and minimize discarded products during an outbreak. Blockchain offers strengths to cover the weaknesses of WGS, enabling officials to trace contaminated food products through the supply chain and potentially increasing data liquidity.[102] In turn, whole genomic sequencing methods should enable determining the exact type of pathogen and its geographical origin, when blockchain is limited to tracing backwards rather than starting at the beginning. If combined effectively, the nexus of blockchain and WGS could enhance the capacity of public health actors to respond to and prevent foodborne illness mortality and morbidity.

More specifically, benefits might accrue from fusing the power of WGS methods and government reference databases with the advantages of blockchain containing an authoritative, timestamped, readily searchable record (as depicted in Figure 3). Since blockchain systems likely cannot store the amount of data constituting a full genomic sequence,[103] useful information about each sequenced organism including species and location could instead be recorded directly on the chain.[104] The full DNA sequence of pathogens could instead be stored "off the chain,"[105] with a central authority providing permission to access the full sequence data on request by public health officials. In one possible scheme, during an outbreak of foodborne illness, pathogen information from clinical samples could be compared to reference databases and on-chain data to narrow the search for a matching organism. Permissioned access to off-chain genomic sequences could then be used to infer where the contamination originated and which downstream facilities were affected.

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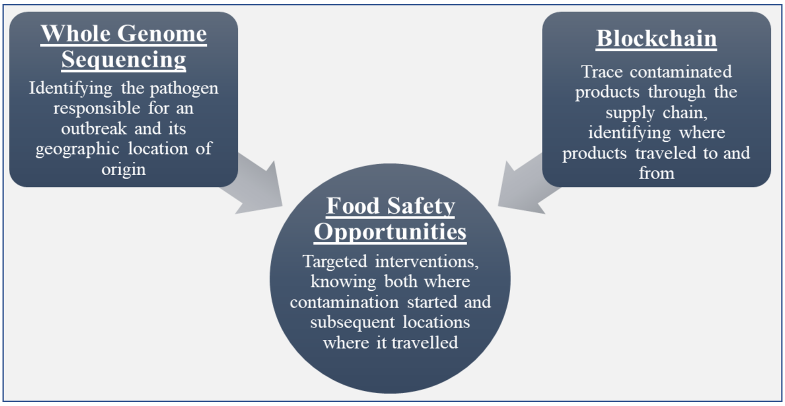
[101] *See Proactive Applications of Whole Genome Sequencing Technology*, U.S. FOOD & DRUG ADMIN. (Nov. 16, 2017), https://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/ucm422077.htm.
[102] Halil Ibrahim Ozercan et al., *Realizing the Potential of Blockchain Technologies in Genomics*, 28 GENOME RES. 1255, 1262 (2018).
[103] *See* Nadon et al., *supra* note 54, at 4–5.
[104] *See* Bellod Cisneros et al., *supra* note 78, at 5.
[105] William J. Gordon & Christian Catalini, *Blockchain Technology for Healthcare: Facilitating the Transition to Patient-Driven Interoperability*, 16 COMPUTATIONAL & STRUCTURAL BIOTECH. J. 224, 228 (2018).

Figure 3. Potential Food Safety Benefits in Integrating Blockchain and WGS



Beyond public health benefits, incentives exist to encourage private actors to pursue the integration of blockchain and WGS in food safety operations. Despite upfront costs in developing or leasing the blockchain platform, the Walmart case study suggests substantial potential savings for food distribution corporations by increasing response time to contamination in food products.[106] The heightened agility and specificity offered by combining WGS and blockchain should therefore promote greater internal savings and less waste for industry actors. More targeted responses to contamination should also protect farming entities from the economic impact of distributors discarding even uncontaminated food products when faced with uncertainty about the source and path of an outbreak.[107] The potential for blockchain and WGS combination systems to streamline and speed compliance should reduce or mitigate regulatory penalties resulting from contamination.[108]

Though offering great promise, excitement for a pragmatic new public health tool should be tempered by a realistic understanding of remaining technical, corporate, and governance challenges.[109] Whether developers can adequately scale up the blockchain supply chain pilot projects remains an open question, and

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[106] *See* IBM Press Release, *supra* note 13.
[107] *See, e.g.*, Finucane & Camero, *supra* note 61.
[108] *See generally*, EMILY M. LANZA, CONG. RES. SERV., R43927, FOOD SAFETY ISSUES: FDA JUDICIAL ENFORCEMENT ACTIONS (2015), https://fas.org/sgp/crs/misc/R43927.pdf.
[109] See CHRIS JAIKARAN, CONG. RES. SERV., R45116, BLOCKCHAIN: BACKGROUND AND POLICY ISSUES 9 (2018), https://fas.org/sgp/crs/misc/R45116.pdf.

may require years to accomplish.[110] Scaling up may also come with added risks of cybersecurity vulnerability.[111] Further increasing adoption of and participation in FDA and CDC pathogen sequencing programs will take time and appropriate standardization of the technology.[112] Deploying blockchain and WGS sequencing technologies at all nodes in a food supply chain will demand substantial time, resources, and, likely, political capital. Notably, while implementing blockchain would allow for improved supply chain management and mitigate the extent and duration of foodborne illness outbreaks, it would not directly resolve existing food safety issues leading to contamination.[113]

Moreover, technical decisions about the most appropriate architecture for a blockchain will be required and have regulatory implications. Blockchain-powered food supply chain systems promise to reduce fraud by holding all users accountable for the data they enter.[114] However, this benefit is only possible from within a permissioned blockchain system, as all users creating blocks must be identifiable to gain permissioned access.[115] Permissionless systems could create insurmountable challenges in data integrity and compliance by enabling any party to add blocks to the ledger.[116]

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[110] Evelyn Cheng, *For All the Hype, Blockchain Applications Are Still Years, Even Decades Away*, CNBC (June 4, 2018), https://www.cnbc.com/2018/06/04/for-all-the-hype-blockchain-applications-are-still-years-even-decades-away.html; Melissa Gilmour, *Blockchain for Supply Chains—More Hype Than Reality?*, SWEETBRIDGE (June 11, 2018), https://blog.sweetbridge.com/blockchain-for-supply-chains-more-hype-than-reality-150f9962b80c.

[111] *See* WORLD ECON. FORUM, *supra* note 84, at 11. *See also,* Aleksey K. Fedorov et. al., *Quantum Computers Put Blockchain Security at Risk*, 563 NATURE 465, 465–67 (2018); *Quantum Computers Pose an Imminent Threat to Bitcoin Security*, MIT TECH. REV. (Nov. 8, 2017), https://www.technologyreview.com/s/609408/quantum-computers-pose-imminent-threat-to-bitcoin-security/.

[112] Jacob Moran-Gilad, *Whole Genome Sequencing (WGS) for Food-Borne Pathogen Surveillance and Control – Taking the Pulse*, 22 EUROSURVEILLANCE 30547, 30547 (2017).

[113] Jenny Splitter, *Walmart's Blockchain Offers Tech Fix, But There's More to Leafy Greens Than Data*, FORBES (Sept. 28, 2018), https://www.forbes.com/sites/jennysplitter/2018/09/28/walmarts-blockchain-offers-tech-fix-but-theres-more-to-leafy-greens-than-data/.

[114] Nir Kshetri, *Blockchain Systems Are Tracking Food Safety and Origins*, THE CONVERSATION (Nov. 21, 2018 6:49 AM), https://theconversation.com/blockchain-systems-are-tracking-food-safety-and-origins-106491.

[115] *See* NIST Report, *supra* note 6, at 5–6.

[116] Les Wilkinson et. al., *Blockchain Meets Healthcare: Understanding the Business Model and Implementing Initiatives*, 2017 ACC DOCKET 57, 59, https://www.nelso

Permissioned systems could also avoid proof of work consensus mechanisms, avoiding substantial energy consumption and environmental impacts upon scaling up.[117]

If permissioned platforms advance, questions may arise about whether industry or government entities will hold centralized control of the blockchain to grant permission to participate and add blocks.[118] The potential public health utility and existing government stewardship over WGS databases may support placing public actors in control of permissioned blockchains. Federal regulators administering the permissioned systems may maximize accountability for industry and the effectiveness of enforcement actions.[119] The possibility of deliberate food contamination in acts of agroterrorism[120] may provide further rationale for federal government control. Yet, the technology and supply chain industries will likely lead the efforts to build blockchain infrastructure in the food supply chain.[121] Despite incentivizes to minimize fiscal harm from contamination, blockchain development will require private firms to expend notable resources in a competitive market. Accordingly, economic factors will likely disincentivize industry members who have invested the most in creating and maintaining platforms to cede control of their permissioned systems to federal food safety regulators.[122]

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nmullins.com/storage/4db2ba62b5531942d89ab659e2921280.pdf ("Depending on the industry, knowing who is on the network may not only be desired but legally required.").

[117] *See* Camilo Mora et al., *Bitcoin Emissions Alone Could Push Global Warming Above 2°C*, 2018 NATURE CLIMATE CHANGE 1, 1.

[118] Australia recently announced a pilot project for a national blockchain to act as a platform for blockchain based commerce in Australia, highlighting the possibility of a state-run blockchain for commercial and potentially regulatory functions. *See* AUSTRALIAN NATIONAL BLOCKCHAIN, https://www.australiannationalblockchain.com/ (last visited Apr. 10, 2019).

[119] Direct federal control would facilitate more traditional command and control regulation, often perceived as more accountable, transparent, and directly enforceable. *See* Diana M. Bowman & Graeme A. Hodge, *'Governing' Nanotechnology Without Government?*, 35 SCI. & PUB. POL'Y 475, 477 (2008).

[120] U.S GOV'T ACCOUNTABILITY OFFICE, GAO-07-310, HIGH RISK SERIES: AN UPDATE 28–29 (2007), https://www.gao.gov/new.items/d07310.pdf.

[121] Bernard Marr, *How Blockchain Will Transform the Supply Chain and Logistics Industry*, FORBES (Mar. 23, 2018), https://www.forbes.com/sites/bernardmarr/2018/03/23/how-blockchain-will-transform-the-supply-chain-and-logistics-industry/#1fbe6eb45fec (highlighting use cases all arising from private industry).

[122] REDUCING THE RISK OF POLICY FAILURE: CHALLENGES FOR REGULATORY COMPLIANCE 18, ORG. ECON. CO-OPERATION & DEV. (2000), https://www.oecd.org/

Further governance challenges could arise in the decision for public or private blockchain architecture. A public blockchain could enable public health officials globally to monitor food safety in the supply chain without procedural constraints on gaining access to the blockchain, likely leading to improved foodborne illness responses. The open-access model of a public ledger may also offer the most pragmatic interface between blockchain and the growing international adoption of GenomeTrakr and the PulseNet International network of WGS public health laboratories.[123] However, a public design would also enable any other party to view data on the chain, including competitors, yielding corporate confidentiality dilemmas.[124] Accordingly, businesses generally seek to utilize private blockchains.[125] Off-chain storage of confidential data could ease such concerns, but off-chain storage can carry independent security vulnerabilities.[126] Though a public blockchain could maximize transparency in supply chain governance,[127] business incentives may resist regulatory moves granting competitors access to confidential supply chain and compliance data.

The presence of competition in crafting blockchain platforms for the food supply chain also highlights the potential for interoperability challenges.[128] Given the competitive pressures to protect confidential data, each supply chain manager will likely

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gov/regulatory-policy/1910833.pdf (illustrating how corporate "[c]ompliance rates are lower when regulation does not fit well with existing market practices or is not supported by cultural norms and civic institutions.").

[123] *See* Nadon et al., *supra* note 54, at 10.

[124] *See* Charlebois, *supra* note 12. Developing new tools for blockchain platforms, including zero knowledge proofs, may mitigate the disclosure of confidential data by enabling parties to reveal no more data than is required for a given transaction. *See* Vinayaka Pandit & Pankaj Dayama, *Privacy in Blockchain Collaboration with Zero Knowledge Proofs*, IBM BLOG (Jan. 16, 2019), https://www.ibm.com/blogs/blockchain/2019/01/privacy-in-blockchain-collaboration-with-zero-knowledge-proofs/.

[125] *See* Jayachandran, *supra* note 74.

[126] Ana Reyna et al., *On Blockchain and Its Integration with IoT. Challenges and Opportunities*, 88 FUTURE GENERATION COMPUTER SYSTEMS 173, 177 (2018).

[127] Benjamin Herzberg, *Blockchain: The Solution for Transparency in Product Supply Chains,* PROVENANCE (Nov. 21, 2015), https://www.provenance.org/whitepaper.

[128] As in health care, blockchain is not an inherent solution to interoperability and issues will likely develop when blockchain platforms are implemented. Raj Sharma, *Don't Look to Blockchain to Solve Healthcare's Interoperability Woes*, FORBES (Sept. 18, 2018), https://www.forbes.com/sites/forbestechcouncil/2018/09/18/dont-look-to-blockchain-to-solve-healthcares-interoperability-woes/#7a19bd5e6eab.

obtain and operate their own blockchain with limited incentives to ensure it could interface with others.[129] Moreover, firms will lack incentives to switch to a new, more centralized blockchain platform once committed to one, as logged data will remain on the original blockchain and protocols to transfer data to a new blockchain remain limited.[130] Food blockchains lacking interoperability may complicate efforts by public health officials to effectively track foodborne illness outbreaks and apply WGS data, particularly when outbreaks span facilities and regions involving multiple supply chains.[131] Food products packaged with multiple types of ingredients,[132] potentially tracked through different blockchains, may exacerbate interoperability challenges.[133] Government pressure or mandates to create interoperable platforms could be opposed by industry, citing potential anticompetitive effects.[134]

No simple solution exists to these governance challenges, given the conflicting public health and business interests in designing and deploying a blockchain to integrate with existing WGS operations. Overly aggressive actions or requirements by regulators, even made in the interest of public health, may disincentivize industry from ever developing the blockchain platforms.[135] Command and control regulatory approaches administered by a central government may suffer from perceived or real inefficiency,

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[129] Absent standardization or other pressures, blockchain developers will have significant latitude to build unique platforms to the specifications of individual clients, likely resulting in interoperability issues. *See* DAVID SCHATSKY, ET. AL., BLOCKCHAIN AND THE FIVE VECTORS OF PROGRESS 4, DELOITTE, (2018), https://www2.deloitte.com/content/dam/insights/us/articles/4600_Blockchain-five-vectors/DI_Blockchain-five-vectors.pdf.

[130] *See* JAIKARAN, *supra* note 109, at 8.

[131] *See* Aung & Chang, *supra* note 57, at 178.

[132] John A. Painter et al., *Attribution of Foodborne Illness, Hospitalizations, and Deaths to Food Commodities by Using Outbreak Data, United States, 1998-2008*, 19 EMERGING INFECTIOUS DISEASES 407, 408–09 (2013) (describing these products as "complex foods").

[133] *See* BLOCKCHAIN USE CASES FOR FOOD TRACEABILITY AND CONTROL 23, KAIROS FUTURE (2017), https://www.sklkommentus.se/globalassets/kommentus/bilder/publication-eng-blockchain-for-food-traceability-and-control-2017.pdf.

[134] *See* IOANNIS LIANOS, BLOCKCHAIN COMPETITION: GAINING COMPETITIVE ADVANTAGE IN THE DIGITAL ECONOMY 73 (2018), https://www.ucl.ac.uk/cles/sites/cles/files/cles_8-2018.pdf.

[135] *See* Laura Shin, *Crypto Industry Frustrated by Haphazard Regulation*, N.Y. TIMES (June 27, 2018), https://www.nytimes.com/2018/06/27/business/dealbook/crypto-industry-regulation.html.

overly burdensome costs to industry, and restricting flexibility to innovate with emerging blockchain systems.[136]

Instead, handling the synthesis of WGS methods and blockchain in the food supply chain may benefit from "softer" regulatory approaches. As opposed to command and control schemes, softer approaches offer a spectrum of regulatory mechanisms lacking traditional legal enforceability.[137] So called "soft law" enables more voluntary, innovative, and adaptable regulatory possibilities by expanding definitions of oversight to include regulation by private or public-private entities.[138] Limitations of these softer approaches should guide their implementation and combination, including the potential for reduced legitimacy, inconsistent enforcement, and regulatory capture, as well as coordination issues in public-private settings.[139]

Softer oversight should offer useful tools for advancing the effective combination of blockchain and WGS technologies while responding to governance challenges. Public-private or voluntary oversight programs[140] may ease tensions between government or industry control over permissioned blockchains through leaving control with industry while creating infrastructure for collaboration. Such arrangements could promote the flow of blockchain and WGS data across the public-private border during an outbreak while also enabling government information gathering to measure the effectiveness of blockchain implementation.[141] Federal regulators already facilitate food industry action on traceability without

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[136] Darren Sinclair, *Self-Regulation Versus Command and Control? Beyond False Dichotomies*, 19 L. & POL'Y 529, 530 (1997).

[137] Kenneth W. Abbott et al., *The Concept of Legalization*, 54 INT'L ORG. 401, 401–02 (2000).

[138] Julia Black, *Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a 'Post-Regulatory' World*, 54 CURRENT LEGAL ISSUES 103, 105–12 (2001); David Vogel, *The Private Regulation of Global Corporate Conduct*, 49 BUS. & SOC. 68, 69–70 (2010).

[139] *See* Bowman & Hodge, *supra* note 119, at 477.

[140] *See* Kenneth W. Abbott, et. al., *Soft Law Oversight Mechanisms for Nanotechnology*, 52 JURIMETRICS 279, 298–300 (2017) (describing voluntary and partnership programs in nanotechnology).

[141] *See* GUIDANCE ON PUBLIC-PRIVATE INFORMATION SHARING 5, WORLD ECON. FORUM (2016) (describing the utility of information sharing in collaboratively addressing cybercrime); Gary E. Marchant, et. al., *Risk Management Principles for Nanotechnology*, 2 NANOETHICS 43, 53–54 (2008) (describing information gathering as a preliminary governance tool for emerging technologies).

wielding formal regulatory power. Following the November 2018 lettuce contamination, FDA coordinated stakeholders in forming a task force to generate recommendations for improving traceability with labeling.[142] These existing relationships could provide the groundwork for close collaboration on governing blockchain and WGS tools.

Technical standards, another soft regulatory tool, could promote interoperability and facilitate common blockchain architecture for WGS compatibility.[143] Third party standards can provide technical guideposts to direct and stimulate innovation in nascent technologies with various forms.[144] Civilian standard setting bodies with high credibility including ISO and IEEE could build on their existing projects on blockchain[145] to craft standards for interoperability in food safety applications and WGS compatibility. In the U.S., the National Institute of Standards and Technology could provide a similar function as a public entity with expertise on blockchain,[146] crafting voluntary standards with stakeholder input to encourage data fluidity across blockchains and intersections with public genomic databases.

V. Conclusion

Blockchain and WGS represent powerful emerging technologies capable of bolstering regulatory and corporate response to foodborne illnesses. The technologies carry complementary strengths, combining increased traceability and accountability in the food supply chain with enhanced identification of pathogens and location of origin. With the clear potential to advance public health, the convergence of blockchain and WGS appears inevitable.

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142 *See* FDA Update, *supra* note 60.

143 For a review of blockchain technical features amenable to standardization, see Advait Deshpande et al., *Understanding the Landscape of Distributed Ledger Technologies/Blockchain*, RAND (2017), https://www.rand.org/pubs/research_reports/RR2223.html.

144 Knut Blind, et. al., *The Impacts of Standards and Regulation on Innovation in Uncertain Markets*, 46 RES. POL'Y 249, 258 (2017).

145 *ISO/TC 307: Blockchain and Distributed Ledger Technology*, ISO, https://www.iso.org/committee/6266604/x/catalogue/p/0/u/1/w/0/d/0 (last visited Apr. 11, 2019); *P2418.3 – Standard for the Framework of Distributed Ledger Technology (DLT) Use in Agriculture*, IEEE, https://standards.ieee.org/project/2418_3.html (last visited Apr. 11, 2019).

146 *See* NIST Report, *supra* note 6, at ii.

However, synthesis and implementation will require addressing technical and governance challenges.

Government-based WGS operations must effectively intersect with industry-driven blockchain developments to realize the promise of both technologies. Questions arise over whether public or private entities should retain control of permissioned platforms, whether to use public or private blockchain architectures, and how to address interoperability. Soft regulatory approaches offer a path to balancing public and private interests in resolving these governance challenges, though selecting exact oversight instruments should be reevaluated as both technologies mature independently and together. Successfully navigating governance and technical challenges to bring blockchain and WGS together, though complex, should promote public health and reduce foodborne illness burdens.