February 22, 2021

Docket Clerk
United States Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Proposed Rule, Requirements for Additional Traceability Records for Certain Foods [Docket No. FDA-2014-N-0053]

To Whom It May Concern:

The Center for Science in the Public Interest, Center for Foodborne Illness Research and Prevention, Consumer Reports, and STOP Foodborne Illness respectfully submit these comments on the U.S. Food and Drug Administration ("FDA") Proposed Rule: Requirements for Additional Traceability Records for Certain Foods [Docket No. FDA-2014-N-0053].

The undersigned organizations thank the U.S. Food and Drug Administration (FDA) for providing the opportunity to comment on the proposed rulemaking. We generally support the FDA's proposed food traceability rule and offer specific comments to refine and improve the proposal.

The Center for Science in the Public Interest (CSPI) is America's food and health watchdog. Since 1971, CSPI has worked to improve the public's health through better nutrition and food safety. The organization's work is supported by subscribers to its Nutrition Action Healthletter, one of the nation's leading health newsletters. CSPI is an independent organization that does not accept government donations or corporate funding.

The Center for Foodborne Illness Research and Prevention (CFI) is a national, 501 (c)(3) nonprofit organization founded to drive the development and implementation of innovative, science-based solutions for the food safety challenges of the 21st Century. CFI views itself as a knowledge broker, working to translate science into practical, evidence-informed policies that protect public health and prevent foodborne disease. CFI's objective is to provide an independent voice, committed to using the best available science to develop evidence-informed policies and practices that create a positive food safety culture from farm to table and beyond. The group advocates for science-based policies and the use of best practices throughout all food production and food safety systems.

Consumer Reports is a non-profit organization that works for and with consumers for truth, transparency, and fairness in the marketplace. We use our independent and rigorous research,

consumer insights, journalism, and policy expertise to inform people's purchase decisions, improve the products and services businesses deliver, and drive regulatory and fair competitive practices. Our work helps create a safer, fairer, and more transparent marketplace.

Stop Foodborne Illness (STOP) is a non-profit organization that for over 25 years has worked with illness victims and their families to advocate for and support best practices and continuous improvement in food safety. STOP called for reforms in the FSIS inspection program following the Jack in the Box outbreak in 1992-93 and was part of the consumer-industry coalition that supported and gained enactment of the Food Safety Modernization Act ("FSMA") in 2011. In addition to constituent support and policy advocacy, STOP collaborates with food companies to bring personal experiences with serious illness into company training and food safety culture programs.

I. Lack of Traceability Prevents Public Health Officials from Adequately Addressing Foodborne Outbreaks

Lack of traceability in the food system is a significant public health challenge, preventing public health officials from adequately addressing foodborne outbreaks. When an outbreak of foodborne illness occurs, FDA must partner with the Centers for Disease Control and Prevention (CDC) and state public health organizations to detect clusters of sick consumers, identify the foods they consumed, and trace those foods back through the supply chain to find points of convergence. Only then can FDA try to pinpoint the source of the contaminated food and, if indicated, request a recall.[1]

The process of tracing those foods back through the supply chain to identify the contaminated food (traceback) and subsequently tracing of the identified food forward to ensure a comprehensive and effective recall (trace forward) both depend on the availability and implementation of robust, efficient recordkeeping systems. Such comprehensive traceability throughout the food system, enabled by effective recordkeeping, provides crucial benefits for both industry and consumers. These include faster outbreak investigations and consequent illness prevention, narrower recalls and consequent decreased food waste and economic damage, better consumer confidence in the food supply, and enhanced understanding of food safety risks to inform future prevention efforts.

Unfortunately, the recordkeeping systems currently utilized by the food industry often fall well short when it comes to ensuring traceability to realize these potential benefits. As the FDA points out in its traceability rulemaking notice, FDA and its partners in outbreak investigations have experienced significant challenges due to "inconsistent, unstandardized recordkeeping, lack of a deliberate method to connect records, and the frequent lack of lot tracing regarding distribution to specific retail locations."[2]

This lack of adequate recordkeeping and consequent traceability gaps has led to numerous specific instances in which efforts to trace food back in the supply chain from the point of sale to a point of convergence were hindered, leading to avoidable delays that harm both consumers and industry. For example, in a 2018 outbreak of Shiga toxin-producing *E. coli* tied to leafy greens in Yuma,

---

[1] FDA. Chapter 7: Recall Procedures. In: *Regulatory Procedures Manual* (Version 08). Accessed 17 February 2021. https://www.fda.gov/media/71814/download.

[2] "Requirements for Additional Traceability Records for Certain Foods," 85 Fed. Reg. 59984 (Sept. 23, 2020). https://www.federalregister.gov/d/2020-20100/p-82.

Arizona, poor traceability impeded efforts to identify specific lots and growers of contaminated product, leaving the FDA and the CDC with little choice but to warn the public with a broad alert implicating *all* romaine lettuce.[3,4] Such delays leading to sweeping warnings not only leave consumers at risk, they also contributed to significant economic damage and food waste because large amounts of food must be discarded.

Poor traceability also hinders trace forward efforts, leading to delays in removing contaminated foods from the marketplace. For example, in a 2008 outbreak tied to peanut butter that was contaminated with *Salmonella* Typhimurium, it took multiple manufacturers three and a half months to identify and recall almost 4,000 products that contained a specific brand of contaminated peanut butter as an ingredient, exposing consumers to ongoing risks.[5]

Large outbreaks and recalls due in part to poor traceability may have also contributed to significant ongoing economic damage to industry from lost consumer trust. Consumers who experience sweeping public health alerts that forced retailers nationwide to empty entire shelves of certain categories of product (i.e. baby spinach, romaine) may subsequently view such products as high risk and avoid purchasing them due to such safety concerns. The April 2018 outbreak of *E. coli* connected to romaine lettuce had a profound market effect: for the first month following the outbreak romaine lettuce sales were down 41.4% compared to the same period in the previous year, with sales continuing to be depressed compared to the year prior through November, when there was another outbreak tied to romaine.[6] Consumer perception of a product's heightened level of risk may be prolonged. Sales of bagged spinach were estimated to be depressed for at least 68 weeks following a 2006 outbreak of *E. coli* associated with that product.[7]

Delayed and incomplete investigations due to traceability gaps also hinder root-cause analysis to identify the source of contamination and develop measures to control future outbreaks. For example, it took three years and three separate outbreak investigations of *Cyclospora* in the U.S. before FDA was able to issue an import alert in 2015 for the suspected source of the outbreaks, fresh cilantro from the state of Puebla, Mexico.[8] Human feces and toilet paper were found in cilantro growing fields during the agency's follow-up investigation.[9] A more effective traceback system could have allowed FDA to identify these issues years earlier, thereby preventing recurring outbreaks.

---

[3] *Ibid.*

[4] Bottichio L, Keaton A, Thomas D, et al. Shiga Toxin-Producing Escherichia coli Infections Associated With Romaine Lettuce-United States, 2018. *Clin Infect Dis*. 2020;71(8).

[5] *Ibid.*

[6] The drop in romaine sales in the first 40 weeks of 2018 was estimated to account for more than $71,000,000. Taylor K. Romaine Lettuce Sales Are Down More Than $71 Million so Far This Year as the Industry Has Been Pummeled With Food-Poisoning Outbreaks — and Things Are About to Get Worse. Business Insider. Nov. 21, 2018. https://www.businessinsider.com/e-coli-outbreaks-drag-romaine-lettuce-sales-down-2018-11.

[7] Carlos Arnade et al. Consumers' Response to the 2006 Foodborne Illness Outbreak Linked to Spinach. Amber Waves Economic Research Service, U.S. Dept. of Agriculture March 1, 2010. https://www.ers.usda.gov/amber-waves/2010/march/consumers-response-to-the-2006-foodborne-illness-outbreak-linked-to-spinach.

[8] "Requirements for Additional Traceability Records for Certain Foods," 85 Fed. Reg. 59984 (Sept. 23, 2020). https://www.federalregister.gov/d/2020-20100/p-88.

[9] FDA (Dec. 2, 2020). Import Alert 23-24: DETENTION WITHOUT PHYSICAL EXAMINATION OF FRESH CILANTRO FROM THE STATE OF PUEBLA, MEXICO - Seasonal (April 1 - August 30), https://www.accessdata.fda.gov/cms_ia/importalert_1148.html.

II. The Proposed Rule Fills Critical Holes in the Current Traceability System

The undersigned support the overall structure of the proposed rule, which seeks to improve traceability by harmonizing information requirements for foods on the Food Traceability List (FTL) throughout the supply chain.[10] The rule does this by strengthening recordkeeping requirements to ensure entities that manufacture, process, pack, or hold foods on the FTL keep records of information associated with key data elements (KDEs) at critical tracking events.

Examples of KDEs include, but are not limited to, growing area coordinates; location identifiers and location descriptions for the immediate previous source of the food; entry numbers assigned to imported foods; a traceability product identifier and traceability product description for the food; business name, phone number, and point of contact of the harvester of the food and the date(s) and time(s) of harvesting; the quantity of each traceability product description for the food produced through transformation; and reference record type(s) and number(s) relating to transformation.[11] Maintaining records of information associated with KDEs will help to ensure traceability throughout the supply chain by preserving this information as products move between parties.

These proposed requirements would prevent many of the demonstrable consequences of poor traceability. Maintaining data that are accessible in the event of an outbreak and that show the source of origin of a food, as well as key steps in the supply chain, would mitigate investigation delays and inefficiencies due to investigators having to parse through incomplete and non-standardized records. These changes would support efforts to effectively traceback and trace forward, allowing the recalling firm to identify where units of contaminated product may have subsequently traveled within the food system. Recalls would be more likely be swift, efficient, and effective. Food waste and economic damage also would be minimized as recalls would be targeted to affected lots of products. Consumer confidence also would be less likely to be negatively impacted as smaller amounts of contaminated products would need to be removed from store shelves or thrown away in homes, avoiding widely-broadcast public warnings that necessitate the disposal of large categories of foods en masse.

Most importantly, the rule has the potential to prevent illnesses and save lives. As FDA's proposal highlights: "each day that a foodborne illness outbreak remains unresolved, the health of consumers remains at risk."[12] The recalls enabled under the traceability rule would limit consumer exposure to contaminated products by facilitating a faster response time, preventing illnesses and deaths. The proposed rule has been estimated by the agency to decrease traceback time by 84 percent, resulting in an estimated $567 - $626 million in public health benefits from averted illness.[13] This figure does not even include the potential for preventing illnesses and deaths due better outbreak prevention enabled by improved traceability in the future.

---

[10] "Requirements for Additional Traceability Records for Certain Foods," *85 Fed. Reg. 59984* (Sept. 23, 2020), at https://www.federalregister.gov/d/2020-20100/p-55.
[11] FDA. Which Key Data Elements Would Apply to Me? FDA. Updated Sep. 21, 2020. https://www.fda.gov/food/food-safety-modernization-act-fsma/which-key-data-elements-would-apply-me.
[12] "Requirements for Additional Traceability Records for Certain Foods," 85 Fed. Reg. 59984 (Sept. 23, 2020). https://www.federalregister.gov/documents/2020/09/23/2020-20100/requirements-for-additional-traceability-records-for-certain-foods#p-82.
[13] *Ibid.*

III. Specific Comments on Portions of the Proposed Rule

A. Electronic Record Availability

We support the requirement that, when necessary to assist FDA in responding to an outbreak or public health threat and upon request by FDA, entities subject to recordkeeping requirements must provide relevant traceability information to FDA within 24 hours in the form of an electronic, sortable spreadsheet.[14] Notably, and to the benefit of encouraging industry innovation in traceability, this addition may not interfere with firms that already have established electronic record systems. As proposed, § 1.1455(e) establishes that firms subject to recordkeeping requirements would not need to duplicate existing records (provided that those records contain all the information required under the proposed rule).[15]

The agency has indicated that it "strongly encourage[s]," but does not mandate, that all entities in the food industry maintain fully electronic data systems. Other than requiring production of the electronic, sortable spreadsheet upon request, the rule does not require that *all* records be maintained in electronic format.

Given the breadth and technological complexity of the modern food supply chain, the maintenance of electronic records is in the best interest of both business and public health. We recognize that requirements of the rule will create important incentives for firms to adopt an electronic recordkeeping system to comply with the rule. Nevertheless, we are concerned that members of the food industry will delay adopting electronic recordkeeping in the absence of a mandatory standard, which may lead to additional hindered outbreak investigations and limit future technology enabled traceability initiatives. We therefore urge the agency to amend the proposal to require that traceability information be maintained in electronic form and made available under urgent circumstances as quickly as possible, including in less than 24 hours.

Regardless of the particulars of electronic record requirements, the FDA should continue to develop the means to support regulated entities in electronic data migration, tracking, and management as it follows its New Era of Smarter Food Safety Blueprint, including by prioritizing risk-based inspections and import screenings based on the regulated entity's adoption of electronic data management practices.

B. Exemption for Small Retail Food Establishments

The undersigned support the general principles behind a partial exemption (Option 2) from the proposed subpart S requirements for small retail food establishments (proposed § 1.1305(g)).[16] In general, we would like to encourage the agency to focus on identifying ways to make compliance more accessible for small businesses and entrepreneurs, provided there is not an increase in risk to consumers.

Option 2 would provide flexibility for small retailers by requiring them to comply with the core

---

[14] "Requirements for Additional Traceability Records for Certain Foods," 85 Fed. Reg. 59984 (Sept. 23, 2020). https://www.federalregister.gov/d/2020-20100/p-441.
[15] *Ibid.*
[16] *Ibid.*

recordkeeping provisions of the rule, while exempting them from the requirement of providing an electronic, sortable spreadsheet containing the required recordkeeping information to FDA upon request within 24 hours of the request.[17]

We encourage FDA, however, to narrow the parameters regarding which entities qualify as a small retail food establishment under the partial exemption, which is currently proposed to cover retailers with 10 or fewer full-time equivalent employees. New grocery technologies (i.e., automated checkout) are rapidly growing in popularity, meaning the number of employees needed to run a retail establishment is likely to decrease in the coming years, resulting in dwindling coverage for the rule.

To prevent this, we recommend that the agency replace the current requirement with a gross annual income ceiling for qualifying small retail establishments (to be adjusted with inflation over time). For instance, the rule could partially exempt establishments that have carried a gross annual income in the previous fiscal year of no more than X amount (with X to be determined based on the current gross annual income for some proportion of retailers of that size).

C. Scope of the Food Traceability List

We generally support the scope of the food traceability list, which covers many FDA-regulated foods associated with recent foodborne outbreaks, including leafy greens, shell eggs, melons, tomatoes, and nut butter. We also urge FDA to consider expanding the food traceability list to include additional foods associated with outbreaks, including dried and frozen fruits (e.g., coconut,[18,19] strawberries[20]), tahini,[21] pistachios[22] and hazelnuts,[23] and flour.[24]

Notably, the firms that have so far led in adopting traceability requirements generally have not limited those requirements to foods on the traceability list.[25] In addition, given that the current list weighs heavily towards fresh produce, expanding coverage of the rule to cover additional goods may help prevent the rule from having a differential impact on the price and availability of fresh produce (i.e., restaurants and small retailers would be less likely to forgo carrying fresh produce or to raise the price of such items if the same requirements were applied broadly across many goods carried by the store).

---

[17] "Requirements for Additional Traceability Records for Certain Foods," 85 Fed. Reg. 59984 (Sept. 23, 2020). https://www.federalregister.gov/d/2020-20100/p-190.

[18] CDC. Multistate Outbreak of Salmonella Typhimurium Infections Linked to Dried Coconut (Final Update). Published May 18, 2018. https://www.cdc.gov/salmonella/typhimurium-03-18/index.html.

[19] CDC. Salmonella Infections Linked to Frozen Shredded Coconut (Final Update). Published Feb. 15, 2018. Accessed Feb. 16, 2021. https://www.cdc.gov/salmonella/coconut-01-18/index.html.

[20] CDC. Multistate Outbreak of Hepatitis A Linked to Frozen Strawberries (Final Update). Published December 16, 2016. Accessed Feb. 16, 2021. https://www.cdc.gov/hepatitis/outbreaks/2016/hav-strawberries.html

[21] CDC. Multistate Outbreak of Salmonella Montevideo and Salmonella Mbandaka Infections Linked to Tahini Sesame Paste (Final Update). Published June 21, 2013. https://www.cdc.gov/salmonella/montevideo-tahini-05-13/; CDC. Outbreak of Salmonella Infections Linked to Karawan Brand Tahini. Published June 26, 2019. https://www.cdc.gov/salmonella/concord-05-19/index.html.

[22] CDC. Multistate Outbreak of Salmonella Montevideo and Salmonella Senftenberg Infections Linked to Wonderful Pistachios. Published May 20, 2016. https://www.cdc.gov/salmonella/montevideo-03-16/index.html

[23] CDC. Multistate Outbreak of E. coli O157:H7 Infections Associated with In-Shell Hazelnuts. Published April 7, 2011. https://www.cdc.gov/ecoli/2011/hazelnuts-4-7-11.html

[24] CDC. Multistate Outbreak of Shiga toxin-producing Escherichia coli Infections Linked to Flour. Published Sep 29, 2016. https://www.cdc.gov/ecoli/2016/o121-06-16/index.html; CDC. Outbreak of E. coli Infections Linked to Flour. Published July 11, 2019. https://www.cdc.gov/ecoli/2019/flour-05-19/index.html.

[25] Costco Wholesale Corporation. Food Safety Audit Expectations for Costco Suppliers. Vol. v.1. 2014:22. https://azzule.com/wp-content/uploads/2019/05/Master-Audit-Expectations-V1-0.pdf.

D. Produce that is Rarely Consumed Raw

As produce that is rarely consumed raw (RCR) is exempt from the recordkeeping requirements of the proposed rule,[26] we urge FDA to devote further resources to the development of the RCR list in consideration of its relevance to the FTL. The whole population datasets and criteria used to determine which products are RCR may not be sensitive to detecting important nontraditional products for certain populations that are not consumed raw, thus subjecting these products to needless regulatory burden. This may be particularly important for immigrant communities in the United States with niche food markets. For example, preliminary data from a recent survey conducted by the University of California, Davis indicates that several niche crops grown by Hispanic and Asian farmers are rarely consumed raw (and not on the RCR list), such as several species of cucurbits.[27] Alternatively, the rarely consumed raw list may include products which in fact are consumed raw by certain underrepresented populations in the datasets or due to emerging food trends, and thus should be subject to the traceability rule.

IV. Conclusion

Improved traceability should be viewed as a success for both consumers and industry. This proposed rule would greatly enhance the current traceability in the food system and solve many of the problems identified in previous outbreaks. There is room for improvements to the rule, including making electronic recordkeeping mandatory, refining the small business exemption, expanding coverage to additional food categories, and re-evaluating the foods that should be subject to the rule. Nonetheless, the undersigned groups are enthusiastic that the changes this rule will bring to the food system are positive and strongly urge the agency to move towards its swift implementation.

Questions and communications related to these comments can be directed to Sarah Sorscher, Deputy Director of Regulatory Affairs at Center for Science in the Public Interest, at ssorscher@cspinet.org or 202-777-8397.

Signed,

Center for Science in the Public Interest
Center for Foodborne Illness Research and Prevention
Consumer Reports
STOP Foodborne Illness

[26] "Requirements for Additional Traceability Records for Certain Foods," *85 Fed. Reg. 59984* (Sept. 23, 2020) https://www.federalregister.gov/d/2020-20100/p-180.

[27] DiCaprio, E., Pires, A., Dahlquist-Willard, R., et al. Rarely Consumed Raw Consumer Survey of Specialty Asian Crops: Report of Preliminary Data Analysis. Unpublished Report of Preliminary Data. https://www.regulations.gov/contentStreamer?documentId=FDA-2020-N-1119-0062&attachmentNumber=2&contentType=pdf