Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

May 24, 2018

Dear Commissioner Gottlieb:

The undersigned consumer and food safety groups write to urge that the Food and Drug Administration (FDA) propose, within six months, requirements for comprehensive and rapid traceability of produce, including leafy greens. Specifically, the FDA should implement the long-overdue directive laid out by Congress in the Food Safety Modernization Act (FSMA) requiring the agency to issue a proposed rule establishing recordkeeping requirements for high-risk foods. This will improve the agency's ability to quickly trace the source of foods linked to outbreaks of foodborne illness, so it can initiate swift recalls. The FDA should also immediately provide advice and communication to the leafy greens industry on existing requirements and best practices to enhance traceability.

These actions are urgently needed in light of unsolved multistate outbreaks of pathogenic *E. coli* in leafy greens in recent months. The FDA is currently still investigating an unsolved outbreak of *E. coli* O157:H7 infections linked to romaine lettuce. As of the date of this letter, more than 170 people are known to have been made ill in that outbreak. One of those people has died.[1] While the current outbreak seems to be nearing an end,[2] the FDA has given no indication that it is any closer to identifying the farm or farms that produced the contaminated lettuce. The failure to fully solve this outbreak comes on the heels of another unsolved *E. coli* outbreak linked to leafy greens last fall.[3]

Current technology makes it possible for retailers to track and trace products with extraordinary speed and accuracy. Retailers using advanced technology, such as blockchain, now report they can identify the origin of certain produce shipments in as little as 2.2 seconds.[4] Given these

[1] Food and Drug Administration. FDA investigating multistate outbreak of *E. coli* O157:H7 infections likely linked to romaine lettuce from Yuma growing region. May 16, 2018. www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm604254.htm. Accessed May 21, 2018.
[2] Centers for Disease Control and Prevention. Multistate outbreak of *E. coli* O157:H7 infections linked to romaine lettuce. May 16, 2018. www.cdc.gov/ecoli/2018/o157h7-04-18/index.html. Accessed May 21, 2018.
[3] Food and Drug Administration. FDA ends investigation of *E. coli* O157:H7 outbreak likely linked to leafy greens. February 28, 2018. www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm593896.htm. Accessed May 21, 2018.
[4] Aitken, R. IBM forges blockchain collaboration with Nestlé & Walmart in global food safety. August 22, 2017. www.forbes.com/sites/rogeraitken/2017/08/22/ibm-forges-blockchain-collaboration-with-nestle-walmart-for-global-food-safety/#22b6aafb3d36. Accessed May 21, 2018.

advances, it is no longer acceptable that the FDA has no means to swiftly determine where a bag of lettuce was grown or packaged.

We therefore urge you to act swiftly to carry out the Congressional requirements in FSMA to identify a list of high-risk foods and issue a proposed rule to enhance recordkeeping for those foods. In particular, we urge you to designate produce, including leafy greens, as a high-risk food category and propose regulations that will enhance product tracing for produce in the event of an outbreak. We also urge you to use the recent high-profile outbreaks as an opportunity to enhance communication with members of the produce and leafy greens industries to ensure compliance with existing rules (including those requiring one-up, one-back recordkeeping and supplier verification) and encourage the adoption of voluntary measures to improve traceability.

I. FSMA Traceability Requirements

The Food Safety Modernization Act, passed with strong bipartisan support and signed into law on January 4, 2011, was designed to proactively strengthen food safety throughout every segment of the food supply chain, from farm to fork. Part of the purpose of this landmark legislation was to enhance traceability in the event of an outbreak of foodborne illness, allowing the FDA to trace back illness to its source and implement swifter and more accurate recalls.

Prior to the enactment of FSMA, certain firms involved in the produce supply chain were required to register under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and to keep records on their immediate suppliers and customers ("one-up, one-back" traceability). Under this regulatory framework, efforts to trace the movement of produce through the supply chain during outbreaks of foodborne illness have long been plagued by a tangled web of inconsistent and inadequate records. In one particularly high-profile outbreak investigation in 2008, the FDA struggled for months to identify the source of illness originally thought to come from tomatoes, but that was eventually traced back to peppers.[5]

The FDA Food Safety Modernization Act included a provision to address these challenges by creating enhanced recordkeeping requirements for high-risk foods. Specifically, Section 204 required the FDA, within one year of the date of FSMA's enactment, to "designate high-risk foods for which the additional recordkeeping requirements … are appropriate and necessary to protect the public health."[6] The law further directed the agency, within two years of its enactment, to publish a notice of proposed rulemaking to establish enhanced recordkeeping

[5] Produce Safety Project. Breakdown: lessons to be learned from the 2008 *Salmonella* Saintpaul outbreak. November 17, 2008. www.pewtrusts.org/~/media/legacy/uploadedfiles/phg/content_level_pages/reports/psprptlessonssalmonella2008pdf.pdf. Accessed May 21, 2018.

[6] FDA Food Safety Modernization Act § 204, Pub. L. No. 111-353, 124 Stat. 3885. www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf. Accessed May 23, 2018.

requirements for facilities involved in the supply chain for high-risk foods. In addition, FSMA required the FDA to study the issue of traceability through a set of pilot projects, and to report its results and recommendations back to Congress.

The FSMA pilot projects were completed in 2012[7], and a report was submitted to Congress in 2016.[8] Yet, seven years after the enactment of FSMA, the FDA has yet to carry out Congress's mandate to create a list of high-risk foods and issue a proposed rule for enhanced recordkeeping. Instead, the FDA has devoted years to developing a "Draft Methodological Approach to Identifying High-Risk Foods."[9] That document, which is a draft methodology for proposing a future list, was released in February 2014 and remains unfinalized.

Such a lengthy and resource-intensive process for identifying high-risk foods is at odds with the one- and two-year timeline that Congress set out in FSMA. It is also unnecessary for the purposes of determining whether produce, especially leafy greens, is a category of high-risk food; it clearly is. Data on the relative food safety risks presented by produce and leafy greens is already available from the Centers for Disease Control and Prevention (CDC). Most recently, the Interagency Food Safety Analytics Collaboration (IFSAC) released a report showing that between 2009 and 2013, produce accounted for 58.6 percent of *Listeria* cases, 51 percent of *E. coli* O157 cases, 46 percent of *Salmonella* cases, and 33 percent of *Campylobacter* cases.[10] Leafy greens, in particular, have been a prominent source of outbreaks. The IFSAC report showed that vegetable row crops (including leafy greens) accounted for more cases of *E. coli* O157 between 2009 and 2013 than any other food category.[11]

Given the overwhelming evidence that leafy greens are high-risk foods, the FDA should take swift action to protect consumers from that risk. In fact, the agency has a readily available framework for generating enhanced recordkeeping requirements: the recommendations from the final report on the product traceability pilots, which, as we have noted above, was completed in 2012.[12] That report, drafted by the Institute of Food Technologists (IFT) with input from

---

[7] Institute of Food Technologists. Pilot projects for improving product tracing along the food supply system – final report. August 2012. www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM341810.pdf. Accessed May 21, 2018.

[8] Food and Drug Administration. Report to congress on enhancing tracking and tracing of food and recordkeeping submitted pursuant to Section 204 of the FDA Food Safety Modernization Act, Public Law 111-353. www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM540940.pdf. Accessed May 21, 2018.

[9] Food and Drug Administration. Draft methodological approach to identifying high-risk foods under Section 204(d)(2) of the FSMA. February 2, 2018. www.fda.gov/Food/GuidanceRegulation/FSMA/ucm380210.htm. Accessed May 22, 2018.

[10] Including seeded vegetables, row crop vegetables (including leafy greens), fruit, sprouts, and other produce. The Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2013 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States. December 2017. www.cdc.gov/foodsafety/pdfs/IFSAC-2013FoodborneillnessSourceEstimates-508.pdf. Accessed May 21, 2018.

[11] *Ibid*.

[12] Institute of Food Technologists. Pilot projects for improving product tracing along the

industry, government, consumer advocates, and other stakeholders, identified widespread inconsistencies in industry recordkeeping that impeded and slowed the FDA's ability to trace back products in the event of an outbreak. It made specific recommendations for the FDA to establish a uniform set of recordkeeping requirements for FDA-regulated foods, and it highlighted areas where the agency could improve its communication to industry, including by identifying key information that must be recorded and preserved to facilitate product tracing in the event of an outbreak.

The long delay in acting on these recommendations, and otherwise implementing Section 204, is untenable in light of the recent unsolved outbreaks linked to romaine lettuce and leafy greens. Tracing the source of such outbreaks is vitally important to improve the speed of the FDA's recall process, an issue that you, as the FDA commissioner, have recently highlighted as a public health priority.[13]

Product traceability is also essential to monitor the effectiveness of other protections in FSMA. The two recent outbreaks associated with romaine and leafy greens may signal that FSMA's requirements for produce safety (which have already been implemented voluntarily across much of the leafy greens industry[14]) may not be working effectively to protect consumers. Because the causes of the recent outbreaks are unknown, it is not clear whether this failure is due to gaps in compliance, or instead signals a need to reassess and strengthen some of the underlying rules. Without effective traceability, neither the agency nor industry can begin to address these challenges and prevent future outbreaks.

We therefore urge the agency, within the next six months, to:

1. Designate a list of high-risk foods that includes produce (or at a minimum, leafy greens), based on the history and severity of foodborne illness outbreaks linked to this food category; and
2. As required by Congress, issue a notice of proposed rulemaking outlining enhanced recordkeeping requirements for designated high-risk foods, ensuring better traceability during outbreaks of foodborne illness.

food supply system – final report. August 2012.
www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM341810.pdf. Accessed May 21, 2018.

[13] Statement from FDA Commissioner Scott Gottlieb, M.D., on new policy steps for strengthening public warning and notification of recalls. January 18, 2018. www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592777.htm. Accesses May 21, 2018.

[14] California Leafy Green Products Handler Marketing Agreement. LGMA Metrics Fully Align with FSMA Produce Safety Rule. August 28, 2017. www.lgma.ca.gov/2017/08/lgma-metrics-now-alignment-fsma-produce-safety-rule/. Accessed May 21, 2018.

II. Opportunity for Immediate Advice and Communication

The recent high-profile outbreaks also present an opportunity for the FDA to promote education and engage in constructive communication with industry on compliance and best practices related to recordkeeping. These recalls have been devastating not only to the consumers affected but also to the leafy greens industry. This spring, sales of romaine lettuce plummeted after consumers were warned by the CDC not to eat romaine unless they could confirm that it did not come from the Yuma, Arizona, growing region. This warning also appears to have affected consumer behavior for other types of lettuce not implicated in the outbreak, including iceberg lettuce, red leaf lettuce, and endive.[15]

Repeated outbreaks of this nature have the potential to modify long-term consumer perceptions around the safety of leafy greens, and fresh produce more generally. This would have lasting consequences across the produce industry, as well as a negative impact on consumers deterred from eating these healthy and nutritious foods. These outbreaks should therefore provide strong motivation to members of industry to comply with existing requirements and adopt voluntary practices. We urge the FDA to use this moment as an opportunity to advise and communicate with industry by providing guidance on compliance and best practices related to recordkeeping.

There are several recordkeeping requirements beyond section 204 that could be helpful in tracing the source during an outbreak investigation. In addition to the longstanding requirements to register and keep records providing for one-up, one-back traceability under the bioterrorism law, the supplier program included in the FSMA Final Rule for Preventive Controls for Human Food (which is soon to come into full effect) requires facilities that receive produce from large farms to have in place a supplier verification program, including for any suppliers used on a temporary basis. The recent outbreaks present an additional opportunity for the FDA to educate industry on these existing requirements and also communicate advice on methods of compliance that would enhance product tracing efforts.

The FDA can also encourage members of industry to undertake and coordinate voluntary efforts to improve traceability, based on lessons learned from recent investigations and the FSMA traceability pilots. Such advice could include:

- Advising each member of the food supply chain, including growers, processors, distributors, and point of sale vendors, to develop, document, and exercise a product tracing plan to track each product as it moves through the supply chain.

[15] Celebrating national salad month amid romaine lettuce worries. *Nielsen*. May 9, 2018. www.nielsen.com/us/en/insights/news/2018/celebrating-national-salad-month-amid-romaine-lettuce-worries.html. Accessed May 21, 2018.

- Identifying the information that the agency needs to conduct product tracing investigations, including key data elements and critical tracking events that should be identified and maintained in records under each firm's product tracing plan.
- Advising members of the food supply chain to maintain records providing traceability beyond the immediate supplier, ideally back to the point of origin (i.e., the grower, in the case of produce).
- Specifying the formats for recordkeeping (e.g., electronic, searchable) that are the most useful during a traceback investigation.
- Encouraging members of industry to preserve the traceability information obtained from suppliers (e.g., advising that distributors ensure that the lot number or bar code assigned by the grower can be easily linked to any internal coding system, such as a "license number" applied to each pallet at the distribution site).
- Encouraging industry members throughout the food supply chain to adopt uniform terminology and practices, and to participate in voluntary efforts to enhance traceability, such as the Produce Traceability Initiative.

III. Conclusion

The repeated outbreaks linked to produce and leafy greens since passage of FSMA leave no doubt that these products belong in the "high-risk" category. The FDA should act promptly to improve the traceability of these foods and protect consumers. We urge you to take these actions swiftly to address traceability before the next outbreak, so that consumers can have confidence that government and industry have the information they need to quickly and effectively respond and protect the public's health.

Sincerely,

Center for Foodborne Illness Research & Prevention
Center for Science in the Public Interest
Consumer Federation of America
Consumers Union
Food & Water Watch
National Consumers League
The Pew Charitable Trusts
STOP Foodborne Illness
Trust for America's Health