



Consumer Federation of America

February 22, 2020

Frank Yiannas
Deputy Commissioner for Food Policy and Response
U.S. Food and Drug Administration

RE: Requirements for Additional Traceability Records for Certain Foods

VIA ELECTRONIC SUBMISSION

Dear Deputy Commissioner Yiannas:

Consumer Federation of America (CFA) appreciates the opportunity to submit these comments in response to the Food and Drug Administration's above-referenced proposed rule. We commend the agency for developing requirements that will greatly improve public health authorities' ability to protect the public from foodborne illness.

CFA is an association of non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. Today, more than 250 of these groups participate in the federation and govern it through their representatives on the organization's Board of Directors.

When a foodborne illness outbreak arises, time is of the essence. As long as the source of an outbreak remains unidentified, consumers remain at risk and avoidable illness, hospitalization, and death may occur as a result. In the highly interconnected U.S. food system, the status quo "one-up, one-back" tracing requirements are inadequate, as several recent foodborne illness outbreaks have demonstrated. The requirements set forth in the proposed rule represent an important step forward towards a safer food supply.

Several recent outbreaks show why this rule is needed. For two consecutive years, the Centers for Disease Control & Prevention (CDC) has warned consumers not to eat romaine lettuce because the product was linked to an outbreak of Shiga toxin-producing *E. coli*. As the proposed rule notes, traceback data led the agency to identify a specific growing region from which the contaminated lettuce originated, but the records maintained by food companies were not sufficient to allow the agency to identify specific lots or growers. As a result, broad recalls and advisories against eating romaine lettuce followed, at a high cost to industry, consumers, and public health. Disconcertingly, the precise cause of the contamination events remained shrouded in mystery.

The COVID-19 pandemic has inserted more uncertainty into foodborne illness investigations, resulting in a greater need than ever for improved traceability. Social distancing

imperatives have led to increased use of telehealth services and other changes in medical services, which appear to have contributed to a decline in reported cases. Similarly, laboratory capacity for testing fecal specimens has shifted to COVID-19 related activity in many cases, further contributing to the dearth in data on foodborne illness outbreaks.¹ Notably, in 2020, CDC and FDA investigated several multistate outbreaks of *E. coli* O157:H7 infections and were unable to identify a source for two such illness clusters of significant size, which caused a combined 50 illnesses, 21 hospitalizations, and 1 death. For another 2020 *E. coli* outbreak, epidemiologic and traceback evidence showed that leafy greens were the likely source, but investigators were unable to identify a specific type or brand of leafy greens with the traceback data available. Already this year, a cluster of *E. coli* illnesses has cropped up, causing 16 illnesses, 9 hospitalizations, and 1 death, with no food source yet identified.² As the proposed rule explains, resolving foodborne illness outbreaks such as these relies on both the capacity to trace a food back in the supply chain, and to trace a food forward to its ultimate point of sale. By establishing that capacity, the proposed requirements will help to avoid more unsolved foodborne illness outbreak mysteries.

Current traceability requirements are inadequate. Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, certain food companies must keep records on their immediate suppliers and customers, so-called “one-up, one-back” traceability. As the proposed rule points out, however, inconsistent, unstandardized recordkeeping often prevents FDA from determining the links in a product’s supply chain, even when all of the companies in that supply chain comply with the one-up, one-back requirements.

Fortunately, many food companies have worked with their supply chain partners to move beyond one-up, one-back, but the proposed rule is critically needed to leverage existing food industry investment. FDA must lead the way to better traceability. In anticipation of this rule, and with the assistance of new technologies like blockchain, some food companies have achieved remarkable gains in how quickly they are able to pinpoint the origins and retail destinations of their products. The U.S. Department of Agriculture’s Agricultural Marketing Service has proposed its own recordkeeping rules to enhance product traceability in the National Organic Program.³ Voluntary traceability initiatives, led by groups such as the Institute of Food Technologists, the Produce Traceability Initiative, the International Standards Organization, and the Global Food Safety Initiative, have come a long ways towards developing consensus standards regarding the key data elements and critical tracking events that food companies should maintain in their records. Nevertheless, many food companies continue to keep records unique to their individual operations. By codifying consensus standards, the proposed rule will help to break through the inertia that has prevented wider adoption of best practices.

The time for these requirements is long overdue. The Food Safety Modernization Act (FSMA), signed into law by President Obama in 2011, required that enhanced recordkeeping requirements for “high-risk” foods be promulgated by FDA “not later than 2 years after the date of enactment of this Act.” As the proposed rule correctly notes, FSMA section 204 clearly

¹ <https://www.foodsafetynews.com/2021/01/researchers-assess-impact-of-covid-19-measures-on-foodborne-infections/>

² <https://www.cdc.gov/ecoli/2020/o157h7-10-20a/index.html>

³ <https://www.ledgerinsights.com/us-department-of-agriculture-usda-blockchain-for-organic-food-traceability/>

demonstrates a congressional intent to improve traceability recordkeeping throughout the food chain, from farm to fork.

The costs and benefits of this rule will not be distributed evenly. Currently, the general public bears the brunt of the health impacts caused by poor traceability, with poor and minority communities paying an especially heavy toll.⁴ Likewise, entire commodity sectors must pay when overly broad recalls are required, as was the case with spinach in 2006 and, more recently, with romaine lettuce. By contrast, the costs associated with this proposal will fall mostly on growers and retailers who do not already have strong traceability programs in place, rewarding companies that have acted proactively to adopt best practices, which the rule would effectively codify. To the extent that these requirements put pressure on smaller entities, FDA should seek to offset those effects by providing technical assistance.

FSMA does not expressly carve out farms or restaurants from its traceability requirements, however, we agree with FDA that an exemption for small retail food establishments is justified, for reasons including the benefits of maintaining a diverse, competitive food retail market, and the possibility that recordkeeping requirements might discourage some small retailers from carrying designated “high priority” foods. The partial exemption discussed in the proposed rule (“option 2”) strikes an appropriate balance between these competing interests, giving small food retailers with ten or fewer full-time equivalent employees relief from reporting requirements while still supporting widespread adoption of the standards defined in the rule.

As the “tentative food traceability list” in the proposed rule makes clear, the foods that pose a high risk of transmitting foodborne illness are also the foods that make up a significant part of most healthy diets. Improving the safety of these foods therefore contributes to public health both directly and indirectly. If effectively implemented, the proposed rule will reduce foodborne illness. But it will also encourage consumers to eat more of the foods on the list, and less of other “safer” but less nutritious foods, many of which are highly processed and are driving an epidemic of obesity and diet-related disease. FDA should act expediently to finalize this proposed rule and help to reassure weary consumers that fresh produce and other healthy foods are safe to eat, and that if they are not, there will be accountability.

Thank you for your consideration of these comments.

Sincerely,

Thomas Gremillion
Director of Food Policy
Consumer Federation of America

⁴ <https://thewestsidegazette.com/new-report-highlights-disparate-impact-of-foodborne-illness-on-poor-and-minority-communities/>