

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 Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments to the U.S. Food and Drug Administration related to its comment request for the Proposed Rule “Requirements for Additional Traceability Records for Certain Foods.”

Representing more than 107,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States. We are committed to accelerating improvements in the nation’s health and well-being through food and nutrition.

**The Academy of Nutrition and Dietetics supports science-based food and water regulations and recommendations that are applied consistently across all foods and water sectors.**

**These regulations and recommendations should incorporate traceability and recall to limit food- and waterborne outbreaks. Registered dietitian nutritionists and dietetic technicians, registered, are encouraged to participate in policy decisions, program development, and implementation of a food safety.<sup>1</sup>**

In 2010, the Academy adopted the following food safety principles for federal food safety authority in the United States:

1. Food authority should be science-based and consistently applied to all food regulated by all agencies for domestic and imported foods. The Academy supports the concept of a single food safety agency to protect the public’s health.
2. Food authority should be collaborative across national, state and local agencies, and between government and industry partners to foster more robust, consistent, accurate and timely communication and data sharing that leads to efficient and effective decision-making processes.
3. Food protection should include statutory authority by government regulatory agencies for traceability and recall, supported by research, epidemiology and inspection programs.

### **Value of Proposed Rule**

In 2013, the estimated cost of foodborne illness by Salmonella was \$3.66 billion.<sup>2</sup> In 2012, the estimated cost of the top 14 foodborne illnesses was \$14.1 billion. The costs of foodborne illness outbreaks on the restaurant industry range from \$3,968 to \$2.6 million per year depending on

<sup>1</sup>Cody MM, Stretch T. Position of the Academy of Nutrition and Dietetics: food and water safety. J Acad Nutr Diet. 2014;114(11):1819-29.

<sup>2</sup>Marler Clark LLP. The economic impact of salmonella infections. About Salmonella. <https://about-salmonella.com/the-economic-impact-of-salmonella-infections>. Published January 26, 2021. Accessed January 27, 2021.

type of restaurant, affected employees and retraining and legal fees.<sup>3</sup> The average cost to a food company of an illness outbreak and subsequent food recalls is \$10 million; this does not include revenue loss from potential losses due to brand reputation damage.<sup>4</sup> It is estimated that implementation of new traceability rules will cost retail food establishments \$238 million to \$17 billion over 10 years in Option 1 of the proposal. Over the span of 10 years, the top 14 foodborne illnesses at the same rate would cost \$141 billion. Over the course of 10 years, the new rules are likely to decrease foodborne illness by more than \$17 billion, outweighing the costs of implementation. If these new rules are able to decrease Salmonella cases by 25 percent, an estimated \$9.2 million could be saved in health care and productivity costs alone. The estimated public health benefits of the proposed rule shows an estimated 84 percent traceback improvement using several case studies of outbreak tracebacks for four pathogens associated with illnesses caused by foods on the Food Traceability List.

The new traceability system outlined in the proposed rule would provide comprehensive traceability throughout the food system, enabled by an effective traceability rule. In addition, the proposed rule could provide crucial benefits for both industry and consumers: faster outbreak investigations and consequent illness prevention, narrower recalls and consequent decreased food waste and economic damage, better consumer confidence in the food supply, as well as enhanced understanding of food safety risks to inform future preventive efforts.

The Academy supports the overall structure of the proposed rule, which seeks to improve traceability by harmonizing information requirements for foods on the Food Traceability List throughout the supply chain. 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 at critical tracking events. This proposed rule, if executed in a collaborative effort, could eliminate safety and reporting gaps in the current food supply and ultimately decrease consumer exposure to contaminated products because of their enhanced speed of recalls, preventing illnesses and deaths.

### **Considerations for Manufacturers and Consumers**

While the Academy of Nutrition and Dietetics largely supports the proposed rule, we would like to note questions and considerations regarding the estimation of cost and the impact of some required processes as outlined in the proposed rule. It is necessary to review the complexity of the proposed rule as well as potential higher costs, including total compliance costs, additional training expenses, capital investments in infrastructure and technology and labor costs for all parties in the distribution pipeline. Undue burden on industry manufacturers and distributors may also affect consumer price point, making certain food items, particularly those on the Food Traceability List, which includes many fresh fruits and vegetables, more difficult to procure due to increased cost. This could be particularly problematic for consumers in economically-stressed areas with a limited food budget. The Academy continues to advocate for accessibility of nutrient-dense food to all consumers while maintaining a safe food and water supply.

The Academy appreciates the opportunity to submit comments related to the proposed rule, “Requirements for Additional Traceability Records for Certain Foods.” We urge FDA to support

<sup>3</sup>Bartsch SM, Asti L, Nyathi S, Spiker ML, Lee BY. Estimated cost to a restaurant of a foodborne illness outbreak. *Public Health Rep.* 2018;133(3):274-286. doi:10.1177/0033354917751129

<sup>4</sup>USDA ERS - cost estimates of foodborne illnesses. <https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses/>. Accessed January 27, 2021.

traceability efforts and help provide the assistance and allocation needed to minimize foodborne outbreaks. Please contact either Jeanne Blankenship at [jblankenship@eatright.org](mailto:jblankenship@eatright.org) or Pepin Tuma at [ptuma@eatright.org](mailto:ptuma@eatright.org) with any questions or requests for additional information.

Sincerely,

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<sup>3</sup>Bartsch SM, Asti L, Nyathi S, Spiker ML, Lee BY. Estimated cost to a restaurant of a foodborne illness outbreak. Public Health Rep. 2018;133(3):274-286. doi:10.1177/0033354917751129

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