

October 17, 2022

Shalanda Young  
Director  
Office of Management and Budget  
725 17th Street, NW  
Washington, DC 20503

**Re: RIN: 0910-AI44, “Requirements for Additional Traceability Records for Certain Foods,” Docket No. FDA–2014–N–0053, Comment on Final Rule at the Office of Management and Budget**

Dear Director Young:

The National Grocers Association (NGA) submits the following comments in response to RIN: 091—AI44, the final rule for Docket No. FDA–2014–N–0053 for “Requirements for Additional Traceability Records for Certain Foods” (the rule) at Office of Management and Budget (OMB). We thank OMB for the opportunity to discuss how this Food and Drug Administration (FDA) rule might affect independent retail and wholesale grocers and the families they serve.

**About the National Grocers Association**

NGA is the national trade association representing retail and wholesale grocers that comprise the independent sector of the food retail and distribution industry. An independent retailer is a privately owned or controlled food retail company operating in a variety of formats. Independents are the true “entrepreneurs” of the grocery industry and dedicated to their customers, associates, and communities. Much of NGA’s membership is comprised of family-owned and family-operated small businesses. Nearly half of NGA’s members are single-store operators, and another quarter operate less than five stores. Independent retail and wholesale grocers are an important part of America’s economy. Independent community grocers account for 33 percent of all grocery sales, exceeding \$250 billion, and more than 1 million American jobs. We are inherently tied to the strength and vitality of the markets we serve – at the heart of local communities and the U.S. economy. Having often been in the business for generations, independent grocers are dedicated to their customers, associates, and communities.

As an initial matter, the independent retail and wholesale grocer members of NGA are strongly committed to food safety, security, and good nutrition, and wholeheartedly support the FDA’s important public health mission. However, NGA was gravely concerned with the costs and burdens FDA’s proposed rule, *Requirements for Additional Traceability Records for Certain Foods*, 85 Fed. Reg. 59,984 (Sept. 23, 2020) (proposed rule), would impose upon our members and their communities. NGA submitted substantial comments on that proposed rule, attached here for your convenience. *See also* February 22, 2021 Comments by NGA to Docket No. FDA–2014–N–0053 (also available [here](#)) (February 2021 comment).

NGA remains seriously concerned about the finalization of this rule. We believe this rule would reduce food access across the United States and goes against the Administration's goal of ending hunger by 2030. Below, for the convenience of OMB, we reiterate those harms to the independent retail and wholesale food sector that were set out in our February 2021 comment.

### **FDA Has Substantially Underestimated the Costs of Additional Traceability Records for Certain Foods**

If finalized as it was proposed, this rule will create an immense, if not insurmountable, burden for smaller retailers. The requirements of this overly complex and expansive rule will be expensive to implement and require additional labor that many stores cannot spare. This burden will, at a minimum, substantially and permanently raise costs and add to inflationary pressures on food and could very well lead to the closure of small stores in otherwise underserved urban and rural areas. The result will be to limit consumer access to healthful and nutritious grocery store food, resulting in food deserts. Reducing food access directly contradicts the Administration's stated goal of ending hunger by 2030.

As we explained in our 2021 comment, FDA substantially underestimated the economic impact of the proposed rule. First, FDA assumed that it would take only one individual from each respondent (meaning the regulated entity) an average of 3.3 hours to "read and understand the new recordkeeping requirements." Over 50 percent of NGA's retail members are single store operators that may not have full-time staffers dedicated to reading and deciphering regulations, much less designing, and drafting policies and procedures for compliance, making necessary capital investments for, and implementing new recordkeeping practices. As drafted, the proposed rule would also impose both one-time and continuing costs for NGA's retail grocery and wholesale grocery members as they will be required to develop new business systems, invest in new capital improvements to information infrastructure, and train personnel to mind these new systems and respond to both FDA- and industry-initiated tracing exercises.

Further, we respectfully submit that the asserted benefits of the proposed rule are illusory, such as savings that would purportedly be achieved through more targeted product recalls that would more precisely identify the affected products and lots. The costs associated with obtaining and maintaining Key Data Elements (KDEs) will be constant and ongoing across all Food Traceability List (FTL) products regardless of whether there is ever a product recall. Moreover, in practice, entities throughout the supply chain will continue to apply recalled product identification overly broadly in order to ensure that at least all implicated product is captured and removed from store shelves.

While we recognize that FDA attempted to lessen burdens on small businesses, the proposed exemption level of 10 or fewer full-time employees (FTEs) was so small as to be meaningless for our independently owned community grocers. As we explained in our February 2021 comment, even a small, single-store independent grocery store is likely to have more than 10 FTEs if one counts the number of cashiers to staff a six- or seven-day-a-week schedule with stores open for at least twelve hours a day, and specialized clerks to ensure the purchase, stocking, and care of the healthful foods in meat/fish, produce, and deli departments, as well as stocking clerks, and

management. As originally proposed, the exemption for small retailers was set so low that almost no grocery store could qualify.

If the proposed rule was not amended, it would also, as we explained, burden and inhibit long-standing industry business practices, including broker sales and cross docking. Brokers are invaluable resources for retailers, but they would be neither a source nor a receiver under the rule as proposed. It is unlikely that brokers for FTL products would be able to provide their retailers with the information necessary to comply with the rule, including whether the retailer is receiving product as a first receiver or not. With cross docking, product (usually palletized) passes over a loading dock from one transporter to another, without being held at the cross-docking facility for any appreciable time. Cross dock providers do not hold inventories and typically maintain activity records on paper only; consequently, they would not be able to provide, maintain, or produce the records the rule would require.

We highlighted our full and specific concerns about the outsized impact this rule will have on small retailers in our February 2021 comments.

### **FDA Has Exceeded Its Statutory Authority in This Rulemaking**

NGA explained in its February 2021 comment that the FDA has exceeded its authority under section 204 of the Food Safety Modernization Act (FSMA) in promulgating this rule. We repeat that concern here. As proposed, the rule would be not merely difficult but well-nigh impossible to implement absent case-level tracking, which the agency is specifically prohibited from imposing under section 204(d)(1)(L)(iii).

The requirement for production of a sortable electronic spreadsheet becomes a de facto imposition of an electronic recordkeeping system because it would be impossible otherwise to comply with the 24-hour production requirement in the absence of existing electronic records to populate the sortable electronic spreadsheet. This requirement would therefore violate the statutory limitations under section 204(d)(1)(C). Moreover, by mandating the production of information in this form, the Proposed Rule violates section 204(d)(1)(E) by requiring a record that is overly complex, burdensome, and duplicative of other extant records.

Additionally, the Proposed Rule would conflict with section 204(d)(3) insofar as it calls for dissemination of confidential commercial information. In section 204(d)(3), *Protection of sensitive information*, FDA is directed to “take appropriate measures to ensure that there are effective procedures to prevent unauthorized disclosure of any trade secret or confidential information.” Requiring the maintenance *and transmission* of KDEs to subsequent recipients will disclose the originator, transformer, or creator of the producing entity’s FTL product. Such supplier information is routinely treated as confidential commercial information and the rule made no provision for its protection.

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Given the many costs and burdens the rule would impose, we question its utility and necessity in light of the Preliminary Regulatory Analysis Reference No. 12 of the Institute of Food

Technologists' (IFT) Pilot Projects for Improving Product Tracing Along the Food Supply System (IFT Report). The IFT Report concluded that existing systems, such as examination of purchase orders (POs) have been and are to this day successfully used in product trace exercises. We agree with this assessment – given the large volume of products our members deal with every day, managing product recalls is an established part of independent grocers' daily operations. NGA continues to believe that the public would be better served by building on the many successful systems and practices already employed throughout the food distribution system that will allow us to achieve our shared public health goals of not merely a safe food supply, but an available and affordable safe food supply.

The impacts of this rule present the untoward result of reducing food access for Americans throughout the country going against the commitments by President Biden to end hunger made at the White House Conference on Hunger, Nutrition, and Health. We appreciate the opportunity to comment on this rule and urge you to address directly the issues raised in NGA's comments and our October 17, 2022, meeting with OMB before finalization of this regulation.

Respectfully submitted,

Greg Ferrara  
President and Chief Executive Officer  
National Grocers Association