July 14, 2025

Submitted electronically via regulations.gov

Re: **Request for Information: Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again; Docket No. AHRQ-2025-0001**

Dear Sir or Madam:

Thank you for the opportunity to comment on the Department of Health & Human Services' (HHS or Department) and the Food and Drug Administration's (FDA's) Request for Information (RFI): *Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again*. As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at www.FMI.org.

We strongly support the work of the Department and FDA to identify and eliminate outdated and unnecessary regulations as part of a broader federal effort to reduce regulatory burdens and increase transparency. In our comments below, we highlight several key issues that we believe fit squarely within those stated priorities. Advancing food safety and ensuring access to nutritious food is at the cornerstone of our organization and our industry. Deregulation can help to reduce regulatory inefficiencies that hinder that mission, and ultimately, drive up costs for consumers. We believe that adopting some reasonable revisions to the issues below will improve food safety without unnecessarily increasing food costs for consumers. We appreciate the Agencies' consideration of these key issues, and we stand ready to assist HHS and FDA in working toward improvements that benefit all Americans.

1. FDA Should Revise the Food Traceability Rule

The Food Traceability Rule is one of the most burdensome regulations the industry is facing. As written, the rule will impose significant regulatory costs without a corresponding benefit to public health. We appreciate the Agency's commitment to extending the timeline of the Food Traceability Rule by 30 months and the recognition that more time is needed to ensure that the rule is implemented efficiently. However, during that time period, there are several key flexibilities FDA should implement that would reduce paperwork and unnecessary costs without jeopardizing the rule's public health objective. There is nothing more important to the industry than food safety and the industry is committed to working with FDA in implementing the Food Traceability Rule.

Refining the traceability rule with three key common-sense changes would significantly reduce burdens on the industry, ultimately making the rule more efficient and effective by modifying or rescinding unnecessary elements that divert industry and FDA resources away from the fundamental public health purpose of the rule.

The food traceability rule is ripe for reform for three reasons: the costs it imposes, the lack of authority for key components, and its misplaced focus on reactive versus preventive measures. According to FDA's own estimates, the rule is projected to require more than 3 billion records to be kept and maintained per year, resulting in over 10 million labor hours. The average hourly wage for food and beverage employees is $21.91, resulting in $219 million annually in additional industry costs just for paperwork. Overall, FDA estimates that the rule will cost the food industry over $24.6 billion, an astronomical number that is still significantly lower than our own estimates, which include numbers like $24 million and $500 million per company. Further, elements of the rule exceed FDA's statutory authority and goes well beyond what Congress intended when it passed the FDA Food Safety Modernization Act in 2010. Finally, the rule creates an unnecessary paperwork burden that diverts resources from the primary focus of preventing foodborne illness.

We provide more detail below on several ways FDA can address three key concerns with the rule while meeting the goal of reducing public health risk by facilitating more efficient and effective traceback investigations. Namely, we discuss 1) The need to provide flexibility for lot code traceability at the distribution level to eliminate a de facto case level tracking requirement the rule imposes 2) An exemption for intracompany shipment and 3) An amended definition of the traceability lot code source reference. Implementing these changes, among others, will preserve the rule's core structure and its intended food safety benefits while resolving significant, unnecessary obstacles that will raise costs across the entire food supply chain and for consumers.

Ways to Reduce the Regulatory Burden of the Traceability Rule

Provide Additional Flexibility for Lot Code Traceability to Eliminate De Facto Case Level Tracking

The key driver of regulatory complexity and cost in the food traceability rule is its requirement that distributors and retailers track the lot code for each food they handle. This requirement imposes a de facto case-level tracking requirement on distributors in direct violation of FSMA's mandate that the rule "not require . . . product tracing to the case level by persons subject to [the rule]."[1] Modern distribution systems utilize a "just in time" inventory strategy to deliver a complex variety of foods to individual retail stores on a daily basis. First, distributors receive product from their suppliers in pallets containing multiple cases of product. Some contain cases from the same traceability lot, but often pallets will contain cases of the same product from different traceability lots. Second, distributors then assemble orders for customers by pulling cases from the original pallet, whether directly from the pallet or from pick slots into which the cases from the original

[1] *See* FSMA § 204(d)(1)(L) (21 U.S.C. § 2223(d)(1)(L)).

pallet have been loaded. Because each pallet or pick slot may contain cases associated with different traceability lots, customer shipments will often contain products from multiple traceability lots.

The volume and granularity of data required by the rule – particularly the need to determine the precise combination of traceability lot codes that are in each shipment – creates a de facto requirement for case-level tracking as distributors would have to determine the precise Traceability Lot Code (TLC) associated with each case on the pallet. Then, when assembling orders, distributors will need to track which cases (and thus which TLCs) are pulled from each pallet or pick slot and included in an order. This significant and costly regulatory burden could be alleviated if FDA would allow retailers and distributors to maintain a range of possible traceability lot codes.

The case-level tracking requirement raises a number of significant concerns. First, it exceeds FDA's statutory authority. Section 204(d)(1) of FSMA expressly provides that the rule's recordkeeping requirements must "not require . . . product tracking to the case level."[16] The statute further provides that, to the extent practicable, FDA may not "require a facility to change business systems to comply with [the rule's recordkeeping requirements]"[17] and that the rule must "relate only to information that is reasonably available and appropriate."[18] The food traceability rule expressly violates these limitations by requiring that distributors and retailers engage in case-level tracking.

It also imposes significant costs. One regional supermarket chain estimates that the rule will impact over 8,000 products spanning 500 suppliers. Implementing case-level tracking would cost the company $8 million annually in labor costs. A food distributor estimates that case-level tracking will increase costs by 20 cents for every 100lbs of products shipped for labor and inventory control alone.

These recurring and unnecessary costs can be avoided with changes to the rule. At a minimum, FDA should modify the rule to allow retail stores and distribution centers to maintain a range of traceability lot codes included in a shipment, rather than the precise lot codes in a particular shipment. These additional flexibilities would not materially undercut FDA's ability to conduct traceability investigations. We recognize that in the preamble to the final rule FDA expressed concerns that allowing distributors to pass forward KDE records related to multiple TLCs on a pallet might result in "records that do not distinguish between different [TLCs] on a pallet," such that "the information . . . provided to the subsequent recipient is ambiguous [and] the information provided to FDA may be unclear, which could slow [FDA's] investigation." We note, however, that this would not be the case under our proposed framework. Our framework would still require that distributors maintain and pass forward records tied to only a limited set of TLCs, and that they maintain and pass forward KDE records tied to each TLC. Put otherwise, distributors would still maintain and pass forward, and FDA would still be able to access, a detailed set of KDE records. The number of potential TLCs is unlikely to be large, and in a traceback investigation, the commonality among potential TLCs would likely become readily apparent. While this approach could marginally increase the initial scope of an investigation compared to the rule's existing framework, it would allow stakeholders to share accurate information more quickly, which could

allow FDA to more quickly access the information it needs. By streamlining the rule's requirements and alleviating the rule's excessive burdens on day-to-day operations at distribution centers and retail stores, this approach would also better ensure that stakeholders have the capacity to develop, maintain, and quickly pass forward accurate records. This, in turn, could improve the overall efficiency of investigations while alleviating the rule's excessive burdens on the day-to-day operations of distribution centers. These changes would also help ensure that the rule complies with the statutory limitations prescribed by FSMA.

Exempt Intracompany Shipments from the Rule

In addition to case-level tracking, the food traceability rule requires recordkeeping when foods are shipped between one location owned by a firm to another location owned by the same firm. These transactions should be exempt from the rule. The volume of records required for each shipment associated with each product is leading many retailers to evaluate whether they can continue to offer certain products, limiting consumer choice and convenience. In particular, fresh-cut fruits and vegetables, prepared deli salads, and sushi are products often prepared in central kitchens and shipped to sister retail stores. These types of activities happen so frequently that maintaining full records for these foods will be costly and unnecessary, and may cause these healthy, convenient products to be removed from store shelves. Internal company recordkeeping systems already trace products through intracompany shipments and requiring traceability records for these transfers is duplicative of records maintained by current internal systems that are already used to ascertain the whereabouts of food and facilitate traceback investigations. Understanding that choice and convenience are of paramount importance to consumers, FDA should reduce the regulatory burden imposed on industry by exempting intracompany shipments from the rule's requirements.

FDA Should Amend the Definition of Traceability Lot Code Source Reference

Another challenging and burdensome aspect of the traceability rule is the requirement to maintain and pass forward the traceability lot code source reference. To alleviate these burdens, FDA should amend the definition of "traceability lot code source reference" to allow companies to identify the person responsible for assigning the TLC, rather than the location where the TLC was assigned. This change would lessen the logistical burdens of maintaining records with high levels of specificity without compromising the agency's ability to conduct traceability investigations.

As written, the rule defines "traceability lot code source" and "traceability lot code source reference" in a manner that requires entities to identify the specific *location* where a food's TLC was assigned (i.e., "traceability lot code source" is defined as "the place where a food was assigned a traceability lot code"). Requiring that entities maintain records with this level of specificity will be logistically burdensome, particularly for entities, such as processors, that transform a variety of

food products across many locations within one company system. These burdens have become more apparent as our members have moved toward implementation.

Amending the rule to allow the traceability lot code source reference to identify the person, defined as an "individual, partnership, corporation, and association," responsible for assigning the TLC, will significantly alleviate the burden imposed upon covered entities. With this change, companies could list a Global Trade Item Number (GTIN) or similar identifier identifying the person responsible for assigning the traceability lot code, provided that person is able to identify the traceability lot code source. This amendment would allow the traceability lot code source reference to identify the corporate entity responsible for assigning the TLC, rather than providing the specific location where the TLC was assigned, which is a less onerous requirement for firms operating multiple locations. This change would reduce the burden on industry without inhibiting FDA's ability to conduct foodborne illness outbreak investigations.

As explained above, FMI strongly urges that the Traceability Rule be revised to address the tremendous compliance burden and unnecessary costs that the rule imposes. The food industry, on average, operates on a 1.6% profit margin, and any additional regulatory costs could be passed down to consumers in the form of increased grocery prices. We believe that by refining the rule's scope, these costs can be avoided without undercutting the FDA's ability to conduct traceability investigations or jeopardizing the rule's public health objective.

2. FDA Should Consider Withdrawing the Proposed Rule on Front-of-Package Nutrition Labeling Unless and Until the Agency Obtains the Requisite Statutory Authority to Mandate Such a Scheme

FDA's proposed rule on front-of-package nutrition labeling (FOPNL) would require most packaged foods to display a "Nutrition Info" box on the top third of the front of the package, showing the percent Daily Value for sodium, saturated fat, and added sugars, accompanied by the interpretive markers "High," "Med," or "Low" for each nutrient.[2] If finalized, the proposed rule would impact most packaged foods, and due to its design and the proposed requirement to place the Nutrition Box on the top third of the front panel, would be burdensome and costly to implement because label redesigns will be needed in most cases. These burdens would be undertaken without evidence of commensurate benefits to consumers, particularly considering the lack of evidence suggesting that consumers would change their diets in response to the Nutrition Info box. Consumers seeking information to support personal purchase decisions are aware of and use an existing voluntary front-of-package scheme that provides at-a-glance nutrition facts is widely adopted in the marketplace. Additionally, FDA lacks express statutory

[2] 90 Fed. Reg. 5426 (Jan. 16, 2025).

authority to mandate an FOPNL scheme, and the proposed rule risks violating First Amendment protections.

We acknowledge at the outset that this rule is not yet final and therefore may not qualify as an existing regulation for purposes of Executive Order 14192, "Unleashing Prosperity Through Deregulation"[3]. However, given the significant burdens it would impose, we respectfully request that FDA consider the impact of the proposed rule in the context of the Agency's efforts to reduce regulatory burdens and ultimately keep costs low for all Americans.

The Proposed FOPNL Scheme Raises Significant Statutory Authority and First Amendment Concerns

FDA lacks the statutory authority to implement *mandatory* FOPNL. The Federal Food, Drug, and Cosmetic Act (FFDCA) provides FDA with highly prescriptive instruction as to how the agency is to mandate nutrition labeling and does not include a provision that allows for a mandatory selection of information to be presented separate from the comprehensive nutrition information that includes certain elements specified by Congress.[4] The FOPNL proposed rule is also vulnerable to being struck down as violating the First Amendment's protection of commercial speech, particularly with respect to the required placement and prominence of the scheme and the selection of only three nutrients to limit (saturated fat, sodium, and added sugars), to the exclusion of calories and all other beneficial nutrients. This selection of nutrients is highly likely to over-simplify a food's nutritional content and could lead to misleading results (as just one example, maple syrup would receive "low" interpretive markers for all three nutrients yet dairy foods could bear "medium" or "high" designators for one or more nutrient notwithstanding that dairy foods are encouraged by the Dietary Guidelines for Americans). FMI discussed these important legal considerations at length in our prior comments to FDA on FOPNL, as did other food industry trade associations,[5] and we will also be commenting on the agency's legal authority as part of our comments on the proposed FOPNL rulemaking.

The FOPNL Scheme Would Impose Significant Costs That Are Not Justified by its Anticipated Benefits

If finalized, the proposed rule on FOPNL would require a fundamental redesign of most packaged food labels, imposing significant and unnecessary costs on American manufacturers and retailers

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[3] 90 Fed. Reg. 9065 (February 6, 2025).

[4] In terms of mandatory nutrition information, FDA is authorized to require nutrition labeling that includes the following complete set of information: the serving size, the number of servings per container, calories, total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, total protein, and vitamins and minerals.

[5] U.S. Food & Drug Administration, Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods (FDA-2023-N-0155), Comments from FMI (March 27, 2023), Consumer Brands Association (March 27, 2023), FMI (July 17, 2023), CBA (July 17, 2023), available at: https://www.regulations.gov/docket/FDA-2023-N-0155.

without evidence of commensurate benefits to the public. These immense costs are particularly excessive given that there is a much less burdensome and well-established FOPNL approach that already exists in the US marketplace (Facts Up Front program) that includes factual information on saturated fat, sodium, and added sugars, and would still accomplish the agency's goals.

The anticipated benefits of the proposed rule, on the other hand, are merely speculative and not supported by the scientific literature. FDA asserts that the "[b]enefits of this proposed rule would come from the value consumers receive from the information provided by the FOP label."[6] We agree with the Agency's assessment that this benefit cannot be quantified.[7]. The benefit is theoretical at best, particularly when Congress has not specifically recognized the value of consumers receiving this information as was the case with other new mandatory labeling requirements like nutrition labeling and menu labeling. FDA also presumes that the FOPNL scheme would prompt reformulations to such an extent that it would positively impact the nutritional context of the food supply. Again, this assumption is theoretical and lacks quantification.

More broadly, neither FDA's consumer research, nor FDA's own analysis, nor the broader scientific literature supports that the proposed FOPNL scheme would change consumer behavior to improve health outcomes. Indeed, the Agency's Preliminary Regulatory Impact Analysis does not cite healthier diets due to changes in consumer behavior, nor reduction in chronic disease rates, as purported benefits of the rulemaking.[8] Further, studies on interpretive FOP labeling schemes in place in other countries have not shown that they improve diet quality, consumer health, or obesity rates.[9] Absent such anticipated benefits, with the appropriate substantiation, the proposal's costs would far exceed its anticipated benefits.

FMI, therefore, recommends that FDA consider withdrawing the proposed rule on FOPNL and thoroughly consider appropriate alternatives, such as existing voluntary FOPNL schemes. FDA should refrain from issuing a final rule unless and until the agency obtains the required statutory authority, and believes doing so would remove significant regulatory barriers from American businesses and ensure that regulations are based on the best reading of the underlying statutory authority.

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6 90 Fed. Reg. 5426, 5455 (Jan. 16, 2025).

7 Food Labeling: Front-of-Package Nutrition Information, Preliminary Regulatory Impact Analysis (PRIA), https://www.fda.gov/media/185202/download?attachment.

8 See PRIA, *infra*.

9 Business for Impact, Can Front-of Pack Product Labeling Fix the Obesity Crisis? (Apr. 2025), available at https://georgetown.app.box.com/s/78q85bxgt1grmadx6ck1xagog10j8pfg

Additional Comments

FMI also strongly encourages FDA to review the following additional rules. While FMI does not address these rules in the detailed comments above, we believe they warrant consideration as part of any deregulatory efforts, as their costs outweigh the corresponding benefits.

- **Electronic Recordkeeping Requirements:** FMI recommends that FDA revoke the electronic recordkeeping requirements in 21 CFR Part 11. These requirements are unworkable, outdated, and unfairly restrict innovation for those food producers subject to them (e.g., low acid canned food facilities). They also are unnecessary, as demonstrated by the exemptions from compliance with Part 11 already granted to certain food manufacturing facilities.

- **Warning Statement on High Protein Products (21 CFR 101.17(d)(3))**: FMI recommends that FDA revoke the regulation requiring foods that derive more than 50% of their caloric value from protein and that are represented for weight reduction to bear a warning statement specifying that the product should be used only as a food supplement. This regulation is outdated and unnecessary based on current dietary practices and guidelines, and compliance costs are not justified by a commensurate benefit to public health.

In addition to the rules highlighted above, FMI asks FDA to prioritize finalizing the following rule, which would provide for efficiencies in rulemaking and would facilitate a small step toward modernization of standardized foods:

- **Salt Substitutes in Standardized Foods**: FMI urges FDA to finalize its proposed rule to allow the use of salt substitutes in standardized foods.[10] We encourage the agency to use a horizontal approach to efficiently modernize the food standards of identity that address the use of salt as an ingredient or that would not otherwise allow for use of a salt substitute, and believe doing so would promote innovation and the development of healthier, lower in sodium foods for American consumers

Sincerely,

Stephanie Harris
Chief Regulatory Officer and General Counsel

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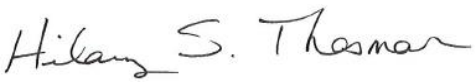
10 88 Fed. Reg. 21148 (Apr. 10, 2023).



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