



May 12, 2025

Submitted electronically via regulations.gov

Re: Request for Information: Deregulation; Docket No. OMB-2025-0003-0001

Dear Sir or Madam:

Thank you for the opportunity to comment on the Office of Management and Budget's Request for Information (RFI) soliciting ideas for deregulation.¹ 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.

As OMB considers opportunities for regulatory reform, FMI urges the agency to prioritize a critical evaluation of three rulemakings – the Food and Drug Administration's (FDA's) final rule on food traceability, FDA's proposed rule on front-of-package nutrition labeling, and the Environmental Protection Agency's (EPA's) final rule on hydrofluorocarbon (HFC) management— each of which do or would impose costly, unnecessary, and unlawful burdens on the food industry without commensurate benefit to public health, the environment or food safety. As explained in more detail below, amending the food traceability rule, revising the HFC management final rule, and withdrawing the front-of-package nutrition labeling proposed rule, would alleviate unnecessary regulatory burdens, ensure that regulations are based on the best reading of the underlying statutory authority, and safeguard American businesses from regulations that impose costs that exceed anticipated public benefits.

1. FDA Should Revise the Food Traceability Rule

Although there are many issues facing the food industry, the food traceability rule is one regulation that is particularly ripe for reform. The rule establishes vast new recordkeeping requirements for certain foods to facilitate tracking and tracing their movement in the supply chain in the event of a foodborne illness outbreak. The rule took effect in January 2023 with a

¹ 90 Fed. Reg. 15481 (Apr. 11, 2025).



compliance date of July 20, 2028.² Although well intended, the rule will impose significant regulatory costs without a corresponding benefit to public health. There is nothing more important to the industry than food safety and the industry is committed to implementing the Food Traceability Rule, but we need FDA to reduce the regulatory burden of the rule and believe it can do so without impacting food safety.

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, which we know are grossly underestimated, it is projected that the rule would 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, the rule exceeds 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 key concerns with the rule while meeting the goal of reducing public health risk by facilitating more efficient and effective traceback investigations. 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 likely consumers.

The Rule Imposes Significant Regulatory Burdens and Exceeds FDA's Statutory Authority

The traceability rule requires the use of traceability lot codes to identify products as they move through the supply chain. The volume and granularity of data required – 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. This requirement imposes an unnecessary and overwhelming paperwork burden on retailers and distributors, many of which handle thousands of products daily and thus will be forced to maintain a tremendous number of records. Because most distributors do not currently conduct case-level tracking, they will need to overhaul their recordkeeping systems and invest substantial resources, diverting efforts from the primary focus of preventing foodborne illness.

Importantly, the case-level tracking requirement significantly exceeds FDA's statutory authority. Congress did not intend for FDA to impose a rule that requires case-level tracking, and the Food

² See FDA Intends to Extend Compliance Date for Food Traceability Rule (Mar. 20, 2025), available at: <https://www.fda.gov/food/hfp-constituent-updates/fda-intends-extend-compliance-date-food-traceability-rule>.

Safety Modernization Act (FSMA) explicitly prohibits it.³

Case-level tracking is just one example of the burdensome requirements under the rule that FDA should reconsider. Therefore, FMI strongly urges that the traceability rule be revised to address the tremendous compliance burden and unnecessary costs that the rule imposes. 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.

Ways to Reduce the Regulatory Burden of the Traceability Rule

Provide Additional Flexibility for Lot Code Traceability

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. Given that 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, this results in a de facto requirement of tracking food to the case level. 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. This simple solution would continue to provide FDA with the information they are seeking while simultaneously reducing significant costs along the supply chain. Allowing companies to provide a limited range of lot codes would preserve the overall efficiency of outbreak investigations while alleviating the rule's excessive burdens on day-to-day operations at distribution centers and retail stores.

³ See FSMA § 204(d)(1)(L) (21 U.S.C. § 2223(d)(1)(L)).

Exempt Intracompany Shipments from the Rule

In addition to case-level tracking, the food traceability rule requires recordkeeping when foods are shipped between retail stores. 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 are well equipped to trace products through intracompany shipments and requiring traceability records for these transfers adds an immense burden without a corresponding benefit to public health. 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 towards 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. EPA Should Rescind the HFC Management Rule

The American Innovation and Manufacturing Act ("AIM Act") was signed into law in 2020 and granted the Environmental Protection Agency the authority to regulate hydrofluorocarbon ("HFC") refrigerants to reduce their impact on climate change. In 2024, the EPA finalized Subsection (h) of the AIM Act, otherwise known as the HFC Management Rule. This portion of the AIM Act sets forth certain obligations that owners/operators of HFC-containing appliances must follow, including extensive recordkeeping and field-work requirements.

HFC refrigerants were, in many cases, developed to replace an older class of refrigerants that contributed to depletion of the ozone layer. Ozone-depleting refrigerants (R-22, for example) are regulated under a different portion of the Clean Air Act. The regulatory requirements for ozone-depleting refrigerants are very similar to the requirements for HFC-containing refrigerants. The issue for end users is not the requirements themselves, which end users have met under previous regulatory frameworks, but the dramatic expansion of appliances now subject to these requirements under the HFC Management Rule.

Beginning on January 1, 2026, the HFC Management Rule will impose significant and costly obligations on owners/operators of appliances that utilize HFC-based refrigerants. These regulatory burdens are related to the management, reclamation, and disposal of HFCs during servicing and repair activities. The rule applies to any refrigerant-containing appliances that have a charge size of 15+ pounds of a refrigerant with a global warming potential ("GWP") of 53+. For appliances meeting this exceedingly low threshold, owners and operators must conduct a complicated refrigerant leak rate calculation every time refrigerant is added to the appliance.

If the leak rate is determined to be above a certain prescribed threshold for the equipment type, then the owner/operator must repair the leak within 30 days of discovering the leak. The repair must be confirmed by two verification tests – one conducted prior to the addition of refrigerant to the system, and another within 10 days after the initial verification test or within 10 days of the system resuming normal operations. The leak rate threshold set by EPA is very low – 20% for commercial refrigeration appliances, 30% for industrial process refrigeration appliances, and 10% for comfort cooling appliances, refrigerated transport appliances, or other refrigerant-containing appliances with a full charge of 15 or more pounds of refrigerant. After a refrigerant-containing appliance has been repaired, the HFC Management Rule requires annual or quarterly leak inspections depending on the size of the appliance and its leak rate, and the inspections must be conducted by a certified technician.

If the owner/operator cannot repair the refrigerant-containing appliance within the short period of 30 days, the owner/operator must request an extension from EPA. If the owner/operator cannot bring the appliance under the leak rate threshold, it must then prepare and initiate a retrofit or retirement plan for the system. The plan is required to be submitted to EPA within 30 days of exceeding the leak rate threshold and the retrofitting or retirement of the system must be completed within 12 months of the plan's submission.

The HFC Management Rule also requires installation of automatic leak detection systems (ALDS) on new and existing refrigerant-containing appliances in the industrial process and commercial refrigeration subsectors with a charge size of 1,500 pounds or more. For new appliances installed on or after January 1, 2026, the ALDS must be installed within 30 days of appliance installation. For qualifying existing appliances, the ALDS must be installed by January 1, 2027.

Beginning on January 1, 2029, servicing and/or repair of refrigerant-containing appliances in the supermarket systems, refrigerated transport, and automatic commercial ice maker subsectors and applications in the refrigeration, air-conditioning and heat pump sectors must be done with reclaimed HFCs. The HFC Management Rule imposes several restrictions on the reclamation of HFCs. The rule prohibits the sale, distribution, or transfer of any recovered HFC unless (1) the HFCs have been recovered by an EPA certified reclaimer, and (2) the reclaimed HFC refrigerant contains no more than 15% virgin HFC refrigerant, by weight.

In sum, the HFC Management Rule imposes burdensome recordkeeping, reporting, and labeling requirements. These requirements will apply to significantly more appliances than previous regulatory frameworks aimed at reducing refrigerant emissions.

The Rule Imposes Significant Regulatory Burdens / Exceeds EPA's Statutory Authority

The HFC Management Rule imposes significant, costly obligations on supermarkets to monitor, repair, retrofit or replace virtually any commercial refrigeration or HVAC system. The HFC Management Rule far exceeds the authority granted by the AIM Act and will force the U.S. food industry spend \$5 billion per year on bureaucratic mandates, such as the installation of unnecessary equipment and excessive reporting, for refrigerants that are already being phased out by 2036. This alone will result in a 22% reduction in industry profitability and will have substantial implications for the financial viability of many grocery stores across the U.S. For more information on compliance costs, please see *Addendum 1: Preliminary Estimates of AIM Act Management Rule Compliance Costs*.

The HFC Management Rule's broad sweep-in of all appliances with a 15-pound or more charge capacity and a greater than 53 GWP significantly and unnecessarily expands the number of appliances covered under other similar regulatory programs related to refrigerant system servicing. With the 15-pound threshold, one company has estimated that the number of covered appliances for its enterprise would increase more than ten-fold (from 600 to 6,100 individual units). This company anticipates that such a dramatic increase in the number of covered appliances would result in approximately \$1 billion in additional capital costs to the company over

the next 10 years. Another company estimates that conducting site surveys of all its stores to identify newly covered appliances under the 15-pound threshold would cost roughly \$500 to \$1,000 per site, depending on location and size. When multiplied across many sites, this would lead to significant costs just to identify newly covered equipment.

The HFC Management Rule also imposes a 20% leak rate threshold for commercial refrigeration equipment (using a rolling average), which means that the average supermarket system may exceed the leak rate threshold from the outset. As a result, the framework for the repair and possibility or retrofit or retirement planning for the system could be triggered almost immediately after installation. With the short timeframe to bring systems into compliance—30 days in most instances—it is unlikely that the average U.S. grocery store would be able to meet the compliance deadlines.

The rule also provides very little time to repair a system before a system owner must plan and begin to implement the complete overhaul, retirement, and/or replacement of their system. Owner/operators must create a retrofit/retirement plan within 30 days of exceeding the leak rate threshold. This might be feasible for small appliances, but this requirement applies to all appliance types, including supermarket rack systems. The impracticability of the deadlines in the rule will require owners to replace their existing systems with new systems using alternative refrigerants prematurely and well before the existing system's end of its useful life. Such a result would require massive expenses and resources.

While the rule places burdensome restrictions and requirements on the process of reclaiming and recycling HFCs, the servicing and repair of refrigerant-containing appliances in the supermarket systems, refrigerated transport, and automatic commercial ice maker subsectors must be done with reclaimed HFCs after January 1, 2029. There is no evidence that there will be an adequate supply of reclaimed HFCs in 2029 to service existing systems and the restrictive regulations will likely make the cost of reclaimed HFCs equally as expensive, if not more so, than new HFCs. Further, as the reclaimed HFC requirements solely target the food industry, the food industry will unfairly bear these costs resulting in increased costs for consumers.

These regulatory burdens are entirely unnecessary to accomplish the AIM Act's goals. The HFC Allowance Allocation Program under the AIM Act phases down the manufacture and import of the most environmentally unfriendly HFC refrigerants, while the Technology Transition Rule prohibits the manufacture and installation of new HFC-containing equipment within the U.S. The HFC Management Rule does nothing but prematurely end the life of existing equipment at great cost to owners/operators.

Moreover, technologies that end users will be forced to adopt upon replacing existing appliances are unproven, inefficient, uneconomical, and technically infeasible. HFC alternative technologies have not developed at a sufficient rate to be a scalable and nationally feasible solution and, currently, the building codes of most jurisdictions within the U.S. would not allow their installation in a grocery store due to flammability and/or toxicity concerns. The HFC Management Rule places

owners/operators into an impossible situation, thus, OMB should direct the EPA to rescind the HFC Management Rule.

3. 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.⁴ 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 existence of a voluntary front-of-pack labeling scheme that has been widely adopted in the marketplace and with which consumers are familiar, and the lack of evidence suggesting that consumers would change their diets in response to the Nutrition Info box (we note here that even FDA does not assert such a benefit). Additionally, FDA lacks express statutory 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 thus may not technically fall within the scope of OMB's request for deregulatory proposals. However, given the significant burdens it would impose, we respectfully request that OMB consider it as part of its deregulatory efforts.

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.⁵ 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 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

⁴ 90 Fed. Reg. 5426 (Jan. 16, 2025).

⁵ 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.

would receive “low” interpretive markers for all three nutrients yet dairy foods could bear “medium” 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,⁶ 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 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.”⁷ The agency itself acknowledges that this benefit cannot be quantified,⁸ and we agree with that assessment. 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. 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.⁹ Absent such anticipated benefits, with the appropriate substantiation, the proposal’s costs would far exceed its anticipated benefits.

⁶ 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>.

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

⁸ Food Labeling: Front-of-Package Nutrition Information, Preliminary Regulatory Impact Analysis (PRIA), <https://www.fda.gov/media/185202/download?attachment>.

⁹ See PRIA, *infra*.

FMI, therefore, recommends that FDA consider withdrawing the proposed rule on FOPNL 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, while also tasking the agency to more thoroughly consider appropriate alternatives, such as existing voluntary FOPNL schemes.

Additional Comments

FMI also strongly encourages OMB 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.

- **Nutrient Content Claims; Definition of Term “Healthy”:** The final rule, issued in December 2024, should be reconsidered as it is concerning from both a legal and practical perspective. In particular, the rule risks consumer confusion and unnecessary costs due to the failure to consider its potential interaction with other FDA regulations and policies. These include, but are not limited to FDA’s Front of Package Labeling Proposed Rule and Sodium Reduction Guidelines.
- **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.
- **Total Fat Limit in Smart Snacks in Schools (7 CFR 210.11(f)):** FMI encourages USDA to revoke the total fat limit imposed on competitive foods (i.e., Smart Snacks) sold in schools. The limit is inconsistent with current nutrition science and the *Dietary Guidelines for Americans*, which emphasize replacing saturated fats with unsaturated fats, rather than focusing on limiting the total amount of fat in the diet. Indeed, FDA recognized this shift in scientific consensus when it updated the definition of “healthy” to remove the previous limitation on total fat.¹⁰ The total fat limit is also unnecessary as existing saturated fat standards (<10% of total calories per item) provide sufficient protection for public health.
- **ETO Emissions Standards:** EPA should revoke its regulations imposing restrictions on emissions from the domestic use of ethylene oxide (the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilizers), which is unfairly burdening the food industry by limiting the use of safe treatments to control

¹⁰ See 89 CFR 106064 (Dec. 27, 2024).

pathogens in foods like spices and creates a double standard for imported vs. domestically treated spices.

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 towards 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.¹¹ 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.

* * *

FMI greatly appreciates your consideration of these comments identifying opportunities for regulatory reform. Please do not hesitate to contact us if we can provide further information.

Sincerely,



Stephanie Harris
Chief Regulatory Officer and General Counsel



Dana Graber
Associate General Counsel & Senior Director, Legal and Regulatory Affairs

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