

February 5, 2018

Karen Strambler
Office of Regulations, Policy, and Social Sciences
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Via Electronic Filing at <http://www.regulations.gov>

RE: Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements, Docket No. FDA-2017-N-5094

Dear Ms. Strambler:

The National Association of Chemical Distributors (NACD) submits the following comments in response to the Food and Drug Administration (FDA) request for public comment regarding Docket No. FDA-2017-N-5094, Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements (notice). As requested, our comments specific to certain FDA regulations are submitted in the format shown in the notice.

About NACD

NACD is an international association of nearly 440 chemical distributors and their supply-chain partners. NACD members represent more than 85 percent of the chemical distribution capacity in the nation and generate 93 percent of the industry's gross revenue. NACD members, operating in all 50 states through more than 2,800 facilities, are responsible for nearly 130,000 direct and indirect jobs in the United States. NACD members are predominantly small regional businesses, many of which are multi-generational, and family owned.

NACD members meet the highest standards in safety and performance through mandatory participation in NACD Responsible Distribution®, the association's third-party-verified environmental, health, safety, and security program. Through Responsible Distribution, NACD members demonstrate their commitment to continuous performance improvement in every phase of chemical storage, handling, transportation, and disposal operations.

Approximately 63 percent of NACD distributor member companies distribute or process chemicals that will ultimately become ingredients in food; the food market is a substantial and growing part of NACD members' business. Keeping the U.S. food supply safe through Responsible Distribution and compliance with FDA food safety regulations is of utmost importance to NACD members.

Additionally, regulatory burden reduction is a top priority for NACD. Our members need regulations that are clear, consistent, non-duplicative, and fairly and reasonably enforced.

NACD supports the objectives of Executive Orders (EO) 13771 and 13777, Reducing Regulations and Controlling Regulatory Costs and Enforcing the Regulatory Reform Agenda, respectively.

FDA Should Re-Propose and Update the International Adulteration Rule

NACD urges FDA to re-propose the Mitigation Strategies to Protect Food Against Intentional Adulteration rule (the intentional adulteration rule) to account for existing regulatory and industry standards concerning food defense. The intentional adulteration rule as written is too prescriptive to apply to the multitude of types of food businesses in the marketplace and doesn't leverage existing regulatory schemes or industry standards that already meet some of the requirements. Additionally, some of these industry standards and other regulatory requirements go above and beyond FDA's food defense regulations, creating a redundant regulatory system. FDA should acknowledge the industry programs and regulatory standards in existence that may meet provisions of the Intentional Adulteration rule, such as:

- Responsible Distribution, NACD's third-party-verified environmental, health, safety, and security program, contains several codes of management practice, including Code 13 on Security. The Security Code requires the prioritization and periodic analysis of *internal* and external potential security threats, vulnerabilities and consequences, in addition to implementation of security measures and regular audits.
- The Safety Quality Food Institute (SQF) Edition 8 contains Section 2.7 Food Defense and Food Fraud, which is substantially similar to FDA's Intentional Adulteration rule. SQF Section 2.7 requires companies to have a food defense plan and a food fraud plan that identify, implement, and document the "methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident."
- The Department of Homeland Security's (DHS) Chemical Facility Anti-Terrorism Standards (CFATS) requires covered chemical facilities to maintain and implement a Site Security Plan, which often requires extensive security measures including fencing, lighting, personnel surety programs, video monitoring, etc. Facilities that are covered by CFATS are often inspected by DHS on an annual or, at the very least, a biennial basis.

We strongly recommend FDA re-propose the rule and acknowledge and leverage these existing programs to meet the provisions of the intentional adulteration rule. As is, some businesses already meet some or all of these requirements and should not be forced to modify significantly or create entirely new programs when they are already taking measures to protect food from intentional adulteration. As requested in the FDA notice, below please find NACD's regulation-specific comments in the specified format:

Name of the Regulation	Mitigation Strategies to Protect Food Against Intentional Adulteration
Type of Product or FDA Center Regulating the Product	Center for Food Safety and Applied Nutrition (CFSAN)
Citation to Code of Federal Regulations	21 CFR Part 121

<p>Brief Description of Concern</p>	<p>The requirements of FDA’s <i>Mitigation Strategies to Protect Food Against Intentional Adulteration</i> are significantly different from current successful practices employed by food manufacturers to protect the consumer from illness or injury through intentional adulteration (aka food defense). While the food industry is aligned with the requirement for each facility to have a food defense plan, the rule as written is overly prescriptive, costly, and deviates from the current successful practices that have been used to protect our nation’s food supply. Food manufacturers have several other internal programs in place that either provide direct security against intentional adulteration or provide ambient intentional adulteration security due to existing measures or other regulatory programs. FDA does not cite any U.S. events in food manufacturing that these rules would address. Instead, FDA cites an event in Japan, where a disgruntled employee intentionally adulterated several frozen foods with pesticide. To our knowledge, there has not been a case of <i>intentional</i> adulteration event in the U.S. in food manufacturing in years or decades. While this does not predicate the need for regulations guarding against intentional adulteration, the regulations should accurately reflect the level of risk and likelihood of such an event. Neither the final rule nor the rule’s preamble discuss the role of probability or likelihood. Thus, if something “could” happen, a facility must design a food defense mitigation strategy for that possible event.</p> <p>The Intentional Adulteration rule is a product of the 2011 Food Safety Modernization Act (FSMA) that instructed FDA to promulgate seven new regulations. For Part 121, interface with stakeholders was limited when compared to the other six FSMA regulations.</p> <ul style="list-style-type: none"> • There was one proposed rule published December 20, 2013. Final comments were due June 30, 2014.
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	<ul style="list-style-type: none"> • There was no Advanced Notice of Public Rulemaking. • A re-proposed rule was never issued for stakeholder comment as was done for the other six FSMA-proposed regulations. • The last public meeting on the rule was in March 2014; there was no additional communication with stakeholders before publication of the final rule on May 27, 2016.
<p>Available Data on Cost or Economic Impact</p>	<p>NACD has contracted with the New York City-based economics firm John Dunham & Associates (JDA) to create an economic impact analysis of the industry. In 2017, the chemical distribution Industry was responsible for creating a total of 214,930 direct and indirect jobs, of which 72,948 persons were directly employed by distributors. The industry also generated \$42.2 billion in economic output across the United States.</p> <p>According to the FDA in its regulatory impact analysis, it is expected that the costs of the proposed rules (per facility) would be between \$9,000 and \$16,000 per year on an annualized basis. Taking the average of these two extremes (\$12,500) as the cost per facility and extrapolating that across the 4,861 chemical distribution facilities in the United States results in a total annualized cost of \$60.76 million. Based on surveys of the NACD membership, 63 percent of chemical distribution companies handle food-related products. Taking this percentage of the total cost results in an expected cost of about \$38.28 million across our industry, with potentially 3,062 facilities being impacted in the chemical distribution sector.</p> <p>NACD asked John Dunham & Associates to model how these increased costs would impact the chemical distribution industry. As with most industries, increased costs need to be passed through either to customers, shareholders, or wage earners. Since chemical distribution is what economists</p>

	<p>would call a “normal good,” one could expect demand to fall as prices rise, also impacting wages and jobs.</p> <p>Based on a detailed model of the industry, JDA calculates that these costs would result in an increase of \$0.56 per ton of product shipped or in other words an increase of about 0.16 percent in prices. While this may seem small, it would lead to changes in product demand. Based on the JDA model, this would lead to a reduction in industry employment of about 857 full-time equivalent positions. Industry workers would receive nearly \$51 million less in wages, and the overall economy would see a reduction in economic output of nearly \$156 million.</p> <p>In other words, costs imposed by the regulations would have a multiplier of 4.07, so what might seem like a minor inconvenience for chemical distribution firms actually has a very large economic cost.</p>
<p>Proposed Solution</p>	<p>FDA should re-propose the existing rule with one that provides at least the same level of public health protection as the existing rule and adds needed flexibility to account for existing regulatory programs and industry standards, and reduces the cost burden on industry to be commensurate with the public health benefits to be achieved.</p> <p>FDA should acknowledge existing food defense regulatory schemes that may apply to certain sectors of the food industry. For example, DHS’s Chemical Facility Anti-Terrorism Standards (CFATS) program calls for significant security measures on facilities that go above and beyond the Intentional Adulteration rule. In cases where a facility is regulated by both CFATS and FSMA, that facility may already be meeting those requirements, although likely in a different format with other terminology. FDA should acknowledge and provide positive confirmation that other existing regulations and industry standards may completely cover or partially fulfill FDA’s own regulations.</p>

	Additionally, FDA should extend the rule's compliance date, so all stakeholders have ample time to review and comment on the re-proposed rule, prepare facilities, and train employees for effective implementation of the revised rule.
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FDA Should Release Additional Guidance for the FSMA Rules and Streamline Its Website

FDA has yet to release several much-needed FSMA guidances that will help businesses better understand FDA interpretation of the rules and provide regulatory certainty. We strongly urge FDA to complete and publish additional draft guidances pertaining to the seven foundational rules of FSMA. We note that although additional guidance is needed, it should not be a substitute for problems in the rules themselves, such as in the intentional adulteration rule as listed above.

Finally, FDA's website is confusing to navigate and has contributed to some of the confusion concerning the requirements of the FSMA rules for several reasons. It's difficult to find accurate information using the search function and it often retrieves results that are irrelevant. The navigation from the FDA landing page is not intuitive enough to allow visitors to find quickly the information they need. The overall design doesn't appear to follow a format that is the same from page to page, requiring visitors to search each page top to bottom. We recommend that FDA make significant efforts to re-organize, streamline, and update its website to make it easier for the regulated community to navigate.

Conclusion

NACD appreciates FDA's efforts to update and revise regulations. We believe the recommendations outlined above would significantly reduce regulatory burden upon businesses.

Thank you for the opportunity to comment on regulatory reform. If you have questions or need additional information, please do not hesitate to contact me.

Sincerely,



Jennifer C. Gibson
Vice President, Regulatory Affairs