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Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA–2018–D–1398 for "*Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry*" (Publication Date: June 20, 2018)

Dear FDA Desk Officer:

The Natural Products Association (NPA) is submitting this letter as general comment to docket FDA–2018–D–1398 (Docket Name: National Bioengineered Food Disclosure Standard). The NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products, including conventional foods, medical foods, dietary supplements, and foods for special dietary use. The NPA is a non-profit 501(c)(6) association whose mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products. We are the oldest and largest trade association in the natural products industry representing over 1,100 members accounting for almost 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, homeopathic products, and health/beauty aids. Many of our members manufacture, distribute, or sell food products, and therefore NPA has an interest to submit comments on this topic. Thank you for the opportunity to comment.

Background

On May 27, 2016, FDA finalized a final rule, "*Mitigation Strategies to Protect Food Against Intentional Adulteration*". The final rule requires domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to address hazards that may be introduced with the intention to cause wide scale public health harm. These food facilities are required to conduct vulnerability assessments to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. This rule was issued as part of FDA's implementation of the Food Safety Modernization Act (FSMA). While the effective data (July 26, 2016) was selected as 60 days after the final rule was published, the actual compliance data was lengthened to allow for facilities addition time to come into compliance. Facilities other than small and very small businesses have 1 year after the effective date to comply (July 26, 2017) with part 121.5(a). Small businesses (i.e. those employing fewer than 500 persons) would have 2 years after the effective date for compliance (July 26, 2018) with part 121. Very small businesses (i.e. businesses that have less than $10M in total annual sales of food, adjusted for inflation) would have 3 years after the effective date to comply (July 26, 2019) with the IA Final Rule. The FDA's proposed guidance, which has the same name as the final rule, was published June 20, 2018. This guidance is only one of three parts and includes an introduction of food defense, four chapters and an appendix.

The Mitigation Strategies to Protect Food Against Intentional Adulteration (Food Defense) final rule established requirements for companies to create a food defense plan, aimed at preventing intentional adulteration from acts intended to cause wide-spread harm to public health, including acts of terrorism targeting the food supply. The final rule primarily covers large companies whose products reach many people, and thus the regulation exempts very small businesses and sets a higher dollar threshold for the definition of very small business than under the other FSMA final rules. The food defense plan must include the following:

- A vulnerability assessment to identify significant vulnerabilities and actionable process steps
- Mitigation strategies for identified actionable process steps
- Procedures for food defense monitoring of the implementation of the mitigation strategies
- Procedures for food defense corrective actions
- Procedures for food defense verification

All food defense activities must be documented by the facility and will be subject to FDA inspection.

To assist food facility compliance with the Food Defense Plan requirement, FDA identified four "*key activity types*" that FDA considers significant vulnerabilities. These activities include: 1) bulk liquid receiving and loading; 2) liquid storage and handling; 3) secondary ingredient handling; and 4) mixing and similar activities. Instead of conducting its own vulnerability assessment, a facility can meet the requirements of the rule by addressing these key activity types to identify actionable process steps and develop its own Food Defense Plan.

What Changed in the Final IA Rule

FDA made changes in the Intentional Adulteration Final Rule over the proposed rule. FDA removed the early distinction between "*broad*" and "*focused*" mitigation strategies. It added requirements to consider the possibility of an inside attacker. Key Activity Types (KATs) were removed from the regulation, but they would be identified and detailed in the guidance. Firms must now provide written explanations as to their reasoning behind making certain conclusions in their Food Defense Plan. It adds additional training requirements for employees conducting activities under the rule, including Food Safety Preventive Controls Alliance (FSPCA)-Intentional Adulteration training. The final rule specifies multiple elements that now must be considered

(see above) during vulnerability assessment. Finally, it requires the consideration of each point, step, or procedures in the food operation as part of the vulnerability assessment.

Key Activity Types Removed from Proposed Rule and Specified in Guidance

The guidance and the IA final rule for developing a Food Defense Plan is new regulatory ground for the FDA and industry. The guidance document is supposed to illustrate different ways that each facility can meet the requirements of the rule as well as provide for a range of options to identify and reduce vulnerabilities. One issue is that KATs were removed from the proposed rule in the final rule; however, they appear to be expanded upon in the guidance. This may be an Administrative Procedures Act (APA) violation. Under the APA, notice-and-comment rulemaking is required whenever a federal agency wants to act in a way that materially changes established burdens and benefits "*by which rights or obligations have been determined, or from which legal consequences will flow.*" It looks like rulemaking was started with KATs, but removing them from the final rule, only to have them placed into level 1 guidance where they are expanded upon is not the proper procedures. If the concept of KATs are removed during the rulemaking process, then adding them into guidance at a later date seems to send a message that Agencies can legislate through guidance. NPA objects to the inclusion of KATs into this guidance rather than rulemaking.

FDA removed the term "*qualified facility*" from the proposed rule and instead chose to use the term "*very small business*" in the exemption under 121.5(a) for the final rule. The guidance continues to refer to "*very small business*". NPA asks whether FDA ran this language of "*very small business*" by the U.S. Small Business Administration (SBA), which is an autonomous U.S. government agency established in 1953 to bolster and promote the economy in general by providing assistance to small businesses. The term "*very small business*" is not used or understood by the SBA. The term "*small business*" has meaning. A small business size standard is numerical and represents the largest a concern can be and still considered a small business. The

regulations specifying size standards and governing their use are set forth in Title 13, Code of Federal Regulations, part 121 (13 CFR part 121), Small Business Size Regulations. SBA's size regulations pertaining to Federal procurement are also found in the Federal Acquisition Regulation, Title 48 CFR part 19.

To qualify as a small business concern for most SBA programs, small business size standards define the maximum size that a firm, including all of its affiliates, may be. The SBA has established two widely used size standards – 500 employees for most manufacturing and mining industries and $7.0M in average annual receipts for most nonmanufacturing industries. In the dietary supplement industry, you have brand and contract manufacturers, own label distributors (typically no manufacturing capabilities) in addition to retailers. If the SBA cutoff for own label distributors to be recognized as small business is $7.0M, how is it that FDA can create a new business category under small businesses, based upon receipt sales, where the cutoff would be less than $10M in total annual sales of food, adjusted for inflation? On one hand, you have a recognized federal definition for some small businesses (excluding brand and contract manufacturers) set at $7.0M and you have a new category created by FDA called "*very small businesses*" set at less than $10M. This language has been propagated into the proposed rule, final rule, and this proposed guidance. NPA believes this should have been vetted more closely by U.S. SBA for their input and comment. The new definition of very small businesses adopted by FDA seems at odds with the regulatory definition of small businesses (less than $10M) in the CFR. FDA should reconcile the confusion in a re-worked final rule and for any subsequent guidance document based upon the final rule rollout.

Enforcement of the Final Rule

NPA would have liked to see a section on enforcement discretion listed in this guidance as it pertains to compliance with the IA Final Rule. NPA would like to see how FDA will enforce

this rule in a consistent manner with regard to imported and domestically produced foods. NPA would like to see in this guidance how FDA will accomplish the following:

- How will FDA develop its inspection and compliance strategy, including how facilities will be selected for inspections?
- How will food defense inspections be conducted for both domestic and foreign facilities?
- How will FDA engage in significant outreach activities, both domestic and international, to facilitate industry compliance with the IA Final Rule?
- How will the Agency communicate its thinking on inspection, compliance, and enforcement strategies?
- When will FDA update its compliance policy guide with the IA Final Rule on food defense?
- In addition to providing IA training for industry, will FDA be developing an auditor check list for industry to use to ensure a level playing field?
- How will FDA enforce domestically across all district office with even handedness?
- How will FDA's inspection and enforcement program be applied consistently throughout the country in a way that truly advances the ultimate goal of improved food defense?

Large Food Facilities Already Have Food Defense Strategies in Place

Many food and food supplement manufacturers already have implemented food defense measures on a voluntary basis. NPA would have liked to see FDA recognize those companies through examples on the importance of leveraging and reinforcing successful industry practices in the IA Final Rule, but that did not happen. Furthermore, the Final Rules should be implemented in a way that is transparent and even-handedly applied throughout the industry here in the U.S. as well as globally since FDA investigates food firms exporting to the U.S.

NPA would also like to point that not only do many food companies have food defense programs in place, but many food defense activities are already conducted under the following programs:

- Department of Homeland Security's (DHS) Customs-Trade Partnership Against Terrorism (C-TPAT) and mutually recognized international programs
- The Chemical Facility Anti-Terrorism Standards (CFATS)
- The USDA Food Safety and Inspection Services (FSIS) food defense plan template

NPA requests that these programs be recognized as meeting the requirements of the IA Final Rule. C-TPAT is a voluntary supply-chain security certification program led by U.S. Customs and Border Protection (CBP). While it focuses on private companies, including food companies, it is vigorous in implementing anti-terrorism measures to protect their supply chains. When companies joint C-TPAT, they sign an agreement to work with CBP to identify supply chain security gaps and implement specific security measures and best practices. CFATS is a DHS program which regulates high-risk chemical facilities to ensure they have anti-terrorism measures in place to reduce risks associated with the storage and use of these high-risk chemicals. Any facility that possesses "*chemicals of interest*," as identified by DHS, in certain quantities is considered a covered facility that must meet some or all of the requirements under CFATS. Covered chemical entities must perform and prepare Security Vulnerability Assessments that identify facility security vulnerabilities and to develop and implement Site Security Plans that identify measures that satisfy risk-based performance standards.

The U.S. military also performs food defense reviews for vulnerability assessment. For example, the Navy uses an Installation Food Vulnerability Assessment, which is a comprehensive security inspection, as described in the Navy Technical Bulletin Tri-Service Food Code (30 Apr 2014). The U.S. Army utilizes Food Defense Assessment Teams (FDATs) whose members conduct thorough and systematic review and assessment of installation food systems using the principles of risk management. The FDAT activities are incorporated under the much larger Antiterrorism

Working Group (ATWG). It assists in identifying potential vulnerabilities, developing mitigation strategies, and determining final residual risks. The FDAT assists in developing and monitoring activities and procedures appropriate at each Force Protection Condition level for the protection of food and bottled water from intentional contamination. FDA should consult with our military as a partner to develop best practices for industry to analyze vulnerabilities, implement food defense practices, and mitigate/reduce risk. Has FDA inquired from Department of Defense, Department of the Army, or Department of the Navy as to how they have dealt with food defense at military installations? NPA believes it would be a great starting point for revision of their final IA Rule.

There are also global food safety schemes that include food defense requirements which could be leveraged in inspections and implementation. The Global Food Safety Initiative (GFSI)'s latest edition addresses food defense. Many of the GFSI-recognized schemes include more specific food defense requirements. The Safe Quality Foods (SQF) Code includes food defense elements as well as methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident. The International Featured Standards (IFS) specifies areas critical to security to be identified. This is followed by food defense hazard analysis and assessment of associated risks that are to be conducted annually or upon changes that affect food integrity. The Supplement Safety and Compliance Initiative (SSCI) will also incorporate an audit for vulnerabilities at steps in the process. SSCI is a new initiative, patterned after GFSI, which exempted dietary supplements. Therefore, SSCI is addressing quality, transparency, safety, and food defense.

Conclusion

If FDA is flat out rejecting these programs as ways to implement a food defense plan, it should explain why in this guidance as examples of how industry adopting food defense programs

would not meet the IA Final Rule. Guidance examples are helpful to the industry. We look forward to reviewing why these programs are not able to address the IA Final Rule.

The NPA thanks FDA for this opportunity to comment, and we look forward to participating in this important regulatory process of public notice and comment in the future with the release of subsequent parts of this guidance on mitigation strategies to prevent intentional adulteration of food. NPA hopes the FDA takes our suggestions for consideration. NPA hopes FDA will consider the suggestions, guidance, and changes offered up in these comments. Finally, NPA reserves the right to comment on this part and parts of this guidance to be released in the near future, as parts 2 and 3 are to be released for public notice and comment in 2019.

Respectfully submitted,

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