Council for Responsible Nutrition
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June 30, 2014

VIA ELECTRONIC SUBMISSION

Division of Dockets Management

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, MD 20852

Re: Focused Mitigation Strategies To Protect Food Against Intentional Adulteration; Proposed Rule. 78 *Fed. Reg.* 78014-78061 (December 24, 2013). Docket No. FDA–2013–N–1425

Dear Sir or Madam:

The Council for Responsible Nutrition[1] (CRN) applauds FDA for releasing the proposed rule titled "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" to

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 100 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

implement the FDA Food Safety Modernization Act and appreciates the opportunity to provide comments.

The agency's proposed rule describes, for the first time, a regulatory requirement for dietary supplement facilities to develop and implement strategies to protect against intentional adulteration. Food defense, compared to food safety, is a new requirement for the supplement industry, as well as the food industry as a whole, and the development and implementation of food defense plans will require substantial education and training over time as well as appropriate guidance(s) from FDA, especially as methodologies evolve. It is essential that food defense regulations meet the goals of protecting the public health while taking into consideration the diversity of facilities and the need for flexibility in building food defense plans that are facility-specific.

FDA should consider harmonizing requirements in the proposed rule with existing food defense programs such as C-TPAT. C-TPAT is a voluntary industry-government partnership initiated by the U.S. Customs and Border Protection (CBP) in 2001 and codified in the SAFE Port Act of 2006[2]. The program helps firms ensure their supply chains are secured against intentional adulteration while facilitating efficient importation into the U.S[3]. Similarly, the American Institute of Baking (AIB) helps firms to develop individualized food defense plans that are based on a valid vulnerability assessment, testing of the plan, evaluating recall strategies, employee training, and auditing against recognized standards[4]. The current proposed rule may

[2] The Security and Accountability of Every Port Act of 2006, Pub. L 109-347.
[3] U.S. Customs and Borders Protection, A Guide to Program Benefits, CTPAT program.
[4] American Baking Institute (AIB) International Food Defense, http://www.aibonline.org/aibOnline/en/food-defense-services.aspx.

result in duplicative requirements for firms that already participate in other food defense programs.

Consideration of existing industry food defense programs could help FDA refine the scope of the rule, which in its current form is broad in its approach to food defense. CRN recommends that FDA issue a revised proposed rule that incorporates these existing programs and provide stakeholders a second opportunity for consultation and feedback prior to issuance of a final rule. This approach would facilitate the formation of a final rule that provides practical, focused, and cost-effective guidance to the food and dietary supplement industries.

Vulnerability Assessments

A comprehensive assessment of production conditions and practices of a facility is essential to identification of significant vulnerabilities and development of mitigation strategies to prevent or significantly minimize those vulnerabilities. Thus, proposed 121.130(b) is appropriate to permit the owner, operator, or agent in charge of a facility to conduct or have conducted a vulnerability assessment instead of using FDA-identified key activity types to identify and prioritize actionable process steps. This option provides facilities with the flexibility to make their own assessments and consider various vulnerability attributes such as the manufactured food's shelf-life, turnover in the marketplace, batch size, serving size, distribution and consumption patterns, and intended consumer, as stated in the proposed rule. Different attributes present different level of vulnerability (or can reduce vulnerability) and are facility specific.

As an example, many dietary supplement manufacturers perform "mixing" as part of the production process. FDA has identified "mixing" as one of several FDA-identified key activity

types that would require food defense measures. However, attributes of the dietary supplement that is being produced, a firm's production conditions and practices, and the intended consumer can directly influence vulnerability. For example, the vulnerability of a powdered dietary supplement that is intended to be consumed by older adults, which requires the manual addition of ingredients by employees, is significantly higher than flavored whey protein powder, intended to be ingested by adults, that is produced with an automated process in small batches with little employee involvement. The difference in vulnerability could be modified further based on the firm's general security measures in the production area.

Further, CRN contends that a thorough vulnerability assessment could include analysis of the contribution of a facility's existing programs and procedures to the overall food defense plan, such as the employment of broad mitigation strategies and employee training to instill a culture of food defense. The proposed rule's preamble describes several currently available FDA resources for food defense planning, but only encourages facilities to review FDA's 2003 guidance documents providing best practices in food defense and implement broad mitigation strategies that are appropriate to minimize the risk for intentional adulteration of food. The proposed rule's requirement for implementation of focused mitigation strategies at actionable process steps only may not be sufficient for adequate food defense and ignores important aspects of a comprehensive vulnerability assessment. In addition, allowing for the incorporation of existing programs reduces the cost of implementation of food defense plans as some food defense measures would have already been in practice.

The proposal also requires—and CRN agrees—that the vulnerability assessment must be conducted by individual(s) "qualified by experience and /or training using appropriate methods."

CRN recommends that further information on "appropriate methods" be provided in guidance documents that can be updated with new methodologies over time.

For the FDA-identified key activity types, a variety of focused mitigation strategies may be applicable, dependent both on the food manufactured, processed, packed, or held at the facility and on the practices and processes employed at that facility. CRN appreciates the examples of focused mitigation strategies that may be appropriate to implement at actionable process steps for each of these four key activity types, but would like to underscore that the decision of which and how many focused mitigation strategies that would be appropriate is dependent upon the physical layout and operation at a specific facility, and therefore these examples should be provided as examples only and not as a prescriptive list. Therefore, CRN affirms that it is appropriate that these examples be developed into industry guidance, rather than into the final rule.

Economically Motivated Adulteration

FDA has tentatively determined to address economically motivated adulteration (EMA) separately from the current proposed rule regarding intentional adulteration and would consider proposing to amend part 111 (dietary supplement GMPs) at part 111.70 (b) and (c) to include EMA that could result in serious adverse health consequences or death. Current 111.70(b) and (c) require establishing component specifications and in-process specifications to ensure the identity, strength, and composition of the dietary supplement. CRN contends that part 111 appropriately addresses EMAs in sections dealing with establishing raw material specifications related to identity, purity, strength and composition and appropriate testing methodology for such specifications. CRN suggests FDA not amend part 111, but instead issue industry guidance to further clarify how dietary supplement manufacturers can establish specifications for EMAs.

Food Defense Plan

Proposed 121.130(a) and 121.130(b) (requirement for identification of process steps, either by using FDA-identified key activities or facility conducted vulnerability assessments) would require that the process of identification of actionable process steps be done for each type of food manufactured, processed, packed, or held at the facility. Proposed 121.126 (requirement for a written food defense plan) would provide flexibility in the development of the food defense plan by allowing facilities to group food types or production method types if the vulnerabilities, focused mitigation strategies, and other required procedures, such as monitoring, are essentially identical. CRN agrees with the proposed rule that the vulnerability of a food to intentional adulteration may differ based on the type of food and associated process, practices and conditions at the facility—thus actionable process steps need to be identified for each type of food. However, having the flexibility to group food types or production method types, based on risk assessment, is necessary to avoid duplication.

Other Considerations

The proposed rule includes a definition for the term "contaminant," which is used widely in the food and dietary supplement industries. If FDA were to include a definition for this term, it must employ a definition that is consistent throughout all regulations pertaining to food and dietary supplements. In addition, the proposed language defining "contaminant" could be interpreted to include an ingredient intentionally added to food that resulted in harm, even if unintentional, such as an unintended allergic or other adverse health response.

CRN encourages FDA to finalize a rule that provides the foundations for industry-wide defense against intentional adulteration of the food supply and to utilize guidance as tools to help

industry build on those foundations in the development of food safety plans that are meant to achieve the goal of protecting the public health. However, developing and implementing a food defense plan is a complex process that requires specific expertise and extensive costs. Therefore, CRN requests that FDA issue a revised proposed rule for additional stakeholder feedback prior to issuance of a final rule.

Respectfully submitted,

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