AMERICAN SPICE TRADE ASSOCIATION, INC.

1101 17th Street, N.W. • Suite 700
Washington, DC 20036 USA
Tel: 202-331-2460 • Fax: 202-463-8998
E-mail: info@astaspice.org
Web: www.astaspice.org

June 30, 2014

Via electronic submission

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Food and Drug Administration, HHS Docket No. FDA-2013-N-1425; *78 Federal Register 78013* (December 24, 2013)

Dear Sir or Madam:

The American Spice Trade Association (ASTA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) proposed rule, Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (78 *Fed. Reg.* 78013 (December 24, 2013)), implementing the intentional adulteration provisions in the FDA Food Safety Modernization Act (FSMA).

The proposal would establish new regulations relating to the intentional adulteration of food (also known as "food defense"), which represent the first time that FDA is establishing mandatory requirements in this area. Based on our members' experience implementing food defense programs voluntarily since September 2001, ASTA offers feedback on FDA's proposal to hopefully strengthen the integrity and effectiveness of this proposed rule.

Introduction

American Spice Trade Association

ASTA was established in 1907 to provide representation for the American spice trade. Its members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. On behalf of its members, ASTA works with federal and state regulators and

legislators and assists its members in addressing a variety of technical issues to help members provide an adequate supply of safe and wholesome spices for their industrial, food service and consumer customers.

Joint Role to Protect Public Health and the Food Supply

Passage of FSMA, signed into law on January 4, 2011, underscores FDA's role to protect human health and the critical mission it plays in ensuring that our nation's food supply is safe. ASTA shares FDA's commitment to food safety and food defense. The highest priority to ASTA and its members is providing clean, safe spices to customers: food manufacturers and consumers. ASTA continues to engage actively in the regulatory process by providing comments to FDA as it implements FSMA. ASTA also continues to provide needed resources to members to share with the entire supply chain as appropriate, including tools to assist in the manufacturing, handling, and processing of clean safe spices.

General Comments

ASTA supports efforts that strengthen and modernize our nation's food safety system. ASTA supports both the general requirements of FSMA as well as the critical role FDA plays to ensure the safety of our nation's food supply. ASTA firmly believes that FSMA rules, including the proposal on intentional adulteration, must be science- and risk-based. The regulations should be outcome-focused, while providing the flexibility needed for the food industry, including the spice industry, to be able to properly and effectively implement measures to minimize the potential for intentional adulteration as necessary.

Vulnerability Assessments, Key Activity Types, and Mitigation Strategies

ASTA believes that all suppliers and manufacturers across the entire supply chain have the duty to protect their products from intentional adulteration. Food Defense Plans (FDPs) should be required for all food facilities. The focus of FDA's regulation should be on the processes that provide the most vulnerability. Thus, each facility should start by conducting a vulnerability assessment to understand the specific threats that could affect its processes. In some instances, the vulnerabilities may align with the key activity types that FDA sets forth in the proposed rule, however these factors are so broad that they encompass the entire food industry and, therefore, are not risk-based on their own. A spice manufacturer may not be high risk for food defense simply because it engages in secondary ingredient handling, mixing, or similar activities. Additional factors influencing the potential risk of harm need to be considered, such as downstream processing steps, the volume of product, its shelf life, marketplace turnover, and consumption patterns.

Thus, ASTA agrees that an owner, operator, or agent in charge should objectively determine a facility's vulnerabilities by conducting a vulnerability assessment but we do not support the narrow focus of the rule on key activity types, with the option to conduct a vulnerability assessment as an optional alternative. The proposed approach is not adequately analytical, as it discourages facilities from engaging in critical thinking about their vulnerabilities. There are many existing guidance tools that can assist facilities in conducting a vulnerability assessment. For example, use of FDA's Food Defense Plan Builder (FDPB) tool should be permissible to satisfy the requirement to conduct a vulnerability assessment.

Mitigation strategies for significant vulnerabilities should be implemented based on the outcome of each facility's vulnerability assessment. ASTA supports a regulation that allows facilities to implement whatever mitigation strategies are most appropriate, regardless of whether they are broad or focused. Facilities also should be able to take account of existing programs that may be in place, including food safety programs that also provide food defense benefits (e.g., GMP zoning policies that use color coded uniforms to limit employee movements).

ASTA also urges FDA to permit requirements that are already in place by other government agencies to count as mitigation strategies, when appropriate based on a thoughtful vulnerability assessment. In particular, the Customs-Trade Partnership Against Terrorism (C-TPAT) program has proved successful in requiring that broad mitigation strategies be addressed, including physical security, personnel security, ingredient storage and inventory procedures, and crisis management planning. Furthermore, the C-TPAT program aims to mitigate terrorist risk and applies directly to the statutory directive mandated by Congress to prevent or mitigate risks posed by intentional adulteration of our nation's food supply. These strategies often are sufficient to serve as an effective barrier to ward off unwelcome breeches. Industry should be provided the flexibility to consider and implement focused mitigation strategies as needed, and as determined by each facility, taking into consideration unique aspects of the facility, the manufacturing processes, and the risk of the significant vulnerabilities identified by the vulnerability assessment. These focused strategies would complement a framework that builds on broad facility-wide measures as the first line of defense.

Qualified Individuals

ASTA urges that FDA maintain flexibility and not mandate specific training or experience required of qualified individuals conducting vulnerability assessments. Qualified individuals may vary from company to company due to a variety of factors. The industry should be provided the ability to make the determination of who best can meet the qualifications to carry out a thorough and thoughtful vulnerability assessment and then develop a FDP based on that assessment. In some cases, food facilities may wish to conduct their own assessment, but in other instances facilities may opt to call on outside subject matter experts. Providing companies the flexibility to decide who is best situated to make these thoughtful determinations permits industry to use resources efficiently.

Confidentiality of FDPs

It is critical that FDPs be held confidential unless serious incident or suspected incident requiring an investigation makes disclosure necessary. Thus, FDA should not copy these plans as part of routine food facility inspections—but rather only should do so in an emergency as authorized by the Bioterrorism Act's emergency records access provisions (Federal Food, Drug, and Cosmetic Act section 414). And in the event of such an emergency incident, FDA should maintain the utmost of sensitivity to maintaining the confidentiality and integrity of such information, recognizing that it not only is confidential business information but also may have national security protections. Even in the context of an emergency incident, FDA should only copy the bare minimum information that is necessary to assist in the investigation.

Furthermore, detailed information beyond the mere existence of a food defense plan should not be mentioned in FDA's Establishment Inspection Reports (or corresponding records created by state inspectors operating on FDA's behalf), as this information could divulge weak points in a facility's food defense program. Further, it is risky and burdensome to rely on FDA's Freedom of Information Act officers to properly redact such information given the significant national security vulnerabilities it can present.

Proposed Exemptions Based on Business Size

Food defense is distinct from food safety in many ways, and therefore needs to be regulated in a tailored manner. However, like food safety, defense of the food supply does not discriminate based on company size. Those wishing to inflict harm on others will look for vulnerabilities no matter where they present themselves. It is imperative to ensure all parts of the food supply chain are safe and secure. ASTA cautions

FDA against finalizing the proposed definition of "very small business" food facilities as businesses with $10,000,000 or less in annual food sales. Even though this would mean that many of our members would be exempt, we are concerned that this approach creates a major hole in the safety net that will be easy for potential wrongdoers to exploit. Furthermore, FDA identified ingredient handling as a vulnerability, and many small businesses make ingredients (like spices) for large national brands. This underscores why all ingredient manufacturers need to be covered.

ASTA does, however, encourage FDA to provide guidance and resources to assist businesses and very small businesses in implementing food defense measures. ASTA agrees with FDA's approach relating to effective dates for implementation and supports providing small businesses and very small businesses with additional time in order to comply with the rule. But this is different than exempting very small businesses entirely. It is critical for the entire supply chain to have measures in place to minimize the likelihood of intentional adulteration.

Economically Motivated Adulteration

Economically motivated adulteration is not addressed in the proposed rule and FDA states that it is planning to address the issue in a separate rulemaking. ASTA supports FDA's decision to address economically motivated adulteration separately from food defense. However, we encourage the agency to wait to regulate economically motivated adulteration until after all of the seven major FSMA regulations have been implemented, so that the agency can better assess the need to specifically address this issue through a regulation. If the agency does determine it is necessary to specifically regulate economically motivated adulteration, we encourage FDA to adopt a stand-alone regulation on this issue rather than fitting it within preventive controls, as the issue only sometimes fits within the food safety framework and often is best approached differently than traditional food safety hazards.

Reproposal

Given the significant changes ASTA believes are warranted to FDA's initial proposal, we urge FDA to consider our comments and those of other food industry trade associations and issue a reproposal for public comment. We believe that will result in a far better final rule. Given that the court deadline for publication of the food defense final rule is not until May 2016, we believe FDA has ample time to go through this important step.

Conclusion

On behalf of ASTA and its members, we thank you for the opportunity to provide input on this important subject and respectfully request your consideration of our comments.

Sincerely,

Cheryl Deem
Executive Director