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U.S. Pharmacopeial Convention

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Submitted Electronically
Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Room1061
Rockville, MD 20852

Subject: Comments on "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration", Docket No. FDA-2013-N-1425 [Food Safety Modernization Act]

Dear Sir/Madam:

Thank you for the opportunity for the United States Pharmacopeial Convention (USP) to comment on the U.S. Food and Drug Administration's (FDA) proposed rule on intentional adulteration.

Of specific concern to USP is FDA's decision to address Economically-Motivated Adulteration (EMA) of food through preventive controls. While USP agrees with the Agency that it is far from ideal to handle EMA under a typical food-defense/vulnerability approach, we believe EMA would be equally misplaced under preventive controls—EMA should be addressed as its own unique category of food adulteration. Standards can also play a helpful role, as described below.

I. Statement of Issue

A traditional hazards analysis and preventive controls approach assumes the successful identification of specific potential hazard(s) that are "reasonably likely to occur" as a basis for characterizing public health risks in a food supply or system. This assumption is not compatible with EMA since its associated hazards are difficult to predict, often involving novel and unanticipated means of deception. Incidents have included dilution (e.g., watered down products using non-potable water, olive oil diluted with potentially toxic tea tree oil); substitution (e.g., sunflower oil partially substituted with mineral oil, hydrolyzed leather protein in milk); concealment (e.g., harmful food coloring applied to fresh fruit to cover defects); mislabeling (e.g., toxic Japanese star anise labeled as Chinese star anise, mislabeled/recycled cooking oil); and unapproved enhancements (e.g., melamine added to enhance protein value, use of unauthorized additives such as Sudan dyes in spices). Any ingredient can be adulterated, and the list of potential adulterants is equally unlimited—the key driver being profit and the perpetrator's desire to evade detection.

A regulatory regime for EMA that protects consumers and safeguards industry therefore needs to focus more on determining whether EMA is likely to occur at all (estimating ***likelihood*** of EMA occurrence through a vulnerabilities assessment)—a more useful indicator of potential public health risks than relying solely on hazards identification that would be part of traditional hazards analysis and preventative controls approach. While FDA suggests EMA's ***likelihood*** could be inferred from geographic origin and past occurrence, USP believes that although this information is important, a more comprehensive framework is necessary to accurately make this determination.

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II. Suggested Approach

USP recommends FDA consider a "hybrid" framework tailored to the specific nature of EMA that draws on elements of other approaches as the basis for a regulatory regime. Such a framework would include two components (1) a **vulnerability assessment** mostly focused on determining the likelihood of EMA occurring but also including a component of public health risk assessment, and (2) a **vulnerability control plan** to mitigate these risks. Given risk points *external* to the facility, the review should focus on *raw ingredients* (as opposed to the facility itself or final food product).

A vulnerability assessment should first weigh the factors known to contribute to EMA likelihood, including but not limited to the degree of supply chain integration, supplier audit strategy, EMA history of raw material, geographic origin (e.g. sufficiency of regional or national regulations and level of local enforcement to ensure safety and deter EMA), potential vulnerability of methods used to test raw materials, and economic anomalies (e.g. unusual changes in raw material production and pricing). Potential hazards should also be identified and characterized, including an assessment of the severity of public health risks, as well as consideration of economic trade disruption and erosion of consumer confidence caused by EMA. Qualified experts should be given the flexibility to determine which of these factors are the most appropriate to consider as part of a suitable assessment.

Control measures should mitigate identified vulnerabilities and risks by deploying resources in a manner that is proportional to the assessed degree of vulnerability and risk. These resources should include but not be limited to testing, specifications, supply chain management, and supplier audits (such measures may be helpful to regulatory agencies as well as to manufacturers).

Resources[1] currently exist that catalog incidents of EMA, and in conjunction with other analytical and compendial tools, may be helpful for carrying out both EMA vulnerability assessment and control measure planning. USP's work plan is to develop additional tools in this area.

III. Role of Public Standards

Publicly available standards for food ingredients—including tests for identity, purity, and impurities, establish verifiable specifications that can help define the food ingredient. A number of well-respected and globally-recognized food ingredient standards[2] exist that can be used directly by a manufacturer or as a component of a third party certification system. Recommended standards include written (documentary) specifications, test methods, and associated physical (chemical, botanical, and biological) reference materials. All three elements are indispensable to determine the authenticity of a food ingredient. Standards help assure food integrity throughout the complete supply chain by excluding ingredients that have been substituted, diluted, or replaced, through fraud or other means. While standards of identity and purity in themselves are useful to help establish product integrity, standards can also be specifically developed or revised to help safeguard against adulteration (e.g., melamine in skim milk). *Demonstrated compliance with food ingredient standards can be an indication the company is monitoring against EMA.*

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[1] See, e.g., www.foodfraud.org.
[2] E.g., www.usp.org/food-ingredients/food-chemicals-codex.

IV. Conclusion

Food fraud/EMA is a significant concern: it destroys markets, disrupts trade, erodes consumer confidence, and poses the threat of unspecified harm to consumers[3] because it puts control of the supply chain in the hands of criminals. Given the unique nature and risks of EMA, it should be handled separately from food defense and preventive controls using the means identified above—and standards can also help.

Thank you for considering our views. Should you require more information, our staff contact is Ben Firschein, USP's Director of Government Affairs and Policy, baf@usp.org (301) 816-8235.

Sincerely,

Ronald T. Piervincenzi, Ph.D.
CEO and Chair, Council of Experts

[3] Even an adulterant as simple as water can introduce the possibility of contamination, illness, and death into the food supply if it contains pathogens or other contaminants—the perpetrator may be unaware of the risk, or simply may not care in the quest to profit.