

## VIA ELECTRONIC SUBMISSION

April 21, 2017

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### Re: **Proposed *Safe Food for Canadians Regulations***

The United States Pharmacopeial Convention, Inc. (USP) appreciates this opportunity to submit comments on the proposed *Safe Food for Canadians Regulations* (the *Proposed Regulations*).<sup>1</sup>

In the United States, USP has been working to support the U.S. Food and Drug Administration (FDA) in its implementation of the FDA Food Safety Modernization Act (FSMA). We understand that the framework established by the *Safe Food for Canadians Act* has many parallels with FSMA. We also are aware that the Canadian Food Inspection Agency (CFIA) has been working with counterparts in the U.S. on various food safety initiatives. Considering the significant similarities between these food safety frameworks, the close trading relationship between the U.S. and Canada, and the interconnectedness of the global food supply, USP believes there is synergy between our efforts in the U.S. and the Canadian government's implementation of the *Safe Food for Canadians Act*. In particular, we feel that our activities in the food fraud mitigation area can play a vital role in supporting Canadian regulators and helping the food industry address hazards associated with economically motivated adulteration (EMA) or "food fraud," which is an important part of a robust preventive controls-based compliance strategy.

In the following pages, we summarize USP's ongoing activities in the area of food fraud mitigation, highlighting resources currently available to interested stakeholders. We also discuss the utility of the *Food Chemicals Codex (FCC)* as a resource for establishing and maintaining the identity, purity, and quality of components in the food supply.

### I. **USP's Food Fraud Mitigation Tools Help Combat EMA in the Context of a Preventive Controls-Based Framework**

As you may know, both FSMA and the *Safe Food for Canadians Act* take a preventive controls-based approach to food safety. FDA's regulations to implement FSMA define a "hazard" and require food facilities to develop a hazard analysis and risk-based preventive controls (HARPC) plan to protect the food supply.<sup>2</sup> FDA expressly states that the hazard definition encompasses hazards that "may be intentionally added to a food for purposes of economic gain" (i.e., economic adulteration).<sup>3</sup> The *Proposed Regulations* similarly require regulated

<sup>1</sup> See Canada Gazette, Vol. 151 – January 21, 2017, available at: <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-01-21/html/reg1-eng.php#reg>.

<sup>2</sup> 21 CFR 117.126; 117.130.

<sup>3</sup> 21 CFR 117.130(b)(2)(iii).

facilities to perform a hazard analysis and to prepare a preventive control plan (PCP). Although the *Proposed Regulations* do not expressly reference EMA, we encourage CFIA and Canadian stakeholders to consider the impact of this hazard on the food supply. EMA costs the food industry an estimated \$10 to \$15 billion USD on an annual basis.<sup>4</sup> The consequences of EMA can range from lost revenue to adverse health consequences, including consumer deaths. As part of a robust preventive controls-based framework, EMA hazards should be addressed among the “biological, chemical and physical hazards that present a risk of contamination of a food.”<sup>5</sup>

It is in the context of addressing EMA risk that USP’s Food Fraud Database and Food Fraud Mitigation Guidance can serve as useful tools to food industry stakeholders. Both resources were developed based on extensive input from USP’s food ingredient expert volunteers and evaluated by food experts around the world. We were fortunate to have had U.S. and Canadian government liaisons participate in the Expert Panel that developed the Food Fraud Mitigation Guidance. They provided invaluable feedback as we developed our food fraud mitigation resources, which we hope will help regulators, the food industry, and other stakeholders to combat food fraud and to improve the overall quality and safety of the global food supply.

#### A. Food Fraud Database

USP has worked to develop a Food Fraud Database (FFD), which FDA has referenced in its Draft Guidance document related to the HARPC provisions under FSMA.<sup>6</sup>

Launched in July 2016, FFD Version 2.0 (<https://www.foodfraud.org/>) is a continuously updated collection of thousands of food fraud-related records gathered from scientific literature, media publications, regulatory reports, judicial records, and trade associations from around the world. With over 6,500 records and growing, our goal is to maintain the largest and most current database of historical records of food fraud in existence. In its current iteration, the FFD is a subscription-based portal that provides a user-friendly way for interested parties to review, search, and analyze data related to food fraud incidents around the world. The FFD features records that include ingredients that were adulterated, the identity of the adulterant, the method used to detect the adulterant, and whether the adulterant is hazardous to human health. Users can identify trends and vulnerabilities specific to ingredients of interest and receive updates as new records are added to the database. From a regulatory compliance perspective, the FFD is now enhanced to generate EMA hazard identification reports that users may find beneficial in developing and implementing PCPs under the *Proposed Regulations*.

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<sup>4</sup> Grocery Manufacturers Association, *Consumer Product Fraud: Deterrence and Detection* (2010), available at: <http://www.gmaonline.org/downloads/research-and-reports/consumerproductfraud.pdf>.

<sup>5</sup> *Proposed Regulations* sec. 44(1).

<sup>6</sup> FDA, *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food*, at page 63 (August 2016) available at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517610.pdf>.

## B. Food Fraud Mitigation Guidance

FDA also referred to another USP resource in its Draft HARPC Guidance – the Food Fraud Mitigation Guidance (FFMG).<sup>7</sup> Published in 2015, the FFMG (<http://www.usp.org/food/food-fraud-mitigation-guidance>) is a free online resource that provides a comprehensive, practical approach to help food suppliers perform a food fraud vulnerability assessment on an ingredient-specific basis and to develop a customized mitigation plan. The FFMG is neither country- nor sector-specific, and CFIA and Canadian stakeholders can use this document as an EMA risk assessment and mitigation tool.

It is our hope that these food fraud resources will be used more broadly by regulators, industry, and other stakeholders to enhance global food quality and safety.

## II. The FCC Serves as a Resource to Enhance Food Ingredient Identity, Purity, and Quality

Originally published in 1966, the *Food Chemicals Codex (FCC)* is a compendium of food ingredient standards. Since assuming stewardship of the FCC in 2006, USP has worked to develop and update validated, peer-reviewed public standards, called “monographs,” for food substances that include tests, procedures, and acceptance criteria to ensure the identity, purity, and quality of such products. We are grateful to have active and engaged government liaisons from Health Canada on the USP Food Ingredients Expert Committee, which works to develop FCC monographs. At present, the FCC contains monographs for more than 1,200 food substances. In conjunction with FCC monographs, USP also develops and supplies the industry with reference materials for food substances, as well as for related impurities and contaminants. These reference materials are highly characterized substances intended for use in conducting quality control tests and analytical procedures associated with specifications in established monographs.

As you know, Canada’s *Food and Drug Regulations* require that food additives meet certain standards for identity and purity in order for an additive to be considered food-grade. Where the *Food and Drug Regulations* do not prescribe specific requirements, food additives, including most food colours, must meet the specifications of either the FCC or of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).<sup>8</sup> In the U.S., FDA has issued more than 200 regulations for food substances that incorporate FCC specifications by reference. The FCC also is recognized by regulatory bodies around the world, including Australia, New Zealand, and Brazil. Even where not expressly recognized in the food regulatory framework, FCC monographs are widely used as a benchmark for food-grade quality specifications in contractual agreements among food producers to ensure supply chain integrity.

In USP’s view and experience, in-depth knowledge and understanding of food ingredient specifications can serve as a helpful prerequisite to developing a robust preventive controls-based compliance plan, such as the one required by the *Proposed Regulations*. FCC monographs and their associated reference materials can help food ingredient suppliers ensure that quality standards are met and that test methods are performed appropriately.

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<sup>7</sup> *Id.* at page 78.

<sup>8</sup> *Food and Drug Regulations* B.01.045(b).



We encourage CFIA, industry, and other stakeholders to collaborate with USP in our efforts to develop transparent, science-driven standards – such as those in the *FCC* – because they serve an important role in helping to secure the quality and safety of food ingredients in the global supply chain.

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We thank CFIA for the opportunity to submit comments on the *Proposed Regulations*, and we look forward to working collaboratively with the Canadian government and others in this area to ensure that USP can serve as a resource in enhancing the quality and safety of the food supply.

In particular, we would welcome the opportunity to meet with Canadian government officials to fully explore and expand upon our shared goals and to discuss opportunities where USP may offer resources and support to complement CFIA's efforts in this area. We look forward to providing more detailed information on the food fraud mitigation tools discussed above – including an in-depth demonstration of the FFD – to the Agency at your convenience. Please feel free to contact Elizabeth Miller, Vice President, U.S. Public Policy and Regulatory Affairs, at [ehm@usp.org](mailto:ehm@usp.org); (240) 221-2064, with any questions or to schedule a meeting.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Venema", is written over a horizontal line.

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