Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PAR 15–312, State Occupational Safety and Health Surveillance Program (U60).

Date: January 25–27, 2021.

Time: 8:00 a.m.–5:00 p.m., EST.

Place: Virtual Meeting.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505, Telephone: (304) 285–5951, *MGoldcamp@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1869]

Alignment of Third-Party Food Safety Standards With Food Safety Regulations: Notice of Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is seeking requests for participation from members of the public, including owners of third-party human food safety standards, interested in participating in a voluntary pilot program to evaluate third-party food safety standards. On July 13, 2020, FDA announced the New Era of Smarter Food Safety Blueprint and the desire to explore the increased use of reliable third-party audits to help ensure safer food, including exploring the use of reliable audit data in risk-prioritization for FDA regulatory activities, for example, with respect to inspections of both imported and domestically produced foods. Under the pilot program, FDA will assess third-party food safety standards for alignment with certain FDA food safety regulations. Knowing that these third-party standards align with certain FDA food safety regulations would give those relying on audits conducted to those standards confidence that they are meeting certain FDA requirements for supplier verification audits. The pilot will enable FDA to gain information and experience that will allow the Agency to evaluate the resources and tools required to conduct alignment reviews.

DATES: The pilot will conclude October 26, 2021.

ADDRESSES: Submit written or electronic submissions for the pilot program to *StandardsAlignmentPilot@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Franciel Ikeji, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–4971.

SUPPLEMENTARY INFORMATION:

I. Background

Ensuring the safety of food for human and animal use is a shared responsibility between the public and private sectors. FDA has established regulatory standards, inspects facilities, and may take action if there are violations. But it is primarily the responsibility of industry to ensure that food products intended for human and animal consumption in the United States are safe and meet applicable food safety requirements. The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) modified the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301, *et seq.*.) to establish a framework that focuses on prevention and recognizes the important part we all play in protecting consumers from unsafe food.

FSMA and the implementing regulations place new obligations on certain entities in the food industry to verify that their suppliers are meeting FDA safety standards. More specifically, three regulations that FDA issued under FSMA have supplier verification requirements. Those regulations are the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PCHF) regulation (part 117 (21 CFR part 117)); the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (PCAF) regulation (part 507 (21 CFR part 507)); and Foreign Supplier Verification Programs for Food Importers (FSVP) regulation (21 CFR part 1, subpart L). Subparts A, C, D, E, F, and G of part 117 in the PCHF regulation include requirements for domestic and foreign facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) to conduct a hazard analysis and implement risk-based preventive controls for human food (the human food preventive controls requirements). Subpart G of part 117 requires the receiving facility to establish and implement a written supply-chain program (21 CFR 117.405(a) and (b)) and conduct appropriate supplier verification activities for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control (21 CFR 117.425 and 117.415(a)(3)(iii)). Generally, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death, the

appropriate supplier verification activity is an onsite audit of the supplier, and it must be conducted before using the food and at least annually thereafter (§ 117.430(b)(1) (21 CFR 117.430(b)(1))).

For animal food facilities that are required to register, subparts A, C, D, E, and F of part 507 in PCAF include requirements to conduct a hazard analysis and implement risk-based preventive controls for animal food (the animal food preventive controls requirements). Subpart E of part 507 establishes requirements, similar to those in PCHF, for a supply-chain program for those raw materials and other ingredients for which a receiving facility has identified a hazard requiring a supply-chain-applied control.

Under the FSVP regulation, FSVP importers are required to develop, maintain, and follow a foreign supplier verification program that provides adequate assurances that imported food meets applicable U.S. food safety standards. The FSVP regulation requires importers to conduct a hazard analysis to determine whether there are any hazards that require a control (21 CFR 1.504) and, based on the hazard analysis, determine the appropriate type of verification activity as well as the frequency of conducting the activity. When a hazard in a food is controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death to humans or animals, the default verification activity is to conduct an annual onsite audit before initially importing the food from the supplier and at least annually thereafter (§ 1.506(d)(2) (21 CFR 1.506(d)(2))).

In all three regulations, audits are not required if the receiving facility or importer has made a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate verification. See §§ 1.506(d)(2), 117.430(b)(2), and 507.130(b)(2).

The FSMA supply-chain programs do not require these annual onsite audits to be conducted by auditors accredited under FDA's Accredited Third-Party Certification Programs (21 CFR part 1, subpart M), which established a voluntary program for the accreditation of third-party certification bodies to conduct food safety audits and issue certifications for foreign facilities. The PCHF, PCAF, and FSVP regulations do, however, require the onsite audits under these regulations to be conducted by ''qualified auditors. '' (A qualified auditor means a person who has the technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function). See 21 CFR 1.500, 117.3, and 507.3. Importantly, too, the audits must consider applicable FDA regulations. See 21 CFR 1.506(e)(1)(i), 117.435, and 507.135.

FDA is aware that there are a variety of third-party food safety standards used by industry to assess a supplier's performance and that importers and receiving facilities may voluntarily rely on audits that use those private standards. Because the supply-chain verification provisions of PCHF, PCAF, and FSVP require that audits consider applicable FDA food safety regulations, importers and receiving facilities may seek assurances regarding how these standards align with FDA food safety standards. Having such assurances may provide importers and receiving facilities with confidence that they can use audits conducted under the standards to fulfill the PCHF, PCAF, and FSVP requirements for supplier verification. This pilot will assess whether some of these third-party food safety standards are aligned with food safety requirements in two specific FDA human food safety regulations: The PCHF regulation and the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety) regulation (21 CFR part 112). The pilot will not assess alignment with FDA animal food safety regulations.

FDA has published templates that may be used to help receiving facilities, importers, and other stakeholders compare the third-party food safety standards used in an audit to the food safety requirements in applicable FDA regulations (FDA Audit Comparison Templates) *https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm602286.htm.* The templates are arranged in a table format for easy comparison of the third-party food safety standards to the food safety requirements of FDA regulations.

While these templates are useful, the pilot will allow us to assess how the third-party food safety standards used in audits align with human food safety requirements in the PCHF and the Produce Safety regulations. We expect that FDA alignment determinations would create efficiencies for industry, so that importers and receiving facilities know whether the third-party food safety standards used to audit their suppliers adequately consider food safety requirements in two of FDA's regulations. Similarly, we expect that it would be more efficient for FDA investigators to know if the standards against which a supplier was audited align with FDA regulations, so that the investigators can more efficiently determine whether importers and receiving facilities are in compliance with the FSMA supply-chain verification requirements for audits. The pilot will assist FDA in gathering information to determine whether these expectations are accurate.

The pilot will also evaluate the process for determining alignment, including the resources required for FDA to review and assess third-party standards for alignment with relevant FDA regulations. While the pilot will be focused on human food safety requirements in the PCHF and Produce Safety regulations, any program that FDA puts in place as a result of the Agency's experience with the pilot would likely also include a review of standards for food for animal consumption to assess and determine alignment of third-party animal food safety standards to the food safety requirements in the PCAF regulation.

We also note that the goals of this pilot align with the ''FDA Strategy for the Safety of Imported Food,'' which includes an objective that FDA take into account the public health assurances of reliable audits such as those issued under FDA's Accredited Third-Party Certification Program or pursuant to other assurance programs aligned with FDA food safety requirements. FDA recognizes that audits can provide valuable public health assurances if they are reliable and if the standards under which audits are conducted are aligned with relevant FDA food safety regulations. The goals of the program also align with the New Era of Smarter Food Safety Blueprint. As explained in the Blueprint, FDA is considering the benefits of using reliable audit information in resource allocation decision making and risk prioritization of regulatory activities such as import screening to ensure that food offered for import meets U.S. food safety requirements. Because this pilot is only focused on assessing third-party food safety standards, and not the overall quality of audit programs or the qualifications of auditors, we believe that the pilot will help evaluate the requirements for making alignment determinations as an important step in determining the reliability of third-party audits.

II. FDA Determination of Alignment of Third-Party Food Safety Standards Voluntary Pilot Program

A. Scope and Selection Attributes

FDA is seeking requests for participation from members of the public, including owners of third-party human food safety standards, who are interested in participating in a voluntary pilot program to determine whether third-party food safety standards align with food safety requirements in the PCHF and the Produce Safety regulations. Upon being selected to participate in the program, participants will submit their standards for assessment. FDA plans to select and assess up to five private third-party human food safety standards for alignment with food safety requirements in the PCHF or the Produce Safety regulation. Participants in the pilot program will be asked to provide FDA with technical feedback on the pilot. The Agency will use its discretion in choosing participants for assessment based on (in no particular order):

(1) The order the requests for participation are received;

(2) the desired diversity of third-party human food safety standards for assessment in the pilot (*e.g.,* PCHF, Produce Safety); and

(3) the Agency's determination of available resources to conduct the assessment given the level of effort and other priorities.

FDA reserves the right to request additional information or clarification from participants in the pilot and to rescind participation if the additional information or clarification is not promptly and accurately provided.

B. Duration

The pilot will run for 1 year from the date of publication of this notice and will conclude on October 26, 2021. FDA reserves the right to extend the pilot for more time as needed. To assure we have adequate time to assess the standards during the pilot period, we are asking members of the public, including owners of third-party human food safety standards, to submit their request to participate in the pilot program by November 25, 2020.

C. Submission of Requests To Participate

Members of the public, including owners of third-party human food safety standards, that are interested in participating should submit a written request to participate to Franciel Ikeji (see **FOR FURTHER INFORMATION CONTACT**). Electronic requests should be submitted to *StandardsAlignmentPilot@fda.hhs.gov.* We strongly encourage interested persons to electronically submit their requests to participate. Written and electronic requests to participate in the pilot program should be submitted by November 25, 2020.

The request to participate should include the following information: Company and contact name; contact phone number; and contact email address. Additionally, although not required for consideration, FDA is particularly interested in whether you are the owner of a third-party food safety standard, and the type of food safety standard you have developed (*e.g.,* produce safety, human processed food). For a limited number of applicants that FDA identifies as possible candidates for participation in the pilot, FDA may ask you to submit a completed FDA Food Safety Audit Comparison Template *https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm602286.htm.* If the pilot participant chooses to submit an alternative comparison tool, the format should enable FDA to easily compare the third-party food safety standard to the relevant FDA regulations (*i.e.,* placing the relevant requirements of FDA's regulations in numerical order to the left of any third-party food safety standards). FDA may also ask pilot participants for additional information on submitted food safety standards.

D. Assessment and Alignment of Program Standards

The pilot program will be conducted from October 26, 2020 to October 26, 2021 and may be extended as needed. Each person that submits a request to participate will be notified that FDA has received the request. This notification only acknowledges that FDA has received the request and does not guarantee that FDA will accept you for participation in the pilot. By the conclusion of the pilot, participants will be notified as to whether FDA determined the food safety standard to be in alignment or not in alignment with the relevant FDA regulation.

FDA will publish information on its website regarding the third-party standards that FDA determines to be in alignment with FDA regulations.

E. Evaluation of Pilot Program

FDA intends to evaluate the pilot program on several factors, including, but not limited to, the resources required to review and assess third-party standards for alignment with relevant FDA regulations, the ability of pilot participants to provide adequate information to enable FDA to make a determination of alignment, and whether FDA Audit Comparison Templates are a helpful tool in making alignment determinations. After FDA evaluates the pilot program, the Agency will utilize the information to evaluate the resources and tools required to conduct alignment reviews.

Dated: October 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Dates and Times: Wednesday, November 18, 2020: 10:00 a.m.–5:30 p.m. EST.

Thursday, November 19, 2020: 11:30 a.m.–4:00 p.m. EST.

Place: Virtual.

Status: Open.

Purpose: At the November 18–19, 2020, meeting, the Committee will receive briefings from HHS officials, hold discussions on several health data policy topics and discuss its work plan for the upcoming 12-month period. The Committee will welcome four new members.

The Subcommittee on Standards will provide an update on follow up work from its hearing held in August 2020 to solicit information about the costs and benefits of a new operating rule for connectivity and two operating rules for the prior authorization transaction proposed by the Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE). The Committee will also consider recommendations anticipated from the Office of the National Coordinator for Health Information Technology's (ONC) Health Information Technology Advisory Committee (HITAC), Task Force on Intersection of Clinical and Administrative Data (ICAD), on which four NCVHS members have participated. The Committee will consider next steps for a project to identify and recommend a path toward convergence of administrative and