DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 112, 117, and 507

[Docket No. FDA–2017–D–0397]

Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR Part 112 or the Preventive Controls Requirements in Part 117 or 507; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry entitled ''Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR 112 or the Preventive Controls Requirements in Part 117 or 507.'' The draft guidance describes FDA's current thinking on the concept of ''same level of public health protection'' (SLPHP), and FDA's expectations for how an SLPHP evaluation should be conducted and an SLPHP determination should be reached. The draft guidance identifies certain points to consider that a competent authority, a farm, a facility, an importer, or other relevant entity should take into consideration when evaluating whether a measure that is different from that required under (part 112) 21 CFR part 112 or the preventive controls requirements in (part 117 or part 507) 21 CFR part 117 or 507 meets the SLPHP threshold under the foreign supplier verification program (FSVP) regulation (21 CFR part 1, subpart L) or under part 112.

DATES: Submit either electronic or written comments on the draft guidance by May 25, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0397 for ''Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR 112 or the Preventive Controls Requirements in Part 117 or 507.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3252.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR 112 or the Preventive Controls Requirements in Part 117 or 507.'' We are issuing the draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for

any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

The draft guidance relates to four of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). Table 1 lists these four rules.

TABLE 1—THE FOUR FOUNDATIONAL FSMA RULES RELEVANT TO THE DRAFT GUIDANCE

Title and abbreviations for the purpose of this document	Regulatory codification	Publication
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PC for Human Food regulation).	21 CFR part 117	80 FR 55908, September 17, 2015.
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (PC for Animal Food regulation).	21 CFR part 507	80 FR 56170, September 17, 2015.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety regulation).	21 CFR part 112	80 FR 74354, November 27, 2015.
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP regulation).	21 CFR part 1, subpart L	80 FR 74226, November 27, 2015.

The FSVP regulation requires, in relevant part, that importers develop, maintain, and follow an FSVP that provides adequate assurances that the foreign supplier of a food is using processes and procedures that provide the SLPHP as those required under part 112 or the preventive controls requirements in part 117 or part 507, respectively, if any is applicable. As incorporated in 21 CFR 1.502(a), this means that importers may import food consistent with the FSVP regulation even if their foreign supplier uses a process or procedure that varies in some way from the processes and procedures required under the applicable requirements in these regulations, provided that the importer follows an FSVP that provides adequate assurance that the processes or procedures that the supplier uses provide the SLPHP as those required under the relevant FDA requirement. Similarly, a provision in the FSVP requirements for dietary supplements, in 21 CFR 1.511(c), also requires that foreign supplier verification activities performed under that section must provide adequate assurances that a supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under 21 CFR part 111 (the dietary supplement current good manufacturing practice regulations). In addition, the Produce Safety regulation includes certain provisions whereby farms may use measures different from those required under part 112, provided all relevant requirements are met, including that those measures must provide the SLPHP as the corresponding FDA-established requirement (§§ 112.12, 112.49, and 112.171–182 (Subpart P—Variances)).

The draft guidance describes FDA's current thinking on considerations relevant to SLPHP determinations, specifically in relation to the FSVP, PC for Human Food, PC for Animal Food, and Produce Safety regulations. The draft guidance identifies certain points to consider that a competent authority, a farm, a facility, an importer, or other relevant entity should take into consideration when evaluating whether a measure that is different from that required under part 112 or the preventive controls requirements in part 117 or 507 meets the SLPHP threshold under the FSVP or Produce Safety regulations. In addition, FDA expects to apply these same points in our own evaluations of whether a measure that is different from that required under the applicable provisions of these regulations provides the same level of public health protection as the corresponding requirement.

These points are intended to provide a general framework for evaluating the adequacy of a measure to provide the necessary level of public health protection that FDA determined is appropriate by establishing the corresponding requirement. We rely on an overarching principle that an SLPHP determination should be supported by sound scientific evidence that is analyzed by competent individuals, taking into account any unique measure-specific considerations. There are different scenarios under which an SLPHP evaluation may be conducted, and we recognize that an evaluation of a measure's level of public health protection compared to the corresponding FDA requirement can vary widely, including with respect to the scope of evaluation and the entity that conducts the evaluation. Although the points to consider can be flexibly used, as appropriate and applicable, considering the specific circumstances applicable to the measure and the context for its evaluation, we expect using these points will help achieve consistency in the application of the concept of SLPHP across different circumstances and by different entities. As we implement the FSMA rules, FDA will also consider what, if any, training may be necessary for our personnel to better understand and apply these points, and help ensure consistency in our evaluations for SLPHP determinations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 117 have been approved under OMB control number 0910–0751. The collections of information in part 507 have been approved under OMB control number 0910–0789. The collections of information in part 112 have been approved under OMB control number 0910–0816. The collections of information in part 1, subpart L, have been approved under OMB control number 0910–0752.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: January 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01296 Filed 1–24–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2016–D–2343]

Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of another draft chapter of a multichapter guidance for industry entitled ''Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry.'' This multichapter draft guidance is intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under our rule entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.'' The newly available draft chapter is entitled ''Chapter 15—Supply-Chain Program for Human Food Products.''

DATES: Submit either electronic or written comments by May 25, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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Instructions: All submissions received must include the Docket No. FDA–2016–D–2343 for ''Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

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You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–300), 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2166.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production.

Section 103 of FSMA amended section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g) by adding requirements for hazard analysis and risk-based preventive controls for establishments that are required to register as food facilities under our regulations, in 21 CFR part 1, subpart H, in accordance with section 415 of the FD&C Act (21 U.S.C. 350d). We have established regulations to implement these requirements within part 117 (21 CFR part 117).