

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: Guidance for Industry

Draft Guidance

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**U.S. Department of Health and Human Services
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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance describes FDA's current thinking on considerations for determining whether a measure or procedure used in lieu of an FDA requirement in 21 CFR part 112, 117, or 507 provides the same level of public health protection (SLPHP) as the corresponding FDA requirement. FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

FDA established several key regulations, as required under the FDA Food Safety Modernization Act (FSMA), including those related to: (1) foreign supplier verification programs (FSVP; 21 CFR part 1, subpart L); (2) produce safety standards (Produce Safety; 21 CFR part 112); (3) preventive controls for human food (PC Human Food; 21 CFR part 117); and (4) preventive controls for animal food (PC Animal Food; 21 CFR part 507).

The FSVP regulation requires importers to develop, maintain, and follow an FSVP that provides adequate assurances that their foreign suppliers are using processes and procedures that provide

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the *same level of public health protection* as those required under part 112 or the preventive controls requirements in part 117¹ or part 507², 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 nevertheless provide the *same level of public health protection* as those required under the specified 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 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 *same level of public health protection* as the corresponding FDA-established requirement (§§ 112.12, 112.49, and 112.171-182 (Subpart P – Variances)).

In the FSVP and Produce Safety final rules, FDA responded to public comments regarding whether and how SLPHP fits into the various provisions of the FSVP and Produce Safety regulations (80 FR 74226 at 74259 and 80 FR 74354 at 74416; November 27, 2015). This draft guidance contains further information about this concept and FDA’s expectations for how an SLPHP evaluation should be conducted and an SLPHP determination should be reached.

The SLPHP and similar concepts appear in national and international texts related to public health and safety. For example, the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) uses the same phrase, “same level of public health protection,” in relation to its equivalence determination of a foreign country’s regulatory system for meat, poultry, and egg products.³ In addition, the U.S. Safe Drinking Water Act refers to “alternative water” supplied for residential or similar uses for drinking or cooking, to achieve the “equivalent level of public health protection” provided by the applicable national primary drinking water regulation (42 U.S.C. § 300f).

In the international context, under Article 4 of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) (the SPS Agreement), each

¹ The preventive controls requirements, which implement section 418 of the FD&C Act, are primarily located in subparts C and G. Part 117 includes additional requirements that do not implement section 418 of the FD&C Act (i.e., requirements related to current good manufacturing practices (CGMPs)). The SLPHP requirement in the FSVP rule applies only to the requirements in part 117 that implement section 418 of the FD&C Act; it does not apply to the CGMP requirements in part 117.

² The preventive controls requirements, which implement section 418 of the FD&C Act, are primarily located in subparts C and E. Part 507 includes additional requirements that do not implement section 418 of the FD&C Act (i.e., requirements related to current good manufacturing practices (CGMPs)). The SLPHP requirement in the FSVP rule applies only to the requirements in part 507 that implement section 418 of the FD&C Act; it does not apply to the CGMP requirements in part 507.

³ USDA FSIS. “Process for evaluating the equivalence of foreign meat, poultry, and egg products food regulatory systems,” July 2011 (hereafter referred to as “FSIS’ equivalence evaluation process”).

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member nation of the WTO, including the United States, is obligated to accept as equivalent a food regulatory system of another country if it provides the same level of health protection as is provided to consumers by its own system. The SPS Agreement uses the phrase “appropriate level of sanitary or phytosanitary protection” and defines it as follows:

Appropriate level of sanitary or phytosanitary protection – The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the “acceptable level of risk” (Annex A of the SPS Agreement⁴).

This phrase is also used in Codex guidelines related to equivalence and to food import and export inspection and certification systems (CAC/GL 53-2003⁵, CAC/GL 34-1999⁶, and CAC/GL 26-1997⁷).

II. Scope and Purpose⁸

This draft guidance describes FDA’s current thinking on considerations relevant to SLPHP determinations, specifically in relation to the FSVP, PC Human Food, PC Animal Food, and Produce Safety regulations. Below we identify 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 measure⁹ that is different from that required under applicable provisions in part 112, 117, or 507 meets the SLPHP threshold under the FSVP or Produce Safety regulations. In addition, FDA expects to apply these same points in its own evaluations of whether a measure that is different from that required under applicable provisions of part 112, 117, or 507 provides the same level of public health protection as the corresponding requirement.

These *Points to Consider* 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.¹⁰ 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.

⁴ The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Accessible online at: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

⁵ Codex Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems, CAC/GL 53-2003. Accessible at <http://www.fao.org/docrep/009/y6396e/Y6396E05.htm>.

⁶ Codex Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems, CAC/GL 34-1999. Accessible at <http://www.fao.org/docrep/005/X4489E/x4489e04.htm>.

⁷ Codex Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems, CAC/GL 26-1997. Accessible at <http://www.fao.org/docrep/009/y6396e/Y6396E03.htm>.

⁸ The effectiveness of an FDA requirement (or a different measure used in lieu of an FDA requirement) in controlling a food safety hazard can be affected by proper implementation of that requirement (or measure); however, such issues are outside the scope of this guidance.

⁹ For purposes of this guidance, the term “measure” refers to a process, procedure, or practice employed by a responsible entity (e.g., farm, facility, importer, or foreign supplier) during the growing, harvesting, packing or holding of produce, or during the manufacturing, processing, packing, or holding of food.

¹⁰ As appropriate, we may provide additional information on SLPHP issues specific to the FSVP, PC Human Food, PC Animal Food, or Produce Safety requirements in guidance documents specific to that regulation.

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In developing the *Points to Consider*, we referred to existing relevant national and international texts to understand the application of SLPHP and similar concepts in other food safety contexts. In particular, we reviewed FSIS’s equivalence evaluation process; WTO SPS Committee’s “Guidelines to further the practical implementation of Article 5.5”¹¹; Codex “Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems (CAC/GL 53-2003); Codex “Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems” (CAC/GL 34-1999); and Codex “Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems” (CAC/GL 26-1997).

We also considered our experience with equivalence determinations.¹² For example, when a foreign government applies a significantly different measure than FDA to address a specific food safety hazard, FDA reviews that measure to ensure that the public health outcomes are similar, that is, that the measure meets the same level of public health protection that is delivered through our domestic system. In addition, we considered our experience with systems recognition of foreign food safety programs, which has entailed an assessment of comparability of an overall system to ours to determine whether the overall system of controls provides a comparable level of public health protection.

The *Points to Consider* are intended to be broadly applied to evaluations of measures used in lieu of applicable requirements in part 112 or the preventive controls requirements in parts 117 or 507. These points do not necessarily represent the comprehensive set of considerations relevant to any specific SLPHP evaluation, however. There may be other factors not identified in the points below but relevant to an SLPHP evaluation that should also be considered, including as may be discussed in other Agency guidance concerning SLPHP requirements in FSMA regulations.

III. Contexts for SLPHP Evaluations

There are different scenarios under which an SLPHP evaluation may be conducted in relation to the FSVP or Produce Safety regulations, or the preventive controls requirements in the PC Human Food or PC Animal Food regulations. 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. 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.

The scope of an SLPHP evaluation may be limited to the use of an individual measure that is different from a specific requirement in the regulation. For example, an alternative microbial quality criterion (or criteria) for agricultural water may be used in growing produce, in lieu of the

¹¹ World Trade Organization Committee on Sanitary and Phytosanitary Measures. Guidelines to further the practical implementation of Article 5.5, July 18, 2000.

¹² FDA has undertaken equivalence determinations for two commodities, Grade A dairy and dairy products and bivalve mollusks.

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specific criteria established in § 112.44(b) (see §§ 112.12 and 112.49(a)). On the other hand, the scope of an SLPHP evaluation can be broad, such as for a variance involving a set of measures different from a set of requirements in the regulation. For example, a variance for a different approach and/or frequency for testing agricultural water may be used in growing produce, in lieu of the set of requirements established in § 112.46(b) (see §§ 112.182(c)). The scope could also be even broader, potentially involving an entire regulation. Similarly, the nature of an SLPHP evaluation can vary, depending on the corresponding FDA requirement. For example, requirements may be quantitative or qualitative in nature, and may address various aspects of food production, such as the design of equipment or infrastructure, manufacturing processes, monitoring and verification procedures, laboratory tests and sampling methods, personnel training, and documentation.

Evaluations of SLPHP may be conducted by various entities and may occur either prior to use of the measure or, where appropriate, after its use. Evaluating entities can include FDA; a competent authority of a state, tribe, or foreign country; industry (such as an individual farm or facility, an importer, a trade or other industry association); or other stakeholders (such as a private food safety scheme). Examples of these different circumstances include:

- FDA evaluation of a request for a variance from a requirement of the Produce Safety regulation submitted by a state, tribe, or a foreign country, in accordance with subpart P of part 112;
- FDA evaluation of “alternatives” to certain provisions of the Produce Safety regulation under §§ 112.12 and 112.49, in the event that a farm voluntarily consults with FDA before choosing to use the alternative measure;
- A farm, farm coalition, trade association, or other industry stakeholder evaluation of “alternatives” to certain provisions of the Produce Safety regulation under §§ 112.12 and 112.49;
- An importer’s evaluation of a foreign supplier’s use of measures during the importer’s process for verifying foreign suppliers;
- FDA review of an importer’s documentation of its foreign supplier verification activities; and
- FDA review of a farm’s records supporting use of an “alternative” to certain provisions of the Produce Safety regulation under §§ 112.12 and 112.49 during a farm inspection.

We expect these points to be used by FDA, competent authorities, industry, and other stakeholders alike in circumstances where the opportunity to assess the appropriateness of a measure may occur. The type and extent of information available for review is likely to vary depending on the context in which the evaluation is conducted and the nature of the measure involved. Therefore, these points should be applied as appropriate to the specific circumstance while ensuring consistency and integrity of process and validity of conclusions of the evaluation.

IV. Points to Consider

When evaluating whether an individual measure or a set of measures different from those established in part 112 (produce safety) or the preventive controls requirements in part 117 or 507 provide the same level of public health protection as the corresponding requirement in the regulation, the evaluator (FDA, competent authority, industry, or other stakeholder) should ask:

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A. Are the relevant data and information in support of the use of a measure sufficient to make a determination that the measure provides the “same level of public health protection” as the corresponding requirement?

A.1. The use of a measure to address a specific hazard should be sufficiently supported by credible scientific and technical evidence. A review and analysis of scientific and technical evidence should take into account, as appropriate:

- The rigor and robustness of data and factual information, including the methodology used to obtain the data, such as the number of studies, study design, sample sizes, statistical significance, and range of variables, if applicable. For example, with respect to the Produce Safety regulation¹³, an *alternative* microbial die-off rate and accompanying maximum time interval, as permitted under § 112.49(b), should consider a broad range of variables, such as microbial characteristics, environmental factors (e.g., sunlight intensity, moisture level, temperature, pH, presence of competitive microbes, precipitation, crop type, timing of water application, and frequency of water use);
- Any accompanying risk assessment that may be conducted in support of the use of a measure, depending on the nature of the measure and availability of data. A risk assessment may also be used to support that a preventive measure is not needed with respect to the preventive controls rules, e.g., that a hazard presents such a low risk that a preventive control is not needed. Although an assessment of risks is not always necessary to support an SLPHP evaluation, when a risk assessment is conducted, it is preferred that such assessment is based on appropriate methodology and as robust as FDA’s risk assessment¹⁴ underlying the corresponding requirement; and
- The completeness of data and information, as well as the variability and sources of uncertainty in data.

A.2. The use of a measure should achieve any specified numerical criteria associated with public health protection underlying the corresponding requirement. This consideration applies to *quantitative requirements* for which FDA: (1) determined that certain quantitative and prescriptive measures are necessary to help ensure safety of the food, and (2) specified relevant numerical criteria, including the following:

- Rates of illness. For example, in developing the Produce Safety regulation, FDA considered EPA’s analysis of data describing specific illness rates generalized across different bodies of recreational water, as well as WHO’s recommendations for protective and preventive measures to reach the necessary total log reduction of pathogens to achieve a specified target health outcome. FDA considered these data to establish the microbial quality criteria for a certain use of agricultural water (see § 112.44(b) and accompanying discussion in the Produce Safety final rule at 80 FR 74354 at 74416). Any

¹³ This and other examples related to agricultural water used throughout this document reflect the requirements established by the produce safety rule. As noted on March 20, 2017, FDA is exploring ways to simplify the microbial quality and testing requirements for agricultural water established by the [produce safety rule](https://www.fda.gov/food/guidance-regulation/fsma/ucm546089.htm) while still protecting public health (<https://www.fda.gov/food/guidance-regulation/fsma/ucm546089.htm>). In addition, FDA plans to conduct stakeholder engagement on agricultural water standards (<https://www.fda.gov/food/news-events/constituent-updates/ucm575532.htm>).”

¹⁴ Information about FDA’s risk assessments is available online at: <http://www.fda.gov/food/food-science-research/risk-safety-assessment/default.htm>

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microbial quality standard used in lieu of the microbial quality criteria in § 112.44(b) should be supported by an equally robust and rigorous scientific analysis and be quantitatively demonstrated to be equivalent to the FDA-established criteria.

- Level(s) of risk reduction or established log reduction of pathogen levels. For example, if a requirement specifies a process such as a heat treatment to control a particular pathogen of public health significance, an alternative pathogen control process such as high pressure processing might be appropriate if it results in an equivalent log reduction of pathogen levels.

A.3. The use of any indicator for a hazard should be evaluated for its appropriateness as an indicator for the same hazard or adverse health effect related to the indicator or indicator organism in the corresponding requirement. For example, the Produce Safety regulation allows for the use of an alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination in lieu of the FDA-established microbial quality criteria (see § 112.49(a)), which rely on generic *E. coli* as an indicator of fecal contamination. Any alternative indicator to generic *E. coli* that is used in accordance with § 112.49(a) should be as sensitive to the presence and level of fecal pollution as is generic *E. coli* (see discussion in the Produce Safety final rule at 80 FR 74354 at 74416).

A.4. For *performance-based requirements*, an SLPHP evaluation may not be necessary or, where needed, application of that concept may be less important because of the inherent flexibility of performance-based measures. An example of a performance-based requirement is that, under § 112.54, any scientifically valid controlled physical, chemical, or biological process, or a combination of such processes can be used to treat a biological soil amendment of animal origin that is applied in the growing of covered produce, provided the treatment process has been validated to satisfy the relevant microbial standards in § 112.55. Such processes do not need to be evaluated to determine whether they provide the SLPHP as the regulation because their use satisfies the regulation’s inherently flexible performance-based requirement.

A.5. *Qualitative requirements* are inherently flexible and, therefore, allow the use of different measures within the bounds of the requirement. An example of a qualitative requirement in the Produce Safety regulation is a requirement that equipment and tools used must be of “adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained” (§ 112.123(a)). Similarly, substantial flexibility is provided in PC Human Food and PC Animal Food regulations such that a supplier (including a foreign supplier) is able to use a variety of processes and procedures, such as with respect to process controls, to ensure food safety and still comply with the regulation. An SLPHP evaluation is not likely to be necessary regarding such qualitative requirements because a farm or facility should be able to use practices, procedures, or processes well-suited for its own operations and commodities that comply with such inherently flexible qualitative requirements.

A.6. Scientific and technical conclusions should be based on consideration of all reasonably available and relevant data rather than on a limited dataset selected to favor a desired outcome or on data that are not directly relevant.

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A.7. Scientific data and analysis can be developed by, for example, farms, facilities, or importers; state, tribal or foreign governments; or third parties, such as trade associations and commodity boards; or available in scientific literature.

A.8. Scientific data and other information do not need to be limited to that published in peer-reviewed journals, although we encourage use of peer-reviewed data and information, to the extent available.

B. Are there any unique considerations relevant to the level of public health protection provided by that measure?

B.1. Consideration should be given to whether the hazard or adverse health effect that is intended to be addressed by the corresponding requirement is being adequately controlled through other measures during production of the food or at another point in the supply chain. For example:

- A facility may lack a written hazard analysis that describes how the facility determined which hazards require controls, and instead have in place a HACCP plan that identifies appropriate hazards along with the controls and management components, and also maintain records documenting its implementation of appropriate hazard controls.
- If an importer's FSVP for verifying their foreign supplier's compliance with the PC rule relies on obtaining the food safety records for the imported food but the exporter conducts statistically based end product testing for a specific hazard, the end product testing could be determined to provide the same level of public health protection with respect to the requirement for supply-chain controls (see § 117.410) for that particular hazard.

B.2. Consideration should be given to circumstances where it may be demonstrated that a required process, procedure, or practice is not necessary because of local growing or production environments. For example:

- A state, tribe, or foreign country may conclude that meeting certain requirements of part 112 would be problematic in light of local growing conditions and that a variance from some or all provisions of part 112 is necessary. To support such conclusion, the state, tribe or foreign country might consider the historical performance of industry within their jurisdiction (e.g., as indicated by the epidemiological record) along with the combination of measures taken by that industry.
- The pathogen prevalence and levels in a food in a foreign country may be such that a different log pathogen reduction (compared to that associated with the corresponding requirement) could be deemed adequate to control the risk presented to human health from exposure to that specific hazard.

B.3. Consideration may also be given to relevance of prior SLPHP determinations. An example of such circumstance may be where scientific data and information supporting the use of a measure specific to a commodity, condition, or practice can be appropriately applied to other commodities, conditions, or practices, thereby allowing those data to support use of the same measure across multiple commodities, conditions, or practices. Note also § 112.177, which specifies conditions under which an approved variance may apply to persons other than those identified in the petition requesting that variance.

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B.4. The threshold for SLPHP is likely to be met where the measure reflects a more stringent or restrictive requirement (e.g., a foreign country’s requirement) than the corresponding FDA requirement that addresses the same hazard.

C. Was the evaluation of scientific and technical evidence conducted by competent individuals using an appropriate process?

An SLPHP evaluation may be conducted by various entities, including FDA¹⁵; a competent authority of a state, tribe, or foreign country; an individual farm or facility; an importer; a trade or other industry association; a private food safety scheme; or other stakeholder. Regardless of what kind of entity conducts the evaluation, the process should ensure sufficient knowledge and technical expertise of individuals conducting the evaluation so that the output of that process is adequate, accurate, current, and reliable. Some points to consider in this regard include:

C.1. An SLPHP evaluation should be conducted in an objective manner by experts who are qualified to conduct these evaluations, based on their education, experience, or training (or a combination of these). It is also important that these experts understand the scope and purpose of the evaluation.

C.2. An SLPHP determination should be revisited, as necessary. For example, a reanalysis of an existing SLPHP determination is likely necessary if there is relevant and significant new scientific or technical evidence indicating that the measure (that is the subject of the SLPHP determination) is not as effective as previously demonstrated or that additional controls are necessary for that measure to be effective. As FDA becomes aware of such new information, we will make efforts to share this information with relevant stakeholders and, as warranted, conduct a reanalysis of affected prior SLPHP determinations made by the agency. As another example, significant changes in a farm or facility’s infrastructure or production practices that affect the nature of associated hazards or level of risk may also influence the original SLPHP determination.

C.3. Process-related considerations may be less important for *quantitative requirements* where an SLPHP determination is driven by specified objective outcomes and, therefore, likely less dependent on the judgment of individuals conducting the evaluation. However, an evaluation of whether a measure met the relevant quantitative standard would still need to be conducted by competent individuals.

D. Is the determination of “same level of public health protection” properly documented?

D.1. Documentation of all relevant information pertaining to the SLPHP evaluation is important to provide valid support for the conclusion (and, if applicable, the accompanying process) that a measure provides the same level of public health protection as the corresponding requirement. The regulations include requirements for preparing and keeping appropriate records. For example:

¹⁵ For SLPHP evaluations that FDA conducts in relation to a variance request, under the Produce Safety regulation, the procedures we will follow to approve or deny the petition are described in subpart P of part 112.

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- For SLPHP evaluations in relation to “alternatives” permitted under §§ 112.12 and 112.49, the farm using the alternative measure must establish and maintain documentation of the scientific data and information on which the farm relied to use the alternative measure (see § 112.12);
- For SLPHP evaluations in relation to variance requests submitted to FDA in accordance with subpart P of part 112, the petition must include a “Statement of Grounds” that includes information supporting the variance request (see § 112.173); and
- Under the PC Human Food and PC Animal Food regulations, records documenting the supply-chain program include documentation of the appropriate supplier verification activities (see §§ 117.475(c) and 507.175(c)).

D.2. FDA intends to disseminate useful information, when available, to help industry apply new scientific or other information to their operations, as appropriate. Specifically with respect to variance requests regarding the Produce Safety regulation, we will make petitions submitted to FDA, public comments received on those petitions, and the conclusions of our evaluations publicly available. FDA will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied) (see § 112.176(d)).