May 25, 2018

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: **"**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**" [Docket No. FDA–2017-D-0397]**

CC: Samir Assar, Center for Food Safety and Applied Nutrition
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Stephen Ostroff, M.D., Deputy Commissioner for Foods and Veterinary Medicine
Scott Gottlieb, M.D., Commissioner of Food and Drugs

Dockets Management Staff (HFA-305):

On behalf of our members, the California Leafy Greens Marketing Agreement, Canada Produce Marketing Association, Florida Fruit & Vegetable Association, Georgia Fruit and Vegetable Growers Association, Northwest Horticultural Council, Produce Marketing Association, Texas International Produce Association, United Fresh Produce Association and Western Growers, respectfully submit the following comments on the draft FDA guidance entitled: "Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection (SLPHP) as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507."

We appreciate the opportunity to provide comments on FDA's Guidance to Industry regarding the agency's expectation for an SLPHP evaluation and determination as well as how SLPHP fits into provisions of the Foreign Supplier Verification Program (FSVP) part 1, Subpart L; the Produce Safety Rule (PS rule), part 112; the Preventive Controls Rule for Human Food (PC Human Food), part 117; and the Preventive Controls Rule for Animal Food (PC Animal Food), part 507.

We recognize the intent of the agency is to add flexibility to these Rules by allowing the use of alternative methods and variances that provide, at least, the same level of public health protection; however, as written, this guidance does not facilitate this purpose. A main barrier to effectively using this guidance is that FDA has not answered the basic question, "the same level of health protection as what?". "Same level of public health protection" suggests a quantitative, not qualitative standard. Without quantitative targets (e.g., a log reduction, a Food Safety Objective or Appropriate Level of Health Protection) in each case where a SLPHP alternative is offered, it is

impossible to gather information and conduct an evaluation to determine if each quantitative standard is met.

In addition, we seek clarification of ambiguous language and a clearer process or path to guide industry in the conduct of SLPHP evaluations. We are concerned that many industry members will not have the resources or expertise to be able to conduct SLPHP evaluations as they are currently laid out in this guidance document. This potential inaccessibility may limit the use of practical and protective food safety practices employed by many small- to medium-sized companies.

Below, we have highlighted specific issues (by section) and provide suggestions for consideration.

Introduction

In the introduction, the FDA highlights where the SLPHP term is used in the relevant rules as highlighted here:

> FSVP: *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.*
>
> Produce Safety Rule: *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.*
>
> Subpart E
>
> - *An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination*
> - *An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval*
> - *An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required*
> - *An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required*
>
> Subpart P
>
> - *A State, Federally-recognized tribe (or "tribe"), or a foreign country from which food is imported into the United States may request a variance from one or more*

requirements of this part, where the State, tribe, or foreign country determines that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

Preventive Controls for Human Food Rule

- Although the Guidance to Industry mentions the Preventive Controls for Human Food Rule, the term - SLPHP does not appear in that Rule. The FDA mentions subparts (C, E, and G) that address or involve the SLPHP concept, but it is not clear exactly for which provisions the SLPHP can be evaluated.

Scope and Purpose

"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."

- This lead sentence indicates that this draft guidance describes FDA's thinking on considerations relevant to SLPHP in the FSVP although only the PC Human and Animal Foods and Produce Safety regulations are mentioned in the title. Based on the document title, it is not clear that this document also pertains to the FSVP (Part 1, subpart L).

"…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 measure that is different from that required under applicable provisions…meets the SLPHP threshold under the FSVP or Produce Safety regulations*. *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. 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*."

- What is the SLPHP threshold? Is this the "acceptable level"?
- What constitutes a "competent authority" or a "competent individual"? Is a "competent individual" the same as an expert? What criteria is used to determine if someone is competent or not, and who makes that judgment?
- How does the adjective "competent" relate to individual farmers evaluating scientific evidence?

"The Points to Consider *are intended to be broadly applied to evaluations of measures used in lieu of applicable requirements…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."

- These sentences are confusing. It is not clear if the intent of this statement is to alert the reader that the FDA may have missed a relevant factor when they developed their *Points to Consider* or that the FDA may consider other factors they think are relevant to a particular situation if they were to assess the SLPHP of a grower's alternative method i.e., a microbial quality criterion? Either way it appears to be a disclaimer or "catch-all" statement of sorts indicating to the reader that they may need to consider information beyond this Guidance to Industry. These types of statements undermine growers' confidence in knowing what they need to do to successfully establish alternative methods that will be acceptable to the FDA. If FDA intends that these details will be elaborated upon in forthcoming guidance (e.g., guidance pertaining to the Produce Safety Rule) then this should be stated as specifically and clearly as possible. If FDA intends that this guidance will be the only guidance that addresses the SLPHP topic, we recommend that the FDA clarify their intent and ensure that this Guidance is comprehensive by, at the least, providing a list of other resources or factors that may need to be considered.

Context for SLPHP Evaluations

- Agricultural water: Similar to the FDA's commentary in the PS Rule's preamble, the Guidance document references the U.S. Environmental Protection Agency's data analysis describing illness rates, but does not provide a numeric value for what it considers an acceptable level of PHP adding ambiguity to the assessment of the SLPHP. During the Produce Safety Alliance's Ag Water Summit, FDA officials present at the meeting indicated that the USEPA's public health risk for recreational water quality (32 or 36 gastrointestinal illnesses per 1,000 recreation events) is what the FDA considers acceptable. If that is indeed the agency's stance, then we recommend the agency clearly states in this Guidance for Industry that 32 or 36 gastrointestinal illnesses per 1,000 recreation events is the acceptable level for assessing alternative ag water microbial quality criterion. And if indeed this is the criteria against which to measure the SLPHP, then growers would also need guidance on how they should translate a standard based on "recreational events' to the practice of irrigation. We also seek to understand if a grower using an alternative test method approved by EPA would, therefore, automatically meet the SLPH criteria.

Who determines if an alternative method provides the SLPHP?

"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)…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."

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."*

- It is unrealistic to expect individual farmers and even some industry associations or groups to have the ability and resources to evaluate an alternative method in the same manner as the FDA or another government authority. Most individual farmers are not trained scientists and do not have the scientific knowledge to evaluate, as outlined in point A, whether scientific evidence is "sufficient" or completely entails all relevant data. As currently written, the *Points to Consider* describes a process for a trained professional equipped with the knowledge to assess scientific and technical studies – not a process that can be used by a majority of individual farmers without hiring / enlisting expert assistance, and certainly not by most small farmers with no means to hire professionals to do the assessment.

Points to Consider

- What did FDA consider when developing this guidance?

"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."*

  - *USDA FSIS's equivalence evaluation process*
  - *WTO SPS Committee's "Guidelines to further the practical implementation of Article 5.5"*
  - *Codex "Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems*
  - *Codex "Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems"*
  - *Codex "Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems"*
  - *Our* [the FDA's] *experience with equivalence determinations i.e., with foreign governments*
  - *Our* [the FDA's] *experience with systems recognition of foreign food safety programs, i.e., an assessment of comparability of an overall system to the FDA's system*

- What should the FDA consider?
  - The produce industry's / farmers' experience with conducting an evaluation of SLPHP including their familiarity with and ability to evaluate scientific literature and technical studies. Although this is to be a "Guidance to Industry" it reads more like a "Guidance to Scientists or Academia".

- The produce industry's / farmers' knowledge of / familiarity with the documents they used to write this Guidance to Industry

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."*

- The process created by the FDA as outlined in this Guidance to Industry appears to be designed to be conducted by an expert. However, this appears to contradict the following assertion noted earlier in the Guidance document, *"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)."* We believe the latter statement is misleading in that most individual farms and facilities do not have the expertise to be "evaluating entities" equipped to conduct a SLPHP evaluation as currently written in this Guidance document.

- Currently FDA has a very limited number of experts in the Produce Safety Network (PSN) who may be able to help the industry determine the "same level of public health protection". Per testimony by cooperative extension specialists at the Ag Water Summit, those without FDA authority are hesitant to provide assistance to growers without knowing the levels of public health protection that the FDA considers acceptable. Due to the lack of clarity on some key issues, many extension agents reported they felt their ability to provide advice to growers was compromised. We are concerned that this particular Guidance document will not help to clarify how alternative methods can be used.

<u>Ambiguous, equivocal language</u>

Use of ambiguous language undermines the confidence of an individual farmer or facility in their ability to successfully implement an alternative method.

A.2. "*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 <u>might</u> be appropriate if it results in an equivalent log reduction of pathogen levels."*

- Use of "might", in this instance, is confusing: "…*if it results in an equivalent log reduction of pathogen levels,"* then should it not be considered an appropriate alternative pathogen control process? Would an equivalent log reduction of pathogen levels not be considered the SLPHP in this example?

A.5. "*An SLPHP evaluation is <u>not likely to be necessary</u> 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."*

- Again, we recommend that the FDA avoid the use of vague language (see underlined phrase above) and be more definitive in its statements by either removing equivocal words or making the examples or contextual language more definitive.

Clarification requested

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.

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.6. states that science and technical conclusion should be based on "*all* reasonably available and relevant data rather than a limited dataset…", but A.7. states that farms and facilities can develop their own data *or* use data available in the scientific literature. These two points, as currently worded, need clarification. Is it the FDA's intent that *all reasonably available and relevant data* be considered in an evaluation even when a farm or facility develops their own data?

B.1. *"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."*

- This sentence is problematic in a couple of ways. First, the FSVP applies to importers, and importers have flexibility in determining appropriate verification strategies as part of the rule. If the importer determines that records review is a necessary verification activity, it seems that, if the importer did not review records, they would be violating the rule by not following their established, written program. If the importer felt that product testing was appropriate verification, the importer, not the exporter, should have made that decision.
- Also, product testing may be a useful tool to verify the effectiveness of some food safety systems; however, in the produce industry there are several limitations and challenges to consider. First, even though this example states "*statistically* based end product testing for a specific hazard", it is very difficult and expensive to have statistically based product testing programs in the produce industry. Most food safety experts working in the fresh produce industry agree that product testing is not a good substitute for verifying that process controls are being appropriately used. Furthermore, the FDA also discussed the limited value of product testing in the preamble to the PCHF Rule (in response to comment 525),

> *We do not expect either product testing or environmental monitoring to be common in facilities that process, pack, or hold produce RACs… We also expect that many facilities*

that process, pack, or hold produce RACs that are RTE foods will conclude that the limitations of product testing when applied to produce reduce the value of product testing for their products and would direct their resources to food safety practices and verification measures other than product testing.

This example implies that the FDA views product testing as equal to verification that process controls are being appropriately established and implemented. We recommend that this example be deleted, or otherwise reworded / redesigned to clarify that product testing is not equivalent to verifying a supplier is using appropriate food safety practices and preventive controls in their operations, and to explain that the FSVP importer must follow the plan they themselves established for a supplier/product combination.

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."*

- The two examples provided for this *Point to Consider* is for state, tribe, or foreign country. Could you please provide an example of a situation where an individual farm or facility may establish and implement an alternative method because of local growing or production environments or Is this not an option for an individual farm or facility?

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."*

- We request that the FDA provide examples of this particular point to further clarify why the SLPHP evaluation of alternatives to quantitative requirements may not require an expert's involvement. An example of a quantitative standard would be a log reduction of a pathogen, and in A.2, FDA's use of the word "might" suggests that meeting the same quantitative requirement may not always yield the SLPHP.

Conclusion

The SLPHP evaluation process as currently laid out in this guidance document is not practical and not widely accessible. The limited resources of many small- to medium-sized companies coupled with the limited number of personnel with science degrees and expertise to conduct a SLPHP evaluation will make it nearly impossible for individual farmers to conduct this process. This means they will either need to hire someone or enlist the help of an academic / cooperative extension agent, the FDA's PSN person for their region, a trade association or other industry group to conduct the evaluation for them. Most growers subject to the Produce Safety Rule, registered facilities subject to the Preventive Controls Rule for Human and Animal food and importers may not have the connections or even the awareness of where to turn for help. In addition, the evaluations as outlined require a substantial time commitment and resources, and many industry associations or groups may not have the time/personnel capacity to meet their industry's needs. Regardless of who

conducts the evaluation the process itself remains unclear and the guidance contains several/many inconsistencies as noted above.

For all instances where specified numerical criteria associated with public health protection underlie a corresponding requirement, we recommend that the FDA clearly state those numeric values so there is no ambiguity as to which particular SLPHP is acceptable. “Thresholds” and “acceptable levels” should be clearly defined using numerical values where possible.

We recommend that the FDA avoid the use of vague language such as “might” and “likely” when presenting examples of how to achieve the SLPHP in this Guidance to Industry.

To make the Guidance to Industry clearer, we recommend that the “Points to Consider” specifically addressing the Produce Safety Rule be organized or overtly labeled as to whether they pertain to subpart P (variances) only and are not options available to individual companies.

To make the Guidance to Industry regarding provisions that companies can modify as long as they can demonstrate they are achieving the SLPHP under the Preventive Controls for Human Food Rule, there should be clear, concise and specific language about those provisions so companies can determine alternatives and demonstrate they are achieving the SLPHP.

In conclusion, we appreciate the opportunity to comment on this Guidance to industry and the agency’s intent to provide flexibility and disseminate new scientific or new information related to SLPHP evaluations. We encourage the agency to make adjustments to this Guidance to make it user-friendly and helpful. We offer our expertise as needed and look forward to working with the agency in this process.

Respectfully submitted,

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About the California Leafy Greens Marketing Agreement

The California Leafy Greens Marketing Agreement (LGMA) is a food safety program that verifies science-based farming practices through government on-farm audits. The program ensures that leafy greens farmers do all they can to protect public health by establishing a culture of food safety on the farm.

About the Canadian Produce Marketing Association

Based in Ottawa, Ontario, the Canadian Produce Marketing Association (CPMA) is a not-for-profit organization representing companies that are active in the marketing of fresh fruits and vegetables in Canada from the farm gate to the dinner plate. CPMA members include major grower/shippers/packers/marketer, importer/exporters, transportation, brokers, distributor/wholesalers, retailers, fresh cuts and foodservice distributors/operators, processor integrating all segments of the fresh produce industry. CPMA is proud to represent over 850 international and Canadian members who are responsible for 90% of the fresh fruit and vegetable sales in Canada. CPMA is funded by the industry through voluntary membership and various services, activities and sponsorship programs. For more information about CPMA, please visit www.cpma.ca.

About Florida Fruit and Vegetable Association

The Florida Fruit and Vegetable Association is the state's leading full-service specialty crop organization, serving Florida's grower-shipper community since 1943. FFVA represents a broad range of crops, including vegetables, citrus, tropical fruit, berries, sod, sugar cane, tree crops and more. Our mission is to enhance the business and competitive environment for producing and marketing fruits, vegetables and other crops.

About Georgia Fruit and Vegetable Growers Association

As the number two agricultural cash crop in Georgia, valued at over $1.3 billion at the farm gate, most fruits and vegetables in Georgia are grown for the fresh market, whether to be consumed in Georgia or shipped other states. The GFVGA provides programs and services to the membership designed to increase production efficiencies, provide educational opportunities, promote new markets, monitor legislation and advocate for members, offer food safety consulting services, encourage applied research and improve communications among GFVGA members and industry suppliers. Enjoy the information available and connect with GFVGA online at www.gfvga.org or Facebook at https://www.facebook.com/GFVGA/.

About Northwest Horticultural Council

The Northwest Horticultural Council handles federal and international policy and regulatory issues for the growers, packers, and shippers of apples, pears, and cherries in Washington, Oregon, and Idaho.

About Produce Marketing Association

Produce Marketing Association (PMA) is the leading trade association representing companies from every segment of the global produce and floral supply chain. PMA helps members grow by providing connections that expand business opportunities and increase sales and consumption. For more information, visit www.pma.com.

About Texas International Produce Association

The Texas International Produce Association (TIPA) was created in 1942 with the purpose of representing the business, economic, and political interests of fruits and vegetables grown, handled or shipped through the state of Texas. In 2012, TIPA's mission was further expanded to address the issues and opportunities surrounding the importation and marketing of foreign grown produce that was being shipped through Texas ports. Today, TIPA remains a nonprofit organization dedicated to the interests of the 250 member companies, and their various operations throughout the fresh produce supply chain.

About United Fresh Produce Association

Founded in 1904, the United Fresh Produce Association brings together companies across every segment of the fresh produce supply chain, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. We empower industry leaders to shape sound government policy. We deliver the resources and expertise companies need to succeed in managing complex business and technical issues. We provide the training and development individuals need to advance their careers in produce. Through these endeavors, we unite our industry with a common purpose – to build long-term value for our members and grow produce consumption.

About Western Growers

Founded in 1926, Western Growers represents local and regional family farmers growing fresh produce in Arizona, California, Colorado and New Mexico. Our members and their workers provide over half the nation's fresh fruits, vegetables and tree nuts, including nearly half of America's fresh organic produce. Some members also farm throughout the U.S. and in other countries so people have year-round access to nutritious food. For generations, we have provided variety and healthy choices to consumers. Connect with and learn more about Western Growers on our Twitter and Facebook.