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Rockville, MD 20852

“Hazard Analysis and Risk-Based Preventive Controls for Human Food: Chapter 15. Supply Chain Program for Human Food Products; Draft Guidance” [Docket No. FDA-2016—D-2343]

To Whom It May Concern:

On behalf of our members, the CA Leafy Greens Marketing Agreement (CA LGMA), Canada Produce Marketing Association (CPMA), Florida Fruit & Vegetable Association (FFVA), Georgia Fruit & Vegetable Growers Association (GFVGA), Northwest Horticultural Council (NHC), Produce Marketing Association (PMA), Texas International Produce Association (TIPA), United Fresh Produce Association (UFGA), and Western Growers (WG) respectfully submit the following comments to the draft FDA guidance entitled, Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 15: Supply-Chain Program for Human Food Products; Draft Guidance [Docket No. FDA-2016-D-2343].

Our members regard food safety as the most important component to public safety and in keeping the public’s confidence in the nation’s food supply high. For this reason, our industry is very supportive of guidance documents, such as this chapter on Supply-Chain Program in the Hazard Analysis and Risk-Based Preventive Controls Guidance, to ensure that our practices meet these high standards.

Due to the diversity of many produce operations across the United States, we are thankful for the opportunity to comment on this draft guidance. We look forward to working with the FDA in regard to the important topic of food safety and ensuring the public’s full confidence in the nation’s food supply. Below are the comments with references to the guidance sections.

15.2 Considerations to Keep in Mind if You Establish and Implement a Supply-Chain Program

If you are an importer, see section 15.6.2.1 for a discussion of how we have aligned the provisions for supplier verification in our regulation entitled “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” (21 CFR part 1, subpart L; the FSVP regulation) with the provisions for a supply-chain program in subpart G such that importers and receiving facilities do not have to duplicate verification activities. Importantly, this chapter

of this guidance does not address the responsibilities of receiving facilities that import raw materials or other ingredients to comply with applicable requirements of the FSVP regulation. If you are a receiving facility that is also a food importer, and you choose to comply with the FSVP regulation rather than conduct supplier verification activities in accordance with subpart G (see 21 CFR 117.405(a)(2)), you should refer to our guidance on the FSVP regulation.

Comments: This one-paragraph section discusses how subpart G in the PCHF Rule may overlap with the FSVP for companies that import food, and yet this is not apparent from the section title. Since the main point of the paragraph is a caution to receiving facilities that import food to avoid duplicating their efforts, we recommend the section title specifically state this. Also, this is redundant with **15.6.3 Exceptions to the Requirement to Establish and Implement a Supply-chain Program, 15.6.3.1 Exception for importers** (Please note: erroneously referenced as 15.6.2.1.) where the alignment of the FSVP with subpart G is discussed at length.

Frequently information in the Guidance document is presented in paragraph form when a bulleted list or table format would be more suitable. For example, this section refers readers, if they are importers, to other sections of the document or to separate guidance on the FSVP regulation. This information would be much easier to understand if it were presented in bullets or a table format.

It is also relevant to note that this guidance is ultimately directed to a broad group of regulated parties. The style or format in this draft guidance is often interrupted by references to other documents or sections rendering it difficult to follow. In its final draft, it might be prudent to consider the reader and consider changes that make this more user-friendly. We suggest FDA consider the Q&A format used for the FSVP guidance as a way to ultimately make this document more valuable to the target audience.

15.3 Overview of the Requirements for a Supply-Chain Program (SCP)

15.3.1 Applicable Requirements of Part 117

Subpart C requires a facility to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (21 CFR 117.130) and identifies several types of possible preventive controls, including process controls (21 CFR 117.135(c)(1)), food allergen controls (21 CFR 117.135(c)(2)), sanitation controls (21 CFR 117.135(c)(3)), and supply-chain controls (21 CFR 117.135(c)(4)). The requirements for supply-chain controls are established in subpart G (Supply-Chain Program). We list the requirements of subpart G in Table 15-1. In the remainder of this chapter, we provide recommendations for how you can comply with each of these requirements.

Table 15-1 Requirements for a Supply-Chain Program in Subpart G

Section	Description
117.405	Requirement to establish and implement a supply-chain program

117.410	<i>General requirements applicable to a supply-chain program</i>
117.415	<i>Responsibilities of the receiving facility</i>
117.420	<i>Using approved suppliers</i>
117.425	<i>Determining appropriate supplier verification activities (including determining the frequency of conducting the activity)</i>
117.430	<i>Conducting supplier verification activities for raw materials and other ingredients</i>
117.435	<i>Onsite audit</i>
117.475	<i>Records documenting the supply-chain program</i>

Comment: This section is a good example of how the Guidance document organization is redundant, confusing, and disjointed. In addition to providing a brief one-paragraph overview of the SCP requirements as stated in the title, this section also covers a discussion of specific terms and other FSMA Rules mentioned in this Guidance chapter. We recommend stating upfront in a “scope” section, what is and is not covered by subpart G and FSMA Rules other than the PCHF Rule that are discussed in this Guidance.

Section 15.3.2 *“Receiving facilities” and “Suppliers”*. ... *“Under subpart G, entities such as brokers, produce aggregators, food distributors, and cold storage facilities are neither receiving facilities that are required to establish a supply-chain program nor suppliers...”*

If a registered facility is not a manufacturer/processor, and therefore not a receiving facility, but their Food Safety Plan (FSP) identifies a hazard that is being controlled by a supplier, foreign or domestic, how should this be reflected in their FSP? For example, if a cold storage facility receives a Raw Agricultural Commodity (RAC) for further distribution to a retailer (not further manufacturing/processing), should the hazard analysis indicate the potential for a biological hazard (since FDA assumes that there are biological hazards inherent in RACs that will be consumed raw). If so, how would a cold storage facility defend the absence of a preventive control (which would be a supply chain program) for that hazard or when applicable, should they require a written assurance from their supplier to confirm they have implemented provisions of the Produce Rule for example?

15.4 Understand the Potential Hazard

“Part 117 defines “supply-chain-applied control” as a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt. (See 21 CFR 117.3 and the list of terms in section 15.5.1.) For background and details about hazards, including hazards that could require a supply-chain-

applied control, see Chapter 3 – Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food.”

Comments: This one-paragraph, standalone section, discusses a term. We recommend this discussion be included in **15.5 Terms Used in This Chapter**.

Reference to Chapter 3 for a discussion of what constitutes a hazard requiring a preventive control should perhaps be included up front in the introduction when discussing “scope” or what needs to be covered in a supply chain program.

15.5 Terms Used in This Chapter

“15.5.1 Definitions Established in 21 CFR 117.3. Section III.A in the introduction of this guidance includes a glossary of terms that are used in this guidance and that are defined in 21 CFR 177.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 15-2 for additional terms that are defined in 21 CFR 177.3. We intend to include these terms in the glossary in section III.A in the introduction of this guidance when we update the introduction. When we do so, we intend to delete Table 15-2 from this chapter because it would be duplicative”.

Comments: In section 15.5.1, Table 15-2 lists definitions of importance for this guidance. The manufacturing/processing definition includes several processes such as washing, waxing, and ripening, that are also considered part of harvesting activities that are acceptable in the farm definition. It could be confusing for a farm to determine what activities are considered part of harvesting, packing or holding. It might be helpful to list those activities. Based on this definition, they might believe they meet the definition of a receiving facility, due to the fact that those activities are listed as manufacturing/processing by this definition. In the absence of other information that can clarify this, one would conclude that a produce operation that washes and waxes whole apples would be considered a receiving facility because it is conducting a manufacturing/processing activity. But in the examples listed in section 15.3.2., it is not an example that is listed or alluded to.

In Table 15-2, it is unclear why the definition of RAC calls out fruits but not vegetables. We encourage you to include both if that is the intent.

15.6 Requirement to Establish and Implement a Supply-Chain Program (21 CFR 117.405)

15.6.4 Requirement When a Supply-Chain-Applied Control Is Applied by an Entity Other than the Receiving Facility’s Supplier

When a supply-chain-applied control is applied by an entity other than the receiving facility’s supplier (e.g., when such an entity applies controls to certain produce (i.e., produce covered by part 112)), because growing, harvesting, and packing activities are under different management), the receiving facility must: (1) Verify the supply-chain-applied control; or (2)

obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment. (See 21 CFR 117.405(c).)

The most likely circumstance where this requirement applies is included as an example in the requirement – i.e., when the supplier is a farm and growing, harvesting, and packing activities are under different management. The definition of supplier specifies that the supplier is the establishment that grows the food. However, harvesting and packing operations that are conducted by a business entity separate from the grower do not fall within the definition of “supplier,” even though harvesting and packing operations include some supply-chain-applied controls, such as maintaining wash water temperature adequate to minimize infiltration of microorganisms and establishing and following water-change schedules for recirculated water. A receiving facility has an obligation to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act (21 U.S.C. 342) or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). That obligation includes responsibilities for raw materials and other ingredients when a supply-chain-applied control is applied by an entity (such as a harvesting or packing operation) other than the receiving facility's supplier (the grower).

We do not expect the receiving facility to follow all of the requirements of subpart G applicable to “suppliers” when verifying control by another entity in the supply chain (e.g., a harvesting or packing operation). Instead, we expect the receiving facility will take steps such as a review of that entity's applicable food safety records. For example, if a receiving facility receives produce from a supply chain that includes a separate grower, harvester, and packer, the grower is the supplier and the requirements of subpart G applicable to “suppliers” apply to the grower. To verify controls applied by the harvester, the receiving facility could review the harvester's records, such as records of training for workers who hand harvest RTE produce. To verify controls applied by the packer, the receiving facility could review the packer's records, such as water-change schedules for recirculated water used in packing operations.

See also the discussion in sections 15.8.1 and 15.8.2 of provisions of part 117 that allow entities such as distributors, brokers, and aggregators to determine, conduct, and document verification activities that apply to suppliers as a service to you, provided that you review and assess applicable documentation provided by the other entity and document your review and assessment. (See 21 CFR 117.415(a)(3).) If a harvester determines, conducts, and documents verification activities that apply to the grower (your supplier), you could review and assess the harvester's documentation. Likewise, you could obtain documentation of review of applicable records maintained by the harvester or packer from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

Comments:

In section 15.6.4, FDA explains that receiving facilities are responsible for verifying supply chain controls applied by an entity other than the receiving facility's supplier. The explanation that follows should be replicated in the Foreign Supplier Verification Program (FSVP) guidance. We also submitted comments to that docket to this effect (No. FDA-2017-D-5225). Specifically, FDA states; "We do not expect the receiving facility to follow all of the requirements of subpart G applicable to "suppliers" when verifying control by another entity in the supply chain (e.g., a harvesting or packing operation). Instead, we expect the receiving facility will take steps such as a review of that entity's applicable food safety records." In general, the industry agrees with a records review approach when different entities in the supply chain are controlling different hazards. However, this approach is unclear in FSVP draft guidance. For example, in the case that the supplier is a farm under the Produce Safety Rule (as the control for biological hazards), it appears that a review of records to indicate that a domestic farm is complying with the Produce Safety Rule would be sufficient. However, if the facility is importing fresh produce, the receiving facility would need to conduct a hazard analysis and need to consider all points in the supply chain (FSVP guidance section D.16). In addition, based on the requirements for when a hazard is a serious adverse health consequences or death to humans or animals (SAHCODH hazard) in section 15.11.2 and per E.2 in the FSVP draft guidance, the receiving facility would need to conduct an onsite audit. Furthermore, in the example given where the grower, harvester, and packer are different entities, FDA recommends different types of verification. However, previous instruction suggested that the receiving facility should verify compliance with the produce safety rule rather than focus on very specific elements of hazard control. We seek clarification and consistency as it appears that there are some differences between the supply chain requirements in chapter 15 and the FSVP requirements. It would be helpful to have a better alignment of requirements between the rules or consistent examples to show alignment.

15.7 General Requirements Applicable to a Supply-Chain Program (21 CFR 117.410)

15.7.1 What the Supply-Chain Program Must Include

Subpart G includes a list of the general requirements for what the supply-chain program must include, and provides a cross-reference to where you can find the specific requirements. As specified in 21 CFR 117.410(a), the general requirements are:

- *Using approved suppliers as required by § 117.420 (21 CFR 117.410(a)(1));*
- *Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 117.425 (21 CFR 117.410(a)(2));*
- *Conducting supplier verification activities as required by §§ 117.430 and 117.435 (21 CFR 117.410(a)(3));*

- *Documenting supplier verification activities as required by § 117.475 (21 CFR 117.410(a)(4)); and*
- *When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility’s supplier and documenting that verification as required by § 117.475, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 117.475 (21 CFR 117.410(a)(5)).*

See the discussion of the specific requirements of 21 CFR 117.405(c), 117.420, 117.425, 117.430, 117.435, and 117.475 in sections 15.6.4, 15.9, 15.10, 15.11, 15.12, and 15.13, respectively.

Comments: This section is the “actionable” section of the document – it provides information on what the FDA requires a receiving facility to do as part of an effective, safe food-producing supply chain. The diagrams provided in Figures 1 and 2 are especially helpful for understanding examples presented in the text. We highly recommend the FDA provide more examples and diagrams like this to illustrate how the agency envisions the supply chain functioning under subpart G.

15.7.2.2 Sampling and testing of the raw material or other ingredient (21 CFR 117.410(b)(2))

“Such sampling and testing can be on a periodic basis or on a lot-by-lot basis. We recommend that you establish the frequency of such testing by first conducting the sampling and testing on a relatively frequent basis (e.g., monthly) until the supplier establishes a good history of supplying an acceptable raw material or other ingredient, after which time you could sample and test less frequently, such as quarterly.”

“...we recommend that you obtain samples that are representative of the lot, use a testing method that has been shown to provide reliable results when the analyte of interest is within the food matrix you will be testing, and use a method that has the sensitivity appropriate to detect the hazard”.

Comments: Sampling and testing can be an appropriate supplier verification activity with some foods under certain circumstances. As an example, pesticide drift caused by winds during application might be expected to generate a drift pattern across a wide area of a field that could be sampled and yield useful data as to the extent of the drift and the level of pesticide present. However, random contamination events present much more difficult challenges when designing useful sampling programs. Research studies have shown that pathogen contaminations of produce items at the field level are not uniformly distributed, occur at low

frequencies and at very low concentration levels. Currently, a number of processing companies (receiving facilities) in the produce industry require their suppliers to conduct in-field product testing prior to harvest. In 15.7.2.2, FDA describes using a testing frequency approach “that provides reasonable assurance that the hazard has been significantly minimized or prevented...” How does this recommendation in relation to testing frequency apply to non-uniform, low frequency, low concentration events as observed in the produce production environment with human pathogens? For random contamination events (e.g., wildlife intrusion) testing frequency is not the critical factor in a risk-based testing regiment. For produce suppliers, a risk-based product testing regiment may be based on factor(s) other than testing frequency – i.e., weather events such as heavy rain or flooding or animal intrusion into / activity in close proximity to production areas. We recommend that raw material testing discussion include specific circumstances in the production area in addition to temporal factors.

Research has shown that contamination events can be randomized even within the same plant, i.e. not all leaves of a romaine lettuce head will be contaminated or spinach leaves growing on the same plant may or may not be contaminated but the plant next to it will be totally free of contamination. In these instances, how does one choose a sampling regime that can provide confidence that the hazard has been controlled effectively? For example, a spinach field may have as many as 4 million plants to the acre, each with 4-6 leaves when at harvest maturity. That’s 20 million leaves per acre on average. Most commercial testing programs today might take a dozen, 100 or 200-gram samples in a specified pattern which equates roughly to 100 to 200 leaves per sample or approximately 2,400 leaves; certainly a small fraction of the total (0.1%) and not significant when one considers the non-uniform distribution of human pathogen contamination typically observed. The potential number of individual items of produce (e.g. leaf, fruit, root, etc.) per unit area varies based on commodity and specific growing practices being employed by the grower. Determining a sampling program for human pathogens that provides confidence that contamination has not occurred (or is controlled) is at best challenging with current technology and perhaps beyond the scope of what many growers can implement.

15.7.2.3 Review of the supplier’s relevant food safety records (21 CFR 117.410(b)(3))

FDA guidance under section 15.7.2.3 is clear and generally in line with current practices by many on the produce industry. However, for clarification, could a records review be conducted in place of an onsite audit, specifically with regard to produce, when an onsite audit is the default? For example, instead of receiving facilities conducting the audit themselves, could they rely on a third party qualified auditor to conduct the audit with subsequent review of the audit records by the receiving facility? If so this should be specified in superscript 5, and in Figure 1. Figure 1 is a good depiction of how a supplier might use records review to make sure the hazard is being controlled. We seek to understand FDA’s thinking in terms of doing a record review instead of an onsite audit so it is clear that this is acceptable to FDA.

15.7.3 Assurance that a Hazard Has Been Significantly Minimized or Prevented

The supply-chain program in subpart G is a type of preventive control and, thus, must comply with the requirements applicable to preventive controls in 21 CFR 117.135. Under 21 CFR 117.135(a), a preventive control provides assurance that any hazards requiring a preventive control will be significantly minimized or prevented. To make this clear, 21 CFR 117.410(c) specifies that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. Suppliers that are subject to the PCHF requirements in part 117 are required to develop and implement a food safety plan that will significantly minimize or prevent hazards associated with the food manufactured, processed, packed or held by the facility (21 CFR 117.126) and to document they are following their plan (21 CFR 117.190). Suppliers subject to the produce safety requirements in part 112 must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards. (See 21 CFR 112.11.)

Comments: This is an example of stating an important factor for growers and processors, but it might better be handled in an introductory or scoping section. Is it to point out that suppliers are subject to either the PCHF or the Produce Safety Rule and that under each rule they are required to assure that preventive controls have reduced the hazard? Perhaps this could be highlighted at the beginning of the guidance? We recommend this be included in the Guidance introduction as part of a discussion of the importance of supply chain program for ensuring food safety.

15.7.4.1 Hazard Analysis ... *“the greater the risk presented by the hazard, the more stringently you should assess supplier performance...”*

Comments: We believe FDA intends that the greater the risk, the more stringent the verification of control of the hazard. We disagree that there should be different levels of stringency in evaluating suppliers, which is how this statement could be interpreted.

15.7.4.2 Entity controlling the hazard.

Comments: As clarification, in the example of the seasoning mix in 15.7.4.2; we seek confirmation from FDA that the receiving facility must approve Supplier X, but is not obligated to approve Establishments Y or Z. We expect that Supplier X would be required to approve

Establishments Y and Z. FDA offers that the receiving facility could directly conduct supplier verification activities on these establishments, therefore we seek confirmation that this would occur even though the receiving facility did not approve these establishments.

15.8 Responsibilities of the Receiving Facility (21 CFR 117.415)

Section 117.415 describes your responsibilities as a receiving facility. As noted in section 15.3.2, subpart G includes provisions that provide for an entity other than you to conduct certain activities, provided that you review and assess the entity's applicable documentation, and document that review and assessment. Section 117.415 both specifies this flexibility provided by subpart G and places some bounds on that flexibility. We discuss this flexibility and its bounds in sections 15.8.1 through 15.8.4.

Comments: We recommend that the discussion for “who can do what” be integrated into the discussion of the requirements – i.e., what needs to be done and who can do it. The separation of the responsibilities from the requirements contributes to the disjointed feel of the Guidance. For example:

15.8.1 Your Responsibility to Approve Suppliers

Section 117.415(a)(1) specifies that the receiving facility must approve suppliers. Although 21 CFR 117.415(a)(2) through (a)(4) provide some flexibility for other entities to determine and conduct appropriate supplier verification activities (see section 15.8.2), ultimately the receiving facility is responsible for its supply-chain program (see the discussion in the final rule establishing part 117, 80 FR 55908 at 56097). See section 15.7.4 for considerations in approving suppliers and section 15.9 for the requirements to approve suppliers before receiving raw materials and other ingredients from those suppliers and have written procedures for receiving raw materials and other ingredients.

As noted in section 15.6.1, the definition of “supplier” in part 117 means that a broker or distributor is not a supplier; the supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food. Thus, if you buy raw materials or other ingredients from a broker or distributor, you should ask the broker or distributor to provide you with information that allows you to approve the establishment that manufactures/processes the food, raises the animal, or grows the food as a supplier of the food that you purchase from that broker or distributor. Likewise, if you purchase raw materials or other ingredients from a retail establishment (e.g., a warehouse-style establishment that sells to consumers), some applicable information (e.g., name and place of business of the manufacturer, packer, or distributor) would be on the product label as required by food labeling regulations. (See 21 CFR 101.5.) Also, you could ask the retail establishment to provide you with information that allows you to evaluate the establishment that manufactures/processes the food, raises the animal, or grows the food.

Comments: As a general comment, it would be more beneficial to the reader to have all information about approving and using suppliers in one location in the guidance. As currently written, the general topic of approving and using suppliers is spread across various sections in 15.7, 15.8, and 15.9 that contain redundant information. (Please note, the following paragraph erroneously references section 15.5.1 as 15.6.1: *“As noted in section 15.6.1, the definition of “supplier” in part 117 means that a broker or distributor is not a supplier; the supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food.”*)

An example in section 15.8.1 suggests more flexibility than we thought was provided for in the rule. It states “if you buy raw materials or other ingredients from a broker or distributor, you **should** ask the broker or distributor to provide you with information that allows you to approve the establishments...” As written, this suggests that this process is optional. We suggest that FDA clarify this statement to note that the receiving facility must request and be provided with this information, unless there is an alternate means of identifying the establishment that must be approved.

Additionally, in this section FDA notes that a product label could be used to identify a supplier, but also recognizes that the label might include the name of the distributor. Since a distributor does not meet the definition of a supplier, we caution FDA against suggesting that the name on a label is always the same as the supplier as defined in the rule.

15.9.2 Written Procedures for receiving Raw Materials and Other Ingredients.

Comments: FDA provides an excellent overview of written procedures for receiving raw materials and other ingredients. As a point of clarification, FDA gives an example for sampling and collecting black pepper for *Salmonella*. In this example, product testing is proposed to insure a supplier is properly controlling the risk of *Salmonella* contamination. As discussed earlier in these comments, developing a statistically significant sampling plan can be challenging for some produce items or ingredients and is largely dependent on the nature of the contamination. It might be useful to gain FDA’s insights as to what an adequate sampling plan might be for a produce item or an ingredient and how they might be similar or different.

15.11 Conducting Supplier Verification Activities for Raw Materials and Other Ingredients (21 CFR 117.430)

Section 21 CFR 117.430 specifies requirements to conduct one or more of the supplier verification activities specified in 21 CFR 117.410(b), provides for alternative supplier verification activities in certain circumstances, and prohibits certain financial conflicts of interest. We discuss these provisions in sections 15.11.1 through 15.11.6.

Comments: Again, we believe it is important for this Guidance chapter to be as user-friendly as possible and organizing the content according to the PCHF Rule creates a disjointed, choppy experience as well as many redundancies. We believe the user would be better served if the discussion of conducting supplier verification activities were included earlier in the document within the section on appropriate supplier verification activities (15.7.2.).

15.11.2.1 Requirement for an onsite audit when the hazard requiring a preventive control is a SAHCODH hazard.

- *The appropriate supplier verification activity is an onsite audit of the supplier (21 CFR 117.430(b)(1)(i)); and*
- *The audit **must** be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter (21 CFR 117.430(b)(1)(ii)).*

Comment: Since the audit **must** be conducted before using the raw material, does this mean that a temporary approval may not be used for a food that has a potential to be a SAHCODH Hazard?

15.11.4 Alternative Supplier Verification Activity If the Supplier is a Certain Type of Produce Farm

Section 21 CFR 117.430(d) provides for an alternative supplier verification activity if a supplier is a farm that grows produce and is not a covered farm under the produce safety regulation in 21 CFR part 112 in accordance with 21 CFR 112.4(a), or in accordance with 21 CFR 112.4(b) and 112.5. If this is the case, you do not need to comply with the requirements to conduct one of the supplier verification activities specified in 21 CFR 117.410(b), or conduct an annual onsite audit if the hazard requiring a preventive control is a SAHCODH hazard, for produce that the receiving facility receives from the farm as a raw material or other ingredient if you:

- *Obtain written assurance that the raw material or other ingredient provided by the supplier is not subject to the produce safety regulation in 21 CFR part 112 in accordance with 21 CFR 112.4(a), or in accordance with 21 CFR 112.4(b) and 112.5:*
 - *Before first approving the supplier for an applicable calendar year; and*
 - *On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and*
- *Obtain written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially*

recognized as comparable or has determined to be equivalent to that of the United States).

Under 21 CFR 112.4(a), a farm or farm mixed-type facility that has less than \$25,000 in annual sales of produce averaged over the previous 3-year period is not a covered farm under the produce safety regulation. Under 21 CFR 112.4(b) and 112.5, a farm is not a covered farm if the farm is eligible for a qualified exemption and associated modified requirements based on the average monetary value of all food sold and the relative value of food sold directly to qualified end users as compared to all other buyers⁹, and FDA has not withdrawn the farm's exemption. It is the responsibility of the supplier to determine whether it is not subject to the produce safety regulation; it is your responsibility to obtain written assurance from the supplier that it is not subject to the produce safety regulation. By specifying "by December 31" for the annual written assurance that the supplier is a farm that grows produce and is not a covered farm under the produce safety regulation, the provision provides some flexibility for you to work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify you about its status. You and your suppliers have some flexibility to approach the potential for the status of a facility to shift between "not a covered farm" and "covered farm" (or vice versa) in a way that works best for your specific business relationship.

See section 15.7.4.3 for a discussion of the applicability of relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

Comments: This section is well done and covers a number of scenarios. Does alternative supplier verification also pertain to suppliers of produce that is not covered by the Produce Safety Rule (e.g., rarely eaten raw)?

15.12 Onsite Audit (21 CFR 117.435)

Section 21 CFR 117.435 specifies requirements applicable to onsite audits, including who must conduct an onsite audit; consideration of applicable food safety regulations; and when the written results of an inspection can be substituted for an audit. We discuss these provisions in sections 15.12.1 through 15.12.3.

Comments: We recommend one section addressing onsite audits – when they are necessary and how and by whom they should be conducted i.e., include this section with the previous section, *15.11.2.1 Requirement for an onsite audit when the hazard requiring a preventive control is a SAHCODH hazard*. Section 15.11.2.1 contains details around what is meant by an "annual audit" that should be replicated in or consistent with similar language in question F.10, including that within 13-14 months is reasonably close to one year.

Section 15.12.1 discusses who conducts an onsite audit. One of the examples given for determining competency for a qualified auditor suggests that the person undergo food safety training annually. The produce industry has always understood the value in food safety training at all levels within an organization. Industry practice is that an individual trained in HACCP renew their training every 3-5 years. The Preventive Controls Rule for Human Food does not have a prescriptive training requirement, and if individuals opt to take the FSPCA PCQI course there is no expiration on the certificate and no required training update. We seek clarification on the specificity of frequency of training for qualified auditors.

15.13 Records Documenting the Supply-Chain Program

Table 15-4 lists the records required (as applicable) for the supply-chain program. (See 21 CFR 117.475(c).)

Comments: Table 15-4 is a good resource for users to track the documentation required as part of their supply-chain programs.

In conclusion, we appreciate the thought FDA took in addressing the numerous issues and questions associated with this guidance. We are ready to offer additional detail or clarification and look forward to working with FDA moving forward.

Respectfully submitted:

Scott Horsfall
CEO
CA Leafy Greens Marketing Agreement

Jeff Hall
Food Safety Specialist
Canada Produce Marketing Association

Jill Dunlop
Manager of Food Safety & Sustainability
Florida Fruit and Vegetable Association

Charles Hall
Executive Director
Georgia Fruit and Vegetable Growers
Association

Kate Woods
Vice President
Northwest Horticultural Council

Bob Whitaker
Chief Science & Technology Officer
Produce Marketing Association

Dante Galeazzi
CEO/President
Texas International Produce Association

Jennifer McEntire
Vice President Food Safety & Technology
United Fresh Produce Association

Sonia Salas
Director, Science & Technology
Western Growers

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](#).

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