May 25, 2018

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

Re: **"**Foreign Supplier Verification Programs for Importers of Food for Animals and Humans: Guidance for Industry; Draft Guidance**" [Docket No. FDA–2017-D-5225-0003]**

To Whom It May Concern:

On behalf of our members, the California Leafy Greens Marketing Agreement, Canadian Produce Marketing Association, Florida Fruit and Vegetable Association, Georgia Fruit and Vegetable Growers Association, Produce Marketing Association, Texas International Produce Association, United Fresh Produce Association, and Western Growers respectfully submit the following comments to the draft FDA guidance entitled, Foreign Supplier Verification Programs for Importers of Food for Animals and Humans: Guidance for Industry; Draft Guidance" [Docket No. FDA–2017-D-5225-0003].

The rule requiring the development and implementation of foreign supplier verification programs (FSVP) for FSVP importers is new and complicated and prompts many questions from our members. The draft guidance provides needed clarity to a confusing topic. While the length of the draft guidance speaks to the complexity of the rule, the Question & Answer format includes numerous specific examples that provide excellent insight and assistance as companies seek to determine how to comply with FSVP.

We have many specific comments. They relate to clarification of the information provided in the draft guidance, as well as questions that members have asked that are not addressed in the current draft. We also request that FDA carefully compare the next version of this guidance against the next version of the Preventive Controls Chapter 15 guidance on the supply chain programs. FSVP and the PC supply chain programs are aligned by design. However, in a few instances the guidance documents supporting the respective requirements differ slightly. The format/ presentation of information also differs. We have attempted to highlight examples of these differences in our comments below, and have also submitted comments specific to the supply chain program under its docket (No. FDA-2016-D-2343-0042).

The following are questions that are not addressed in the guidance for which we seek inclusion:

- A requirement of the qualified individual is that they must be able to read the language of records that are being reviewed. May FSVP importers have these records translated if the QI does not read the language of the records? May the supplier have the records translated to English? If there are instances where translation is acceptable, is there guidance around the quality of the translation (e.g., that the translator must have a scientific or technical background that permits context for the translation)?
- Must FSVP importers retain records of foreign suppliers who were not approved?
- If an FSVP importer includes sampling and testing of imported raw material as part of their verification program for a serious adverse health consequence or death to human or animal (SAHCODHA) hazard and finds an issue with the product after it has already been imported, but

destroys or returns the imported product based on the test result (so it does not reach US consumers), must the FSVP importer file a report with the Reportable Food Registry?

- If an established importer who meets the definition of an FSVP importer had a supplier approval process prior to the implementation of FSVP, must they "re-approve" foreign suppliers, or is a long business relationship sufficient to consider them an approved supplier under FSVP (provided that a hazard analysis was already conducted and there are verification activities in place)?
- Section 3, just prior to section B9, addresses importers who are also receiving facilities under the Preventive Controls rule. Many members of the domestic fresh produce industry are registered facilities because they pack or hold fresh produce. They do not meet the definition of a receiving facility, but may still be FSVP importers. Can FDA clarify whether these facilities need to follow FSVP requirements, even though they are not subject to the supply chain requirements of the preventive controls rules? If they are, does this mean that only imported, but not domestically sourced, fresh produce is subject to FSVP requirements?
- If a receiving facility subject to the preventive controls rule is not the FSVP importer directly, but is using product that has already been verified by the FSVP importer, can FDA expand on the requirements. Must both the FSVP importer and receiving facility separately approve the (foreign) supplier (since the response to E9 is that only you can approve your foreign suppliers under FSVP)?
    - Similarly, if a corporate entity is the FSVP importer, how do the individual receiving facilities account for this in their supply chain program?
    - We realize these questions lie at the intersection of the two rules and they will be submitted to the docket for supply chain controls as well.

The following comments pertain to specific questions and answers within the draft guidance:

The answer to question A3 notes that an FSVP importer could be someone who "resides" in the United States. Can FDA expand upon any residency requirements that would defend a claim that one "resides" in the United States?

In the response to question A3 and throughout the draft guidance, FDA refers to the FSVP importer as a "person". Is the FSVP importer an individual person, or a company? Members have sought clarification because this may have legal/liability consequences, and also impacts the name listed as the FSVP importer on the Customs Entry forms (based on the list of FSVP importers recently released by FDA, it appears that a company/business name is listed most frequently, not a person). For example, does this company have to be physically present in the US for a designated period of time, or when they are importing the food?

The second paragraph of the answer to A5 states "When there are multiple unaffiliated US owners or consignees for the same line of an entry of a food, we anticipate that each such entity WILL develop an FSVP for the food and foreign supplier". The regulation requires that one FSVP importer be identified for each line of an entry. We suggest that the sentence be clarified to read "When there are multiple unaffiliated US owners or consignees for the same line of an entry of a food, each such entity should understand the risks associated with the food and evaluate the foreign supplier, even though only one entity will be identified as the FSVP importer".

In the next sentence we seek clarification "However, if one of the entities were willing to serve as the FSVP importer for this food from this foreign supplier, this would be permissible under the regulation.". It was our understanding that this was *required* by the regulation since only one FSVP importer could be listed for each line of an entry of a food.

The answer to A6 states "Typically a buyer of a food issues a purchase order to a seller indicating the product to be purchased, the quantity, and the price". While we understand that this is the written agreement, we seek additional guidance from FDA related to situations where the seller (e.g. a broker) fills the purchase order over time (i.e., not with one shipment from a single supplier). Must or should the buyer specify that the PO can only be filled by approved suppliers? The answer to A8 implies that the PO must dictate the source.

In response to A14, we recognize that since the issuance of the draft guidance FDA has published this list, which is simply a list of names of FSVP importers. Dates or other details of shipments are understandably not provided. We appreciate FDA addressing industry's concern that companies may unknowingly be listed as FSVP importers. We urge FDA to quickly develop a mechanism for industry to identify these possibilities and receive prompt attention. Our understanding is that currently, members who feel they should not be on the list must submit a FOIA request to obtain information about how and why their company name appears. We encourage FDA to develop a better system to address these issues.

A20 mentions that food contact substances are included in the food definition. FDA plans to use enforcement discretion for food contact substances. Are there plans to release a guidance or take other action after the two year extension period? Should importers of food contact substances prepare FSVPs for these product-supplier pairs?

Question B5 addresses the "same level of public health protection". We are submitting comments on the draft guidance that explains how one can ascertain if their practices or procedures meet the same level of public health protection. We find the lengthy response to question B5 to be of minimal value with few exceptions, such as the example of a log reduction using heat treatment versus HPP. We encourage the agency to provide additional practical and applicable examples. We found that the jelly example on page 23 that describes an operation that lacks a written hazard analysis but has a HACCP plan to be inapplicable, since a HACCP plan requires a hazard analysis. We do appreciate FDA's note on page 25 that FDA will make public the response requests for variances under the Produce Safety Rule. We struggle to interpret FDA's comment in the next paragraph on page 25, that "a supplier's use of a process or procedure that differs from those required under the preventive controls or produce safety regulations generally would be relevant to the importer's decision to approve the supplier and to the importer's determination of appropriate supplier verification activities." If suppliers are able to demonstrate that they meet the same level of public health protection as the regulations, it is unclear why they should be scrutinized more intensely than a supplier following the rules.

Question B.6. references an "unsafe" level of a pesticide. We caution FDA against suggesting that a violative pesticide residue is, by definition, unsafe. At a more general level, we would like to better understand how FDA expects FSVP importers to document the need to control unapproved pesticides (either use or level), since FSVP does require that imported products not be adulterated, but a traditional hazard analysis would not necessarily identify them as a public health hazard since they are

unlikely to cause illness or injury even if they are not approved. They, along with heavy metals are provided as examples of potential hazards in response to question D.6.

We suggest revising the response to question C.1. to indicate that one or more qualified individuals (QI) need to perform the tasks. As written, it could be interpreted that there should be one QI who performs all aspects of FSVP development and implementation.

The response to question C.3. should be updated to reflect that the FSVP training developed by the FSPCA is now available (it was available before the draft guidance was issued).

We seek additional guidance related to question C.5., or as a new question, to clarify whether or not it is permissible for documents received by the FSVP importer to be translated. For example, if an FSVP importer determines that they will review food safety records as part of their FSVP program, and the records are in another language, must the qualified individual speak that language, or can the FSVP importer get the records translated for subsequent review by the qualified individual?

We suggest switching the order of questions D.5 and D.6. Otherwise, it could be interpreted that the examples in D.6. of hazards that are known and reasonably foreseeable require a preventive control, since it follows that question.

Question D.9 addresses economically motivated adulteration. While we agree that adulterants that do not pose a hazard (such as corn syrup in honey) should not be included in a hazard analysis, since such an act would render the product adulterated, we question why FDA states that this type of occurrence, if expected to occur, should not be managed by an FSVP, since FSVP requires that importers verify that products are not adulterated or misbranded.

While we believe the response to question D.12 is accurate, in that importers of fresh produce RACs do not need to consider biological hazards in their hazard analysis, we fear that, as worded, it may lead some readers to believe that biological hazards do not need to be addressed by FSVP importers (when actually the opposite is true). We suggest augmenting the response to note that biological hazards are assumed to be associated with fresh produce RACs, and therefore require a control (which is implementation of the Produce Safety rule). We believe the last sentence in response to question D.13 is very clear and suggest that it be emphasized and perhaps reiterated in the response to D.12. We also appreciate the clarity of the response to question D.19, that fresh produce RACs covered by the produce safety rule will always require verification of foreign suppliers.

In the response to question D.16, we question if the evaluation of the likelihood of post process contamination with environmental pathogens should be done for a “typical entity”, or if facility-specific information should be acquired. Further, we would like FDA’s guidance on whether FSVP importers must document their consideration of each of the factors in the bullets associated with this answer. Some activities in the list may be conducted by different parts of a supply chain upstream of the FSVP importer. For example, growing, harvesting and packing may each be conducted by a different entity. However, there is only one “foreign supplier” which, as explained by the draft guidance, would be the entity growing the food (in this example). We seek additional guidance from FDA on how to convey, in the hazard analysis or other documents that are part of the FSVP, that entities that are NOT the “foreign supplier” may contribute to the risk profile of the imported product. In other words, it would be helpful for FDA to clarify if the hazard analysis encompasses all points in the supply chain between the supplier

(e.g., grower of fresh produce) and the FSVP importer. We also seek additional detail on FDA's expectation that these entities be verified by the FSVP importer. For example, FDA states that the hazard analysis for fresh produce RACs does not need to detail the evaluation of biological hazards since they are assumed to exist (and thus the produce safety rule exists). However, if other entities in the supply chain that are not processors but are registered facilities (e.g., independent packinghouse) impact the risk profile of the product, how should this be reflected in the hazard analysis and subsequent verification? See our related comment in response to question E.3.

The response to question D.18 states that the FSVP importer should retain documentation of the assessment of the probability that a hazard will occur and the severity of the hazard if it occurs. These are listed as two different bullets. Recognizing that the rule does not require a specific format for records, some typical hazard analysis templates do separate the assessment of probability and severity. Others, such as the one used in the FSPCA PCQI course do not. There is simply a box to indicate whether or not the hazard requires a (preventive) control. Does FDA wish to see the separate evaluation of likelihood and severity? The response is worded as a "should" not "must".

Question E.3 gives an example of a fruit consolidator and the response is clear. However, if we alter this example to say that the consolidator is a packing operation where this is a risk of environmental contamination, we seek additional detail on how this is accounted for in the hazard analysis (as per our earlier comment) and whether the FSVP importer would need to verify the packinghouse (which does not meet the definition of supplier) as well as the grower (the response to F.9 suggests the packinghouse should also be verified). Unlike other examples, we are not certain that the packinghouse would already be verifying the grower (if they did, we believe the guidance suggests that the FSVP importer could review the packinghouses records pertaining to the grower), because the packinghouse, even if registered with FDA, would not meet the definition of a receiving facility under the preventive controls rule.

We appreciate the statement in response to question E.5, providing clarification regarding how to evaluate a potential foreign supplier's regulatory compliance. The explanation confirms that just because a foreign supplier is subject to an enforcement action, it does not mean an FSVP importer is not able to approve that supplier.

In the answer to E.10, one of the triggers for reevaluation is that the foreign supplier opens a new facility. We find this confusing, since we understood that "supplier", by definition, was the "establishment". Therefore, we believed that a new location would be considered a new "supplier". We seek clarification of this comment.

Question F.2 addresses the use of written procedures. FDA provides as an example that a broker/distributor's employee can date and initial after reviewing an invoice from a supplier. We suggest FDA clarify that this would be appropriate only in the case that the invoice was from the entity that met the definition of the "supplier" and not from a corporate office (that does not indicate the location of the producing supplier), or another member of the supply chain who is not the supplier.

F.4 addresses using a temporary unapproved supplier due to certain circumstances. Would FDA expand on, using examples, what is acceptable and non-acceptable temporary suppliers? When a temporary unapproved supplier is used, does the reason for using the temporary unapproved supplier need to be

documented? Are written procedures, including procedures receiving product, required for the use of temporary unapproved suppliers?

In response to question F.6, FDA suggests that procedures might address an FSVP importers general principles around supplier verification. Since an FSVP is needed for each food-supplier pair, does FDA expect that these procedures are overarching, or specific to each FSVP (i.e., each food-supplier pair)?

The response to question F.9 suggests that the FSVP importer should explain why they decided that a particular verification activity is appropriate. We suggest that FDA offer that this justification could be part of the aforementioned general principles (e.g., an explanation that there is an annual onsite audit of suppliers whose products are associated with SAHCODHA hazards, since the rule recommends that this is appropriate). Otherwise, since each supplier-food combination requires a separate FSVP, this seems like an overly burdensome expectation.

Also in F.9., it is unclear why FDA uses an example of a fruit supply chain and suggests records review such as training records for each harvester and water-change schedules in packing operations, amongst several other suggested records to be reviewed. Because fruit is covered by the produce safety rule, and the default verification is an annual onsite audit, we are concerned that this response suggests that the additional recordkeeping activities should be conducted in addition to the onsite audit. We recognize that in particular circumstances, based on the hazard evaluation and supplier evaluation, an FSVP importer may choose to perform supplier verification activities beyond an annual onsite audit, but believe that the example in the draft guidance portrays this as the expectation, not the exception.

We appreciate FDA's acknowledgement, in response to question F.10, that "annual" means every 365 days, but that there are practical considerations when timing audits that may warrant flexibility around this timeframe. We recommend FDA retain this part of the guidance.

The response to question F.16 states, "Farms are not required under the produce safety regulation to have a food safety plan. However, in some cases, a foreign supplier (such as a large farming operation) might voluntarily elect to establish a food safety plan. In that case, the onsite audit of the supplier would **need** to include a review of the foreign supplier's written plan, and its implementation of the plan, to ensure that identified hazards are being adequately controlled." We strongly disagree with a requirement to evaluate a food safety plan that is voluntarily developed. There are no criteria against which to evaluate the food safety plan. We fear that such a requirement will have the unintended consequence of deterring farms from developing a food safety plan.

The example of produce shipped in open or porous containers or crates being susceptible to environmental contamination if the transportation vehicle is not cleaned and sanitized before loading the produce (response to question F.25) is counter to the principles of hazard analysis and in conflict with the sanitary transportation rule. First, the statement reads that the example is one in which a hazard **needs** to be controlled during transportation. We believe that the hazard analysis should bear out if the hazard **needs** to be controlled. FDA has previously stated that fresh produce transported in vented containers are unlikely to be contaminated by environmental pathogens and that the agency would not expect an environmental monitoring program for RACs. We agree that shippers should ensure that vehicles and equipment are in appropriate sanitary condition before transportation and that cleaning/sanitizing is done if necessary; however, it is impractical and unnecessary to require that a vehicle be cleaned, and sanitized, before every load unless the hazard analysis suggests otherwise. We strongly disagree with the use of this example.

Later in the response to question F.25 FDA states that if the foreign supplier is subject to the sanitary transportation rule, the FSVP importer may request written assurance of compliance with the rule. Unless the hazard analysis shows that the rule is controlling a specific hazard associated with transportation, we do not feel that this is appropriate. The verification activities selected by the FSVP importer should be tied to their hazard analysis. We believe this is appropriately stated in the last paragraph of this section, and suggest FDA revise the preceding parts of the response accordingly.

The second paragraph of the response to F.28 seems to be related to question F.27, not 28.

We seek additional clarification to FDA's response to question J.3 pertaining to record retention. The 4th bullet suggests that if the hazard analysis is updated, the previous hazard analysis must be retained for 2 years. If the previous hazard analysis needs to be retained and not simply replaced, we are concerned that having multiple versions can be complicated and confusing, particularly for smaller importers.

The response to question J. 5 states, "if requested in writing by FDA, you must send your FSVP records to the Agency electronically, or by another means that delivers the records promptly, rather than making the records available for review at your place of business (21 CFR 1.510(b)(3)). We will generally expect you to deliver the FSVP records within 72 hours." Can FDA clarify when the 72 starts? Is it the time an email is sent? Will it be sent with a "read receipt"? We are concerned that if the individual responsible for monitoring the email address is on vacation, etc., there may be an unintentional violation depending on how the 72 hours is calculated.

J.6 and L.26 are very vague in terms of defining what a "reasonable" length of time would be to translate documents and send to the FDA. Could the FDA give a more concrete or extreme example of what FDA would **not** consider to be reasonable?

The responses in questions L.15, which speak to what activities are required for a qualified facility, L.16, which refers to farms that are exempt from the produce rule, state that an importer would need to have written assurances from those suppliers. However L.20 refers to a receiving facility that would receive items from a small foreign supplier and states they would ***not*** need to have written assurances from those suppliers to comply with FSVP. If the reason is because written assurance is required to comply with the Preventive Controls supply chain program, this should be stated (rather than referenced to the CFS) because as written it appears that there are inconsistent requirements.

Relative to section M, we were not aware that FDA has a web page linking to other countries' food safety authorities that maintain a list of suppliers in good compliance standing (or that are specifically not in good compliance standing). As more countries are determined to have comparable food safety systems, we would like to know if it is the obligation of the foreign food safety authority to maintain such a list.

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

Respectfully,

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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, CPMA is a not-for-profit organization that represents a diverse membership of over 850 members who represent every segment of the produce industry supply chain and are responsible for 90% of the fresh fruit and vegetable sales in Canada from farm gate to dinner plate. CPMA is fortunate to represent a sector that is both a significant economic driver for communities and that also improves the health and productivity of Canadians. www.cpma.ca

About Florida Fruit and Vegetable Association

The Florida Fruit & 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 state's number two agricultural cash crop, most Georgia fruits and vegetables are grown for the fresh market to be sold and consumed in other states. The GFVGA provides programs and services to the membership designed to increase production efficiencies, provide educational opportunities, promote new markets, monitor legislation, encourage applied research and improve communications among GFVGA members and industry suppliers.

About Produce Marketing Association (PMA)

Produce Marketing Association 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.

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