DOCKET NO. FDA–2011–N–0920

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING for the PROPOSED RULE for

CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

December 15, 2014

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Prefatory Remarks

The Food and Drug Administration (FDA or the agency) on January 16, 2013 issued a proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (the proposed GMP-HA/PC Rule; Docket No. FDA-2011-N-0920).[1] FDA states in its January 16 notice that it is taking this action as part of its announced initiative to revisit the CGMPs since they were last revised in 1986 as well as to implement new statutory provisions in the FDA Food Safety Modernization Act (FSMA).

Also on January 16, 2013 FDA issued a proposed rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the proposed Produce Safety Rule; Docket No. FDA-2011-N-0921).[2] FDA states in this January 16 notice that the proposed Rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms as is required by the FDA Food Safety Modernization Act (FSMA) requires FDA to establish such standards.

Also related to implementation of FSMA, FDA on July 29, 2013 issued a proposed Rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (the proposed FSVP Rule; Docket No. FDA-2011-N-0143).[3] FDA states in this notice that the proposed Rule would help ensure that imported food is produced in a manner consistent with U.S. standards, and would require importers to help ensure that food imported into the U.S. is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under the hazard analysis and risk-based preventive controls and standards for produce safety sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling. FDA also states in this notice that it is proposing this Rule in accordance with the FDA Food Safety Modernization Act (FSMA).

On September 29, 2014 the agency published supplemental notices of proposed rulemaking in relation to the proposed GMP-HA/PC Rule,[4] the proposed Produce Safety Rule,[5] and the proposed FSVP Rule.[6] FDA states in its September 29 notices that the agency is proposing to amend certain previously-

[1] 78 FR 3646-3824.

[2] 78 FR 3504-3646.

[3] 78 FR 45730-45779.

[4] 79 FR 58523 -58572.

[5] 79 FR 58433 -58473.

[6] 79 FR 58574-58599.

proposed provisions of the Rules because the extensive information received in public comments has led to significant changes in FDA's current thinking on certain key provisions of the proposed Rules.

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

AHPA's members are engaged in the commerce of herbs and herbal products, and some AHPA members are also engaged in farming operations while others import articles that may be used in or as food, including in or as dietary supplements. In the course of this commerce many AHPA members are engaged in activities that would be directly covered by one or more of the proposed Rules, both as originally proposed in 2013 and as revised in the September 2014 supplemental notices of proposed rulemaking. AHPA's members therefore have an interest in these three proposed Rules. These comments are therefore submitted on behalf of AHPA's members and follow on the extensive comments that AHPA submitted in response to each of the original proposed Rules.

AHPA expresses below support for certain of the revisions proposed by FDA to these Rules in its supplemental notices. In spite of numerous improvements to the proposed Rules between FDA's original notices of proposed rulemaking and the supplemental notices, however, AHPA has significant concerns about certain of the revisions proposed in the supplemental notices. The comments below articulate AHPA's concerns and provide specific suggestions for further clarification and improvements to one or more of the Rules.

In addition, AHPA notes many of the issues identified in the extensive comments AHPA submitted in 2013 in response to the original proposed Rules are not addressed in the supplemental notices, and AHPA hereby restates those parts of its earlier submitted comments that address issues not covered or affected by the supplemental notices, and incorporates by reference these earlier comments.

AHPA is submitting on this date comments to all three of these FDA supplemental notices. AHPA notes certain provisions in these three proposed Rules are closely interrelated or overlap with provisions of at least one of the other of these proposed Rules. The comments submitted here therefore address not only the specific Rule identified on the cover page but also the related provisions of the other two Rules as necessary and in fact some portions of each of these comments are reproduced verbatim in each of these AHPA comments.

1. General support for many of the revisions

At the outset of these comments AHPA notes that the clarity and readability of the proposed regulations are much improved compared to the earlier versions. In addition, FDA has in many areas accepted the suggestions of industry, and has taken care to provide flexibility for industry to decide how best to adequately meet the requirements. AHPA greatly appreciates these changes.

AHPA supports many provisions of the revised proposals, and in particular to name a few:

- Broadening the definitions of "farm," "harvesting," "packing," and "holding" and providing additional examples thereof;
- Narrowing the definition of "environmental pathogen";
- Providing flexibility with respect to control and verification activities;
- Providing numerous areas of flexibility with respect to supplier programs and the foreign supplier verification program;
- Providing flexibility with respect to verification activities to be performed in case of hazards that may cause serious adverse health consequences or death to humans or animals and for the use of unapproved suppliers;
- Providing alternative verification activities with respect to suppliers that are qualified facilities and certain types of farms;
- Providing that inspection by FDA or an officially recognized or equivalent food safety authority may substitute for an audit;
- Providing additional due process protections for qualified facilities before FDA would withdraw its exemption, and extension of the time allowed for such a facility to comply with an order withdrawing such exemption;
- Specification that if an importer evaluates the known and reasonably foreseeable hazards in a food and determines that there are no significant hazards, the importer would not be required to determine what foreign supplier verification and related activities it should conduct and would not be required to conduct any such activities;
- Clarification that importers will not be required to make full supplier audit reports available to FDA during inspections.

2. General concern over confusing language

AHPA's membership includes a very large number of small companies, as well as a significant contingent of lawyers and consultants in addition to very large companies. AHPA therefore has extensive experience in counseling small entities with respect to the content, meaning, and import of various regulations, and is well aware of how difficult it is for most small firms to read and understand regulations. Indeed, based on input from members AHPA has found that FDA regulations are often confusing even for knowledgeable parties such as lawyers, consultants, auditors, FDA inspectors, and very large companies. For example, numerous elements of 21 CFR Part 111 (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) have been the subject of extensive debate within the industry, between industry and FDA, and even (as evidenced in various FDA communications) within FDA itself.

AHPA therefore urges FDA in the strongest possible terms to ensure 21 CFR Parts 112 and 117 are written in the clearest possible language. In particular, the Rules should be written in a manner that allows firms to readily determine whether or not they are subject to each Rule (i.e., whether they handle the food or perform the activities that fall within the scope of each Rule) without having to hire consultants or lawyers, or having to wade through hundreds of pages of Preambles, policy documents, and guidance documents (which many small firms will not even realize exist). In order to accomplish this, it is particularly critical that the scope and definitions be set forth in self-explanatory language.

The vast majority of entities affected by these Rules will be small or very small entities, and a large part of them will have little to no experience with how to read and understand FDA regulations, so it is crucial that the Rule be written with their needs in mind. AHPA emphasizes the importance of *communicating in a clear and straightforward manner with the average reader*. The interest of clear communication must be elevated above mere stylistic concerns (such as brevity; or the avoidance of provisions that FDA considers redundant but which can only be recognized as redundant if one happens to have read some other document) or the convenience of government (such as the desire to maintain complete consistency with policy documents created long ago for entirely different purposes).

FDA should not burden industry with definitions that are vague, convoluted, or otherwise confusing, and definitions related to farms should not arbitrarily exclude legitimate farm activities. Rather, the definitions should be simple, straightforward, free of potentially misleading implications, easy to mentally map onto the activities they are intended to include or reflect, and fully inclusive of the range of activities traditionally performed on farms.

AHPA therefore strongly urges FDA to create definitions that (a) are written in clear, straightforward prose, (b) capture the full range of activities normally performed on farms, and (c) are self-contained and fully understandable without reference to information contained in any other documents (including the Preambles).

3. Definition of "farm"

In the supplemental notice of proposed rulemaking for the proposed Produce Safety Rule and the GMP-HA/PC Rule, FDA proposes a revised definition of "farm" as follows:

> *Farm* means an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term “farm” includes establishments that, in addition to these activities:
>
> (i) Pack or hold raw agricultural commodities;
>
> (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and
>
> (iii) Manufacture/process food, provided that:
>
> (A) All food used in such activities is consumed on that farm or another farm under the same ownership; or
>
> (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:
>
> (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and
>
> (2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

AHPA finds the revised proposed definition of "farm" to be generally an improvement from that proposed earlier. It is somewhat less confusing than the original proposed definition, although it still relies heavily on regulatory terminology and obscure concepts whose import will probably not be obvious to the average reader. AHPA strongly supports FDA's proposals to (a) removing the restriction on packing/holding raw agricultural commodities (RACs) grown on another farm and (b) the inclusion of drying/dehydrating RACs to create a distinct commodity within the farm definition. AHPA also supports substitution of the word "establishment" for the term "facility."

However, AHPA has a number of concerns with the revised proposed definition.

1) At first read, AHPA was extremely confused as to why paragraph (ii) of the proposed definition makes reference specifically to paragraph (iii)(B)(1) of the definition but not paragraph (iii)(B)(2). AHPA assumed that since "packaging" was being defined as a manufacturing/processing operation, the output of that operation (i.e., packaged RACs) would naturally be a "processed food." AHPA therefore questioned why, if a farm were to be permitted to pack and hold bulk/unpackaged RACs, it would be precluded from packing and holding the same items in retail-packaged form.

The Preamble to the GMP-HA/PC Rule indicates that the reason paragraph (iii)(B)(2) is not included is that FDA has decided to classify packaged RACs as "RACs" rather than "processed food" (despite their having been subjected to what FDA is now calling a manufacturing/processing operation, i.e., on-farm placement into retail containers), and therefore the packing and holding of packaged RACs is covered in paragraph (i) of the definition.

AHPA finds this to be unnecessarily confusing. As mentioned previously, it is essential that the Rule communicate in clear and straightforward language and be readily intelligible to the average reader without reference to statements made in other places. This is especially important for the definitions that form the foundation of the scope and applicability of the Rule. Clear communication is more important than stylistic concerns such as brevity or the avoidance of theoretical redundancy, especially when the redundancy will not even be apparent to many readers.

If FDA maintains the current structure of the definition, AHPA believes the simplest way to eliminate this source of confusion will be to delete the "(1)" in "paragraph (iii)(B)(1)." In this way, the definition will actually continue to avoid redundancy (insofar as the reader may be aware that "packaged RACs" are still RACs rather than processed food, with all that this implies) while also not on the surface implying that farms are somehow precluded from packing and holding packaged RACs. Thus, paragraph (ii) would read:

> (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)~~(1)~~ of this definition;

Also, insofar as other provisions of Part 110, Part 117 and/or Part 112 may or may not apply to packaged RACs due to their continued status as RACs (as opposed to processed food), AHPA believes it extremely important (if the current structure of the definition is maintained) to explicitly state in the definition itself that such packaged RACs continue to be RACs. AHPA therefore suggests paragraph (iii)(B)(2) should in this case read:

> (2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing. <u>Although packaging is a manufacturing/processing operation, packaged raw agricultural commodities are not processed food for purposes of parts 110, 112, or 117.</u>

2) Notwithstanding the above, AHPA disagrees with FDA's proposal to identify "drying/dehydrating to create a distinct commodity" and "packaging of RACs" as manufacturing/processing activities in a separate section of the definition. Putting them into a separate section and emphasizing their status as "manufacturing/processing" introduces confusion; the reader cannot help but wonder why this was

done and what it implies, and AHPA believes that many readers will erroneously assume the purpose is to provide notice that these activities are subject to Part 117.[7]

AHPA therefore recommends that the definition be reorganized to avoid placing these activities in a separate section identified as "manufacturing/processing." This will avoid the implication that these activities are treated differently under the new regulations than the other activities.

3) With this reorganization in mind, AHPA believes it undesirable to specify "drying/dehydrating raw agricultural commodities *to create a distinct commodity*" (emphasis added). AHPA recognizes that FDA considers such drying to be "food processing" while drying that does not create a distinct commodity is "holding."[8] However, for purposes of the proposed farm definition, such distinctions are not necessary with the reorganization AHPA proposes below in combination with AHPA's proposed revision to the definition of packaging (comment 4 below). Moreover, the inclusion of such a distinction may confuse the average reader because it raises the question of why "drying/dehydrating raw agricultural commodities *to create a distinct commodity*" is expressly recognized as a farm activity while "drying/dehydrating raw agricultural commodities *that does not create a distinct commodity*" is not. The average reader will not readily understand that the latter is not mentioned because it is already included in the word "holding."

4) AHPA is concerned that based on the Preamble, FDA considers that paragraph (iii)(B)(1) of the proposed definition will apply only if the drying process is "akin to harvesting." The proposed regulatory language itself makes no such stipulation, and the Preamble does not explain precisely what FDA means by this. Based on the example provided in the Preamble, AHPA assumes it refers to allowing the crop to dry naturally either *in situ* in the field, or on trays with no heat or mechanical air circulation. But this limitation would not make sense from either a logical, practical or a food safety standpoint:

- Use of heat (generally at 200 °F or less) and/or forced air is common in the drying of non-produce botanicals (i.e., in instances where the drying/dehydrating does not create a distinct commodity). Farmers and others are unlikely to readily understand that heat or forced air drying processes are within the farm definition in one case and not in the other.

- Use of heat and/or forced air will speed drying compared to "natural" drying, thereby minimizing microbial growth and improving food safety. Furthermore, in humid climates or during rainy seasons it may be impossible to achieve drying by any other means. It would be counterproductive and illogical to allow farms to perform "natural drying" while discouraging

[7] Knowledgeable readers may not draw this erroneous conclusion, but AHPA believes it likely the average reader will often do so.

[8] AHPA considers this distinction to be illogical and to be unnecessary for food safety (see paragraph 5 of this comment), but for purposes of discussing the proposed definitions assumes it will not be changed.

them (by imposing all the burdens of Part 117) from performing other types of drying that are as safe if not safer.

- If FDA is attempting to draw a distinction based on use of mechanical equipment to perform operations on the food, AHPA notes that FDA is already proposing to allow farms such use in the definitions of harvesting, holding, and packing (i.e., cooling, sifting, blending, grading, etc. involve use of mechanical equipment). There is no logical or food safety reason that the simple fact of performing an activity using mechanical equipment should place that activity outside the farm definition.

- If FDA is attempting to draw a distinction based on the location at which drying occurs (e.g., in the field vs. in a structure), AHPA notes that many of the activities included in the proposed definitions of harvesting, packing, and holding will occur inside structures. There is no logical or food safety reason that the simple fact of performing an activity inside a structure should place that activity outside the farm definition.

AHPA strongly urges FDA that if specific limitations on "drying/dehydrating to create a distinct commodity" are intended, these should be clearly stated in the text of the regulation itself; but AHPA also strongly urges that any such limitations must be based on logic and food safety, not arbitrary and unrelated considerations such as the pre-existing division of responsibility between FDA and the Environmental Protection Agency (EPA) with respect to antimicrobials.

5) AHPA believes the FDA-EPA policy interpretation that any activity which creates a distinct commodity is food processing leads to strange and confusing outcomes. For example, the activity "drying grapes on the vine to make raisins" would, to any outside observer, appear to be the farthest thing from "food processing," yet that is how it is classified under the FDA-EPA policy interpretation.[9]

AHPA recognizes that the resulting distinction is useful from a food safety standpoint because it provides a convenient way for FDA to specify that dried produce, which is often consumed without cooking or other further processing, is subsequently subject to Part 117 Subpart B, as opposed to other dried food crops which remain RACs, are normally subject to cooking or processing prior to use, and are exempt from Subpart B. However, AHPA believes there are more logical ways to accomplish this outcome - such as the distinction based on produce vs. non-produce[10] crops outlined in the previous sentence - than by creating counterintuitive and confusing classification systems. AHPA does not insist on this point, since it appears FDA is disinclined to make concessions in this area; but AHPA respectfully

[9] EPA/FDA Joint Policy Interpretation, 1998.

[10] For brevity, AHPA uses the term “non-produce botanicals” to refer to all botanical RACs which are intended for human consumption but are not produce, i.e. grains, dry legumes, algae, and those used as or for dietary ingredients, spices, colorants, flavorings, and excipients. For further information see AHPA's previous comments to the originally proposed Produce Safety Rule regarding the definition of the word “produce.”

suggests that if FDA were to rethink its approach it would greatly improve the effectiveness of the Rule by enabling both FDA inspectors and the regulated industry readily to comprehend what the Rule says.[11]

In view of all the above, AHPA suggests the following revisions to the definition of "farm":

> *Farm* means an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes establishments that, in addition to these activities:
>
> (i) Pack or hold raw agricultural commodities;
>
> (ii) ~~Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and~~ Dry/dehydrate raw agricultural commodities using sun, heat, light, and/or air[12], and package and label such commodities without additional manufacturing/processing;
>
> (iii) Package and label raw agricultural commodities, without additional manufacturing/processing; and
>
> (iv)~~(iii)~~ Manufacture/process food, and pack or hold processed food other than raw agricultural commodities that have been dried/dehydrated to create a distinct commodity, provided that~~:(A) A~~ all food used in such activities is consumed on that farm or another farm under the same ownership~~; or(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and (2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing~~.

With respect to FDA's request for comment regarding whether "in one general physical location" should be included in the definition, and if so then how it is to be interpreted: AHPA believes that whether or not this phrase is included, "farm" must be interpreted as a very limited geographic area. In particular, it is important for purposes of the GMP-HA/PC and FSVP Rules that the soil, water, air, and climatic conditions on a "farm" be reasonably consistent, as these factors may affect the hazard analysis for foods sourced from the farm. AHPA does not mean this to imply that, say, a farm consisting of 5

[11] For example, AHPA is aware of a recent instance in which an FDA inspector was uncertain as to whether drying of harvested material that did not create a new commodity required facility registration.

[12] To avoid confusion, AHPA believes the means of drying/dehydrating must be specified, and AHPA believes there is no food safety reason to exclude use of heat or air, especially if sun and light are to be permitted. If there are food safety reasons that certain related activities must be excluded, these limitations should be stated in the definition.

contiguous acres under the same ownership should be divided into separate "farms" due to differences in soil type or water supply on different parts of the property; only that separate locations which are not in close proximity to each other should not be considered the same "farm."

With respect to FDA's request for comment regarding whether a farm supplying produce to another farm that will pack or hold that produce should provide to the farm that receives the produce its name, complete business address, and description of the produce in any individual shipment, AHPA believes this would be appropriate but only if the second farm is not co-owned.

4. Definition of "packaging"

AHPA supports the proposal that all "placing food into a container that directly contacts the food and that the consumer receives " be defined as "packaging" (rather than classified as "packing" under certain circumstances), so long as "packaging" of RACs is included as a farm activity that does not require registration of the farm nor compliance with Part 117, because this change removes the confusion that previously surrounded the distinction between "packing" vs. "packaging."

However, AHPA is concerned that with this change, the various activities that farms (and others) have traditionally performed in connection with "placing food into containers" will, with the proposed revision to the definition, be henceforth classified as "manufacturing/processing" if the container is a retail container rather than a non-consumer container. AHPA believes this would create an inappropriate new limitation on farm activities and would be highly problematic.

For example, if washing of raw agricultural commodities (RACs) during packing is part of "packing" (an interpretation which AHPA strongly supports), then it should not be a "manufacturing/processing" activity when performed during packaging. The definition of "packaging" must include the same "incidental activities" as "packing" does, otherwise the net effect will be to constrain farm activities in ways which have not existed in the past.

AHPA therefore proposes the following revision to the proposed definition of "packaging":

> Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives. <u>Packaging includes activities performed incidental to packaging the food, such as those listed as examples in the definition of "packing."</u>

5. Definitions of "harvesting," "holding," and "packing"

In the supplemental notices of proposed rulemaking for the proposed GMP-HA/PC and Produce Safety Rules, FDA proposes to define "harvesting," "holding," and "packing" as follows:

> *Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, field coring,[13] washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.
>
> *Holding* means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
>
> *Packing* means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

AHPA strongly agrees with the removal in the supplemental notices of limitations related to "farms under the same ownership."

[13] "Field coring" is included in the revised proposed definition in the supplemental GMP-HA/PC Rule in proposed §§ 1.328 and 117.3, but not in the in the revised proposed definition in the supplemental Produce Safety Rule in proposed § 112.3. For consistency, AHPA recommends "field coring" be added to the latter.

However, AHPA does have significant concerns about the revised proposed definitions. AHPA has previously submitted extensive comments regarding the initial proposed definition of "harvesting." Building on our earlier comments, the following responds to FDA's revised proposed definitions of "harvesting," "holding," and "packing."[14]

1) AHPA believes these definitions are unclear and confusing to the average reader, especially insofar as the scope of the specified activity is delimited using the clause "does not include activities that transform a raw agricultural commodity [RAC], as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act." The average reader will have no idea what this clause is meant to convey.

The boundary between activities that do or do not transform a RAC into a processed food has been the subject of much discussion and FDA has developed policies on this topic in conjunction with EPA[15]; the distinction largely hinges on whether or not the activity creates a new commodity (e.g., drying of grapes into raisins). Such information needs to be brought into the text of the Rules themselves, not relegated to separate policy documents where the regulated industry will not know to look, and where furthermore the interpretations are subject to change without notice and comment.

2) The definitions need to encompass the full range of activities traditionally performed by farmers to prepare their crops for use as food as well as for storage, packing, and transportation. The existing definitions are too narrow and fail to include many on-farm activities commonly used in the harvesting, packing, or holding of non-produce botanicals. Non-produce botanicals often require drying; peeling to isolate the desired plant part (e.g., mace, bergamot, cocoa); cutting, slicing, or other size reduction to facilitate peeling, drying, handling, packing, or storage; freezing (e.g., vanilla) to kill the plant tissues, arrest further development, and initiate enzymatic processes or to control insects; wet or dry heat treatment to kill plant tissues (e.g., vanilla), arrest further development, initiate or deactivate enzymatic processes, reduce microbial loads, control insects, or for drying; water treatments to soften woody or fibrous plant parts to facilitate isolation of the desired plant part as well as cutting, slicing, straightening, or flattening; and/or aging or fermenting (e.g., allspice, vanilla, cocoa). When performed on non-produce crops, these activities do not create a new commodity and must be acknowledged as legitimate farm - not food processing - activities.

[14] A complete discussion of concerns with the proposed definition can be found in Comment #5 of AHPA's previous comments to the originally proposed GMP-HA/PC Rule, which is hereby incorporated by reference.

[15] EPA/FDA Joint Policy Interpretation, 1998.

3) The FDA policies on which the definitions are based need to be self-consistent. At the current time, FDA both states categorically that "heat treatment" is a food processing activity[16] (i.e., it transforms a RAC into a processed food and is outside the farm definition) and also states categorically that activities traditionally used by farmers to prepare the crop for use as food are farm activities (i.e., do *not* transform a RAC into a processed food and are inside the farm definition). However, many farm activities do involve heat treatment (e.g., drying of grains or spices; killing of vanilla pods by immersion in hot water to initiate fermentation; heat treatment of oranges, melons, etc. to reduce chilling injury and/or control fungi during storage or packing;[17] or heat treatment of dry RACs to control pests during storage or packing[18]). "Heat treatment" is not a food processing activity when used on a farm for purposes consistent with farm operations, and this needs to be stated plainly so that inspectors, auditors, farmers, and their customers are provided with clear, self-explanatory, self-consistent information on which to base their evaluations and decisions.

4) It is critical that farmers not misunderstand the scope of "food processing" such that they alter their normal activities in deleterious ways, as may occur if there is the erroneous perception that common farm activities now constitute "food processing" and are subject to Part 117. For example, farmers should not be required to substitute use of fumigants or other chemicals in place of heat or cold treatments to control pests and microbes in order to avoid being regulated as a "food processing facility." AHPA emphasizes in the strongest possible terms that farmers must be permitted to continue using thermal treatments to control pests and microbes; and that to classify these activities as "food processing" subject to facility registration and Part 117 requirements will create pressure on farmers to switch to use of chemical treatments, which will be wholly counterproductive not only from a food safety standpoint but also from an environmental, consumer safety, employee safety, marketing (e.g. “organic”), and regulatory compliance point of view.[19] The ongoing development of insect resistance to fumigants such as phosphine, and the phasing out of fumigants such as methyl bromide, make the option to use thermal treatments even more essential.[20]

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[16] In the Preamble to the original proposed GMP-HA/PC Rule, FDA states that delivering a heat treatment “has been, and would continue to be, classified as manufacturing/processing outside the farm definition.” Federal Register, Vol. 78, No. 11, January 16, 2013, page 3684.

[17] Such treatments are used and/or are being explored for a wide variety of crops, even very delicate ones; see for example "Effect of Postharvest Short Hot-Water Rinsing and Brushing Treatment on Decay and Quality of Strawberry Fruit," Jing, W. et al., J. Food Quality, 33 (2010) 262-272; "Hot water and curing treatments reduce chilling injury and maintain post-harvest quality of 'Valencia' oranges," Erkan, M. et al., Int. J. Food Sci. Tech. 2005, 40, 90-96; and "Thermal Control of Fungi in the Reduction of Postharvest Decay" in *Heat Treatments for Postharvest Pest Control: Theory and Practice.* Tang, J. et al. CAB International, Cambridge, MA, 2007.

[18] "Disinfestation of Stored Products and Associated Structures Using Heat," in *Heat Treatments for Postharvest Pest Control: Theory and Practice.* Tang, J. et al. CAB International, Cambridge, MA, 2007.

[19] Many crops have no tolerance established for such chemicals.

[20] "Disinfestation of Stored Products and Associated Structures Using Heat," in *Heat Treatments for Postharvest Pest Control: Theory and Practice.* Tang, J. et al. CAB International, Cambridge, MA, 2007.

Thermal treatments are recognized as among the most environmentally safe treatments to maintain quality.[21] AHPA suggests that if FDA continues to insist that thermal treatments are of necessity "food processing" then this requires an environmental assessment and impact statement to account for the effects of the widespread increased fumigant use that may result when farmers find it necessary to switch from use of thermal controls to chemical controls to avoid the costly burdens of Part 117.

5) With respect to the proposal to include "field coring" as an example of "harvesting," AHPA does not oppose this addition, nor the proposed exemption from Subpart B provided in 117.5(k)(1)(v) for "hulling, shelling, and drying nuts." These provisions appear to have been inserted into the proposed Rule in recognition of specific farming operations (i.e., lettuce growing and nut production). AHPA supports inclusion of these commodity-specific farm activities in the definition of “harvesting” but believes the Rule should not be written in a piecemeal fashion to individually address one or another farming operation. Rather, the Rule should be written to generally, accurately, and unambiguously reflect the full range of activities commonly performed on the full range of types of farms that exist.

6) AHPA disagrees with FDA's statement that "fermenting cocoa beans and coffee beans should be classified as 'holding' rather than as 'harvesting,' because fermentation generally happens after cocoa beans and coffee beans are removed from the plants." (a) This reasoning equates "harvesting" with "removal from the plant," whereas in fact, by definition, harvesting includes not only removal from the plant but also a wide variety of other activities. (b) Fermentation of crops such as cocoa and vanilla is necessary to prepare the crop for use as food. It may be true that fermentation normally requires "holding" for a period of time, but "holding" is not the purpose; if these crops were suitable for use as food without fermentation, farmers would gladly omit the holding step so as to minimize their expenses and recoup their investment more quickly. (c) In many cases, these steps are performed in the field, rather than in a structure or even in containers.

8) AHPA notes that Table 5 ("Changes in Classification of Activities Conducted on Farms or on Farm Mixed-Type Facilities Based on the Proposed Revisions to the 'Farm' Definition") is very helpful in elucidating FDA's thinking regarding various activities. AHPA requests that this Table 5, or similar Table 1 ("Classification of Activities Conducted On-Farms and Farm Mixed-Type Facilities") in the Appendix to the revised Proposed Rule, be significantly expanded with additional examples; that the general ideas contained in these Tables be incorporated directly into the definitions; and that at least one of these Tables be made prominently available on FDA's website wherever the public seeks out information regarding Part 112 or Part 117.

To be most inclusive of a very broad range of types of farms and in view of all the above, AHPA therefore strongly urges the following revisions to the definition of harvesting:

[21] "Hot water and curing treatments reduce chilling injury and maintain post-harvest quality of 'Valencia' oranges," Erkan, M. et al., Int. J. Food Sci. Tech. 2005, 40, 90-96.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act; that is to say, harvesting does not include activities which transform the raw agricultural commodity normally sold in the US into a separate commodity, such as the drying of grapes into raisins.

(i) For raw agricultural commodities which are animals or produce, common examples of harvesting activities include but are not limited to g~~G~~athering, field coring,[22] washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities ~~another farm under the same ownership are examples of harvesting~~. Other activities performed on animals or produce, such as cutting, peeling, slicing, drying, or heating are generally excluded from the definition of harvesting, as these transform the raw agricultural commodity into a processed food.

(ii) For botanical food commodities which are not produce, examples of harvesting activities include but are not limited to:

(a) Activities (e.g., peeling) which isolate the desired commodity from other parts of the plant;

(b) Cutting, slicing, or other limited size reduction to facilitate handling;

(c) Temporary freezing to kill the plant tissue and/or insects;

(d) Use of hot or cold water or steam to soften fibrous or woody materials;

(e) Wet or dry heat treatment (such as blanching, steaming, or hot dry air) to kill the plant tissue, activate or deactivate enzymatic processes, or reduce microbial loads);

(f) Aging, curing, conditioning, sweating, or fermentation, when these are a traditional part of preparing the crop for use as food; and

(g) Drying of botanicals other than produce using sun, light, heat, and/or air;

(h) Limited size reduction to facilitate drying of botanicals other than produce;

(i) Washing in the field;

(j) Other activities traditionally used by farmers to prepare a raw agricultural commodity for use as food, so long as these are performed on raw agricultural commodities.

[22] AHPA supports the addition of "field coring" and believes it should be added in every section where "harvesting" is defined, i.e., it should be added to § 112.3.

AHPA suggests the following changes to the revised proposed definition of "holding," for clarity and completeness:

> *Holding* means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food ~~(such as blending of the same raw agricultural commodity, and breaking down pallets))~~, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding ~~facilities could include~~ structures such as warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks are "facilities" for purposes of paragraph 1.225 of this part except when located on a farm.[23] Examples of activities included within this definition include:
>
> (i) Blending of the same raw agricultural commodity;
> (ii) Wet or dry thermal or chemical treatments to control pests or microbes during storage;
> (iii) Wet or dry thermal treatments to deactivate enzymatic activity during storage of botanicals other than produce;
> (iv) Thermal treatment to reduce chilling damage during storage;
> (v) Breaking down pallets.

AHPA suggests the following changes to the revised proposed definition of "packing," for clarity and completeness:

> *Packing* means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food ~~(such as sorting, culling and grading)~~), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of activities included within this definition include:
>
> (i) Sorting, culling, and grading;
> (ii) Wet or dry thermal or chemical treatments to control pests or microbes, when performed during packing rather than as part of a manufacturing/processing activity;
> (iii) Wet or dry thermal treatment to reduce chilling damage, when performed during packing;
> (iv) Cutting of botanicals (other than produce) to fit containers;

[23] FDA's original sentence ("Holding facilities could include...") was ambiguous as to its interpretation and potentially confusing; therefore AHPA proposes clearer language.

(v) Use of water for washing, or to soften plant tissues to facilitate flattening, straightening or cutting for packing.

AHPA also provides the following comments and suggested changes to Table 5, and repeats its request that this Table be prominently featured on the FDA website in connection with Parts 112 and 117:

Activity	Classified in 2013 Proposed Preventive Controls Rule	Classified in Supplemental Notice of Proposed Rulemaking	AHPA Comments
Cooling	Harvesting; (§ 117.3); Mfg 1/ Processing (§ 117.3)	• Harvesting (e.g., hydrocooling leafy vegetables in the field) • Packing (e.g., hydrocooling in a packing shed) • Holding (e.g., cold storage) • Mfg/processing (e.g., refrigeration of processed food)	AHPA supports the proposed changes
Drying / Dehydrating ~~(incidental to holding)~~	Packing or Holding (Tables 4 and 5)	• ~~Holding~~ Harvesting (e.g., drying hay~~, or~~ alfalfa, wheat, allspice berries, orris rhizome, or cinnamon bark)	AHPA disagrees that "drying/dehydration" should be classified as "holding." "Incidental to holding" should be deleted because drying/dehydrating may be necessary to prepare the crop for use as food. AHPA does not oppose deletion of "packing."AHPA believes additional examples are needed. Collectively, "drying/dehydration of botanical commodities other than produce"
Drying / Dehydrating to create a Distinct commodity (transforms a RAC into a Processed food)	Mfg/ Processing (Tables 4 and 5)	• Mfg/processing (e.g., drying grapes to create raisins, and drying culinary herbs to create a distinct commodity) (because it transforms a RAC into a processed food) (but allowed within the farm definition)	AHPA supports allowing this activity within the farm definition. AHPA believes it important that "herbs" be stated as "culinary herbs" to avoid confusion, as most drying of herbs does not create a distinct commodity.
Fermenting ~~cocoa beans and coffee beans,~~ sweating, curing, conditioning, or aging when traditionally used to prepare the crop for use as food	Harvesting (Footnote 2 in Table 23 of the draft Risk Assessment (Ref. 16))	• ~~Holding~~ Harvesting (e.g., cocoa beans, coffee beans, allspice berries, vanilla pods, mace aril)	AHPA disagrees that these should be classified as "holding." AHPA also believes additional examples are needed to represent the broader category of activities, e.g., fermenting of allspice berries; sweating, curing, or

			conditioning of vanilla pods; curing of mace aril; collectively, "fermenting, sweating, curing, conditioning, or aging of botanical commodities other than produce"
Field coring	N/A	• Harvesting (e.g., coring lettuce in the field)	AHPA supports this change, and urges FDA to make the definitions and Table as comprehensive as possible
Filtering	Harvesting (§ 117.3)	• Harvesting (e.g., filtering honey) • Packing (e.g., before packing honey)	AHPA supports the additional category
Removing stems and husks	Harvesting (§ 117.3)	• Harvesting (e.g., in the field) • Packing (e.g., in a packing shed)	AHPA supports the additional category
Sifting	Harvesting (§ 117.3)	• Harvesting (e.g., in the field) • Packing (e.g., in a packing shed)	AHPA supports the additional category
Using pesticides in wash water	Harvesting (Table 5)	• Harvesting (e.g., in the field) • Packing (e.g., in a packing shed)	AHPA supports this change, but believes use of heat and cold must also be allowed for similar purposes.
Washing	Harvesting (§ 117.3), and Mfg/ Processing (§ 117.3)	• Harvesting (e.g., in the field) • Packing (e.g., in a dump tank or flume in the farm's packing shed) • Mfg/processing (e.g., during production of fresh-cut produce)	AHPA supports the additional categories
Peeling of botanical commodities other than produce to isolate the desired plant part		• Harvesting (e.g., peeling to isolate cinnamon bark, mace aril, nutmeg seed, or bergamot orange peel; removal of skin from orris rhizome)	"Harvesting" in this case must not be limited to "in the field"
Cutting, slicing, or other limited size reduction of botanical commodities other than produce to isolate the desired plant part or to facilitate handling, packing, and/or holding		• Harvesting (e.g., cutting bark to lengths practical for handling; cutting roots away from orris rhizomes; cutting, chopping, splitting, or slicing to facilitate drying) • Holding (e.g., cutting, chopping, or slicing to facilitate drying) • Packing (e.g., cutting large or irregularly-shaped dried items to fit packaging)	"Harvesting" in this case must not be limited to "in the field"
Temporary freezing of botanical commodities other		• Harvesting (e.g. freezing to kill vanilla pod tissues)	"Harvesting" in this case must not be limited to "in the field"

than produce to kill plant tissues, arrest further development, disrupt cellular structures, initiate enzymatic processes, or minimize pests		• Holding (e.g., freezing to kill insects)	
Wet or dry heat treatment of botanical commodities other than produce to facilitate drying, kill plant tissues, arrest further development, disrupt cellular structures, initiate or deactivate enzymatic processes, minimize pests or minimize microbial loads		• Harvesting (e.g. use of hot water to kill vanilla pod tissues and initiate enzymatic processes; use of heated air to speed drying of roots or bark that are not produce) • Holding (e.g., heating to kill insects, or minimize fungal contamination) • Packing (e.g., heating during packing to kill insects or minimize fungal contamination)	"Harvesting" in this case must not be limited to "in the field"
Wet or dry heat treatment to reduce chilling damage or microbial loads		• Holding • Packing	
Water treatment of botanical commodities other than produce (e.g., steaming, soaking, scalding) to soften plant tissues		• Harvesting (e.g. soaking or scalding to facilitate removal of outer layers) • Holding (e.g., softening to facilitate cutting or slicing prior to drying) • Packing (e.g., softening to facilitate flattening, straightening, or cutting prior to packing)	"Harvesting" in this case must not be limited to "in the field"
Shelling of nuts; shelling of botanical commodities other than produce		• Harvesting (e.g. shelling of nutmeg seeds)	"Harvesting" in this case must not be limited to "in the field"
Use of modified storage atmospheres to minimize pests in bulk commodities		• Holding (e.g., holding grains in bulk under high carbon dioxide, high nitrogen, or low oxygen atmospheres to minimize insects)	
Grading and sorting		• Packing (e.g. sorting or grading of coffee beans or nutmeg kernels by floating in water; use of sieves to separate items by size)	

6. Comments regarding testing as a preventive control

AHPA is concerned that FDA does not appear to recognize testing of raw materials and ingredients as an effective preventive control for certain types of hazards. The revised proposed Rule lists testing of raw

materials and ingredients as an element of a supplier program, but not as a preventive control in and of itself. FDA furthermore states in the Preamble of the supplemental notice to the Foreign Supplier Verification Program (FSVP) Rule, "We do not believe...that supplier verification activities actually control hazards. Rather, a key purpose of verification is to provide assurance that hazards are being effectively controlled by the foreign supplier or some other entity." This implies that raw material testing can never "actually control hazards" and can never serve as a preventive control.

AHPA understands that, in the context of traditional HACCP, a "control" is primarily considered to be not the analysis of an attribute of a food but rather an element of the facility's operations, such as heating to a specified temperature for a specified length of time to kill pathogens; use of sieves and metal detectors to remove physical contaminants; use of solvent/solvent (e.g., water/oil) partitioning to remove hydrophilic or hydrophobic chemical contaminants from a liquid food; or storing hazardous chemicals away from food processing areas. However, AHPA believes that in modern food safety systems the concept of a "control" must be expanded to include raw material and ingredient testing at least with respect to chemical testing. While it may be true that testing cannot "actually control hazards" such as pathogens or metal fragments, testing of raw materials/ingredients is both effective and also often the best means of controlling a hazard such as lead. Indeed, regulations such as those set forth in 21 CFR Part 111 and 21 CFR Part 106 explicitly acknowledge that proper evaluation of raw materials and ingredients is an important element of control. One cannot heat or sift the lead out of a raw material;[24] one can only exclude it from the food through proper control of the raw materials/ingredients used, and in many cases the most effective means to do so is to perform testing of the raw material/ingredient.

In cases where testing, alone or in combination with other controls, serves to adequately control the hazards in raw materials and ingredients, AHPA believes the receiving facility should have no obligation to implement a supplier program as outlined in the revised proposed Rule. Indeed, given the proposed definition of supplier (either as originally proposed by FDA or as suggested by AHPA in comment 9.2 below), AHPA believes that it will in many cases be impossible to implement a supplier program since the identity of the supplier will be unknown to the receiving facility and to the intermediary that provides raw materials or ingredients to the receiving facility.

As an example, consider a receiving facility that manufactures ginger candy that is marketed to children. The receiving facility's hazard analysis has determined that pathogens and lead are the two hazards requiring control in its product. The receiving facility controls pathogens by thermal processing, and controls lead by testing each lot of ginger root raw material for lead content. In such a case, the identity and control practices of the ginger root supplier (whether a farm or a processing facility) are irrelevant, and the receiving facility should not have to incur any expenses implementing a supplier program for the ginger root supplier (assuming it is even possible to identify the supplier).

[24] For certain types of foods it is possible to remove lead during processing, but this is rare.

This is not meant to imply that such raw material testing for lead should be required. It is quite possible that another receiving facility making similar ginger candy with the same two hazards could use thermal processing to control the pathogens and use a supplier program to control the lead. For example, if the receiving facility or processor of the ginger root knows the identity of the farm where the ginger is grown, then lot-by-lot testing of incoming ginger root lots would be unnecessary; it should be sufficient for the receiving facility to occasionally verify the lead content of the ginger root and/or to rely on a certificate of analysis provided by the processor. This is because the lead content of the ginger root is determined by the soil, water, and air conditions on the farm and therefore will remain generally consistent over time.

AHPA therefore proposes that § 117.135(c)(4) be renumbered, and new (4) be inserted as follows:

> (4) <u>For raw materials and ingredients received by a receiving facility, testing lots of raw materials and ingredients prior to use;</u>

7. Comments regarding the scope of supplier verification activities

7.1 General comments

AHPA appreciates that the hazard analysis and supplier verification elements common to the GMP-HA/PC Rule and the FSVP Rule have been harmonized to the extent appropriate given the somewhat different purpose of the Rules and the associated statutory language. However, AHPA notes with concern elements of these Rules as currently proposed.

In particular, the Preamble to the original version of the proposed FSVP Rule stated the Rule was intended to "focus on foreseeable food safety risks identified through a hazard assessment process, rather than all risks covered by the adulteration provisions in section 402 of the FD&C Act." AHPA believes this to be an appropriate focus for both the FSVP Rule and the GMP-HA/PC Rule.

However, in addition to requiring verification that a supplier controls identified hazards, the supplier program delineated in the newly-proposed GMP-HA/PC Rule also requires the receiving facility to evaluate whether the incoming raw material or ingredient is "adulterated under section 402" and the supplier produced it in compliance with applicable FDA food safety regulations.[25]

AHPA believes this broad scope to be inappropriate for a number of reasons. To begin with, various "technical" cGMP violations do not pose a significant public health risk and are not amenable to discovery by outside parties. For example, minor cGMP violations may occur (e.g., minor deficiencies in

[25] AHPA furthermore notes that it is not completely clear, in view of § 117.1(a), whether FDA considers any failure to comply with regulations implementing section 418 of the FDCA to constitute adulteration under section 402 of the FDCA, although it appears from the text of FSMA that Congress does not consider it so.

gowning or paperwork) without causing the food processed in a facility to actually be hazardous; furthermore, no matter how many audits or how much testing is performed, there is no way for an outside party to guarantee that such technical cGMP violations never occur.

In addition, under certain circumstances the currently-proposed requirements may inappropriately preclude receiving facilities or importers from approving a supplier. For example, suppose a receiving facility or importer has determined that there are two hazards to be controlled in the food that it processes, pathogens and lead. The facility/importer controls pathogens through thermal processing and controls lead by relying on its supplier's Certificate of Analysis. It is therefore required to implement a supplier program. As part of its supplier verification activities, the facility/importer discovers that the supplier does not have adequate controls for pathogens and perhaps even that food from the supplier in fact contains Salmonella. This would mean the RAC, raw material, or ingredient from the supplier is adulterated because it actually contains Salmonella, or that the supplier is not compliant with Part 117 or other food safety regulations because it is not adequately controlling for the presence of pathogens. As written, the Rule would appear to preclude the receiving facility/importer from approving this supplier, even though the possible presence of pathogens or even the actual presence of Salmonella in the supplier's food is immaterial to the receiving facility/importer since the facility/importer will itself control the pathogen hazard. This is not a logical or practical outcome.

Finally, AHPA believes it inappropriate to create a two-tiered set of requirements, with receiving facilities/importers that rely on a supplier program to control hazards being made responsible for a much wider range of issues than are those that control hazards themselves. For example, if receiving facility A or importer A controls for the presence of lead through testing of each lot, while receiving facility B or importer B relies on the supplier to control the presence of lead and report the results on its Certificate of Analysis, it is inappropriate to make the latter responsible for every element of its supplier's regulatory compliance when the former is responsible only for controlling the lead hazard. To take another example, if receiving facility C or importer C controls for the presence of pathogens through thermal processing of each lot, while receiving facility D or importer D relies on the supplier to control the presence of pathogens (e.g., by performing thermal processing in the supplier's own facility), it is inappropriate to make the latter responsible for every element of its supplier's regulatory compliance when the former is responsible only for controlling the pathogen hazard.

To be clear, AHPA does not disagree that when a supplier is relied upon to control hazards in a given raw material or ingredient or in an imported food, the "supplier risks" should be evaluated in addition to the "hazards requiring control." However, AHPA believes that supplier risks should be evaluated primarily *as they relate to the hazards at issue*. The receiving facility/importer should review (a) the supplier's procedures, practices, and technical expertise as these relate to control of the hazards identified as requiring control by the supplier; and (b) the supplier's diligence and reliability in meeting the obligations it commits itself to. AHPA does not disagree that most of the factors enumerated in § 117.136(b) and § 1.505(a)(1) may be pertinent in this regard and therefore worthy of consideration, but disagrees these factors should be evaluated as broadly as proposed in § 117.136(a)(3)(ii) and § 1.506(c).

7.2 Comments regarding statutory language

AHPA notes that the text of FSMA does not contemplate that a receiving facility should have to ensure that a raw material or ingredient is "not adulterated under section 402" at the time of receipt, but rather that food will not be adulterated when the facility is finished manufacturing/processing it.

FDCA section 418(a) states, "The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice." In explaining the details of how this is to be accomplished, section 418(c) states, "Preventive Controls.--The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that...the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 or misbranded under section 403(w)."

The phrase "the food manufactured, processed, packed, or held by such facility *will not be* adulterated under section 402" (emphasis added) indicates that the issue to be addressed by Section 418 is adulteration which could be caused by the facility itself; if the phrase were intended to apply to raw materials or ingredients received by the facility, the correct verb would be "is" rather than "will be" (as in, "the food...*is* not adulterated").

Thus, AHPA finds that FSMA does not contemplate, much less require, that all raw materials and ingredients received at a food processing facility must be "not adulterated under section 402" at the time of receipt, provided that the receiving facility will itself control the adulterating hazard (although it may through verification activities rely on the supplier to control other hazards).

While it is true that all food suppliers whose crops or processed foods are produced for US consumption are required by law to comply with applicable US food safety regulations, and foods adulterated under section 402 are subject to import refusal and seizure, an efficient food safety system should permit receiving facilities and importers to accept responsibility for controlling potentially adulterating hazards related to supplied raw materials and ingredients.

7.3 Recommended changes to proposed regulatory language

With respect to the GMP-HA/PC Rule, AHPA therefore suggests that § 117.136(a)(3)(ii) should be revised as follows:

(ii) Verification activities and documentation of these activities, as required by paragraph (b) of this section, to verify that:
(A) The hazard is significantly minimized or prevented;
(B) The receiving facility's use of the incoming raw material or ingredient ~~is not~~ will not cause the finished food to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act~~: and~~
~~(C) The incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations~~.

AHPA believes most commenters would agree that (C) should be deleted, since FDA mentions in the Preamble to the GMP-HA/PC Rule that "[m]ost comments do not support...[f]or a receiving facility to identify the regulations to which the supplier is subject (because the distinction would not be material to food safety)."

In addition, AHPA suggests that § 117.136(c)(3)(ii) should be revised as follows:

(ii) Obtains written assurance~~, at least every 2 years~~,[26] that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the receiving facility's use of the raw material or ingredient ~~is not~~ will not cause the finished food to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. ~~The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.~~[27]

In addition, AHPA suggests that § 117.136(c)(4)(ii) should be revised as follows:

(ii) Obtains written assurance~~, at least every 2 years~~,[28] that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the receiving facility's use of the raw material or ingredient ~~is not~~ will not cause the finished food to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

With respect to the FSVP Rule, AHPA objects to the deletion of language that tied the required foreign supplier verification activities specifically to the hazards requiring control. For example, one option for

[26] See comment 13.1 for an explanation of this deletion.

[27] See comment 9.4 for an explanation of this deletion.

[28] See comment 13.1 for an explanation of this deletion.

originally proposed § 1.506 (g) provided, "For a hazard that you have identified as reasonably likely to occur with a food from a foreign supplier and that is not controlled by you or your customer, you must conduct one or more of the verification activities listed in paragraphs (g)(1)(i) through (iv) of this section before using or distributing the food and periodically thereafter. You must determine and document which verification activity or activities are appropriate to adequately verify that the hazard is adequately controlled. You must determine and document how frequently the verification activities must be conducted. In determining the appropriate verification activities and how frequently they should be conducted, you must consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, and the food and foreign supplier's compliance status as reviewed under § 1.504."

AHPA therefore requests that §1.506(a)(1)(iv) be revised as follows:

> (iv) ~~Applicable FDA food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert.~~ Any FDA warning letter or import alert relating to the safety of the food.

AHPA also requests that §1.506(c) be revised as follows:

> Purpose of supplier verification. Your foreign supplier verification activities must provide adequate assurances that the foreign supplier adequately controls all hazards that you have identified as requiring control by the supplier ~~produces the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g, 350h, 342, and 343(w))~~.

7.4 Comments regarding harmonization of the hazard analysis and controls and supplier verification provisions of the GMP-HA/PC Rule and the FSVP Rule

AHPA believes the hazard analysis and controls and the supplier verification provisions of the GMP-HA/PC Rule and the FSVP Rule should be harmonized to the greatest extent possible and appropriate.

However, should FDA determine based on differences in the statutory provisions, the overall purpose of the regulations, or other factors, that one Rule must necessarily impose greater burdens in a particular area than the other Rule, FDA should not harmonize the two Rules with respect to that area. Rather, each Rule should be written in the least burdensome manner possible as appropriate to that particular Rule. In other words, the burdens created in one Rule should not be increased or expanded merely to harmonize with the other Rule.

AHPA furthermore supports deeming any receiving facility or importer that is in compliance with the applicable sections of one Rule to be likewise in compliance with the applicable sections of the other Rule, wherever possible.

With respect to FDA's proposal to exempt an importer that is also a facility subject to the preventive controls regulations from the requirement to conduct foreign supplier verification activities in the FSVP Rule when the facility is exempted from the preventive controls supplier program requirements in the GMP-HA/PC Rule, AHPA strongly agrees with this proposal and agrees that in such cases the foreign supplier verification activities would be an unnecessary and inappropriate burden.

8. Comments regarding hazard analysis in general

8.1 Comments regarding "known or reasonably foreseeable hazards" and "significant hazards"

In the supplemental notice of proposed rulemaking for the proposed GMP-HA/PC Rule, FDA proposes to define "known or reasonably foreseeable hazard" and "significant hazard" as follows:

> *Known or reasonably foreseeable hazard* means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.
>
> *Significant hazard* means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

The term "significant hazard" replaces the following from the original proposed Rule:

> *Hazard reasonably likely to occur* means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.

AHPA has no objection to eliminating the term "hazard reasonably likely to occur," but has a number of comments about the proposed replacement term "significant hazard."

AHPA appreciates that the term "significant hazard" is, in the middle of the definition, tied to the results of a hazard analysis, which presumably would take into account the severity and probability of the hazard (although this is unclear, since the precise nature of the hazard analysis is not specified). However, "significant hazard" is also tied to the term "known or reasonably foreseeable hazard" which merely requires that the hazard have the "potential" to occur. AHPA notes that the previously-proposed term, "hazard reasonably likely to occur," expressly stipulated that there had to be a "reasonable possibility" that the hazard would occur in the absence of controls, which much more clearly established the need to evaluate the risk as well as the hazard.

In addition, it is unclear what is meant by the phrase "...and components to manage those controls...." It is possible that "components" is meant to refer to the components of the food in question (i.e., "a food and its components"). However, it remains unclear what is meant by "a person...would...establish controls to...minimize or prevent the hazard...to manage those controls...." AHPA speculates that "to manage" should be "and manage" (i.e., "a person...would...establish controls to...minimize or prevent the hazard...and manage those controls...").

Finally, AHPA believes the term "significant hazard" is itself likely to be confusing because the adjective "significant" is subject to many interpretations. AHPA suggests the term "hazard requiring control" would be more straightforward, accurate, and suitable.

To improve the clarity of this term for the average reader, AHPA proposes the following changes:

> ~~*Significant hazard*~~ *Hazard requiring control* means a known or reasonably foreseeable hazard which, based on the outcome of the hazard analysis described in § 117.130 of this part, is of sufficient severity and likelihood ~~for which~~ that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would~~, based on the outcome of a hazard analysis,~~ establish controls to significantly minimize or prevent the hazard in a food and its(?) components ~~to~~ and(?) manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

Or, perhaps better yet:

> ~~*Significant hazard*~~ *Hazard requiring control* means a known or reasonably foreseeable hazard which, based on the outcome of the hazard analysis described in § 117.130 of this part, is of sufficient severity and likelihood ~~for which~~ that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would~~, based on the outcome of a hazard analysis,~~ establish controls to significantly minimize or prevent the hazard in a food ~~and components to manage those controls (such as monitoring,~~

~~corrections or corrective actions, verification, and records)~~ as appropriate to the food, the facility, and the control.

In addition, AHPA proposes the following changes to the definition of "known or reasonably foreseeable hazard," both for consistency with the definition given in the revised proposed Foreign Supplier Verification (FSVP) Rule and because the location or type of farm may affect the potential hazards associated with the food grown or raised on the farm. (For example, food sourced from a farm near Chernobyl would potentially have radiological hazards, and the agricultural methods used on a farm can affect the potential hazards to be expected in the farm's products.)

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food, the facility ~~or the food~~ in which it is manufactured/processed, or the location or type of farm on which it is grown or raised.

8.2 Comments regarding § 117.130

With respect to the proposed inclusion of hazards "intentionally introduced for purposes of economic gain" in § 117.130(b)(2)(iii), AHPA agrees it is more practical and appropriate to address such issues as part of the hazard analysis and preventive controls program than it would be to address them along with controls designed to prevent terrorism. However, AHPA emphasizes that such hazards must be subject to the same risk-based evaluation of severity and likelihood as any other hazard. Most importantly, specific controls for such hazards must be required only when the hazard is reasonably likely to occur in the present time (as opposed to historically) and in the country or marketplace at issue (as opposed to globally). For example, while adulteration of green peas with Malachite Green has been reported as occurring in certain countries either currently or within the recent past (measured in some number of years as opposed to decades), AHPA is not aware of any information to indicate such adulteration is likely in the US[29]; therefore, no controls should be required for Malachite Green in green peas sourced from the US. Furthermore, when control of such a hazard is necessary, those controls should apply only to a receiving facility's raw materials and ingredients. In other words, the facility should not be required to implement controls to prevent its own employees from introducing such adulteration; it is very unlikely that an employee of the receiving facility would introduce an economic adulterant unless the management of the facility had made a conscious decision to flout the law, so such a requirement would needlessly burden "good actors" while doing nothing to prevent bad actions by bad actors. AHPA therefore proposes the following revisions to § 117.130(b)(2)(iii):

The hazard may be intentionally introduced into raw materials or ingredients for purposes of economic gain.

[29] AHPA has not made an extensive review of this particular topic and uses it mainly as a theoretical example.

AHPA furthermore proposes the following revisions to § 117.130(a)(1):

> You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility, including hazards in the raw materials and ingredients used in the food, to determine whether there are ~~significant hazards~~ hazards requiring control.

AHPA also proposes the following revisions to § 117.130(c)(1)(i). AHPA believes it important that the Rule acknowledge specific factors that may influence the evaluation of the likelihood or severity of the hazard.

> The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls, including consideration of any relevant geographic, temporal, agricultural, or other factors that may affect the severity or probability of the hazard.

Regarding the proposed inclusion of environmental pathogens in the hazard analysis, AHPA believes that if the finished food is inherently incapable of supporting pathogen survival (e.g., acid or acidified foods) then this should preclude the need for evaluation of environmental pathogens. AHPA therefore proposes the following revisions to § 117.130(c)(1)(ii):

> The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food that is capable of supporting pathogen growth to or survival at infectious levels is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.

AHPA has previously commented on the difficulty of applying the list of factors given in what is currently proposed § 117.130(c)(2) to food that is not ready-to-eat (RTE) food, especially raw materials and ingredients, and the difficulty of determining "the severity of the illness or injury if the hazard were to occur" as mentioned in § 117.130(c)(1)(i). AHPA hereby reiterates its previously-submitted comments on this topic.[30]

[30] See Comment #10.3 in AHPA's previous comments to the originally-proposed GMP-HA/PC Rule.

8.3 Comments regarding § 117.135

Proposed § 117.135(c) provides a list of "preventive controls" that a food processor may use to mitigate hazards. The list includes process controls, food allergen controls, sanitation controls, supplier controls, recall plan, and other controls.

With respect to "food allergen controls" the proposed Rule explicitly stipulates that the control includes "labeling the finished food." AHPA requests that the use of labeling as a preventive control be extended to non-RTE food; i.e., manufacturers of raw materials, ingredients, and other non-RTE food should be explicitly permitted to control hazards by providing proper documentation accompanying the sale of the food, such as a Certificate of Analysis, specification, or other document stating (a) the actual or maximum allowed levels of contaminants or other hazards in the food, and/or (b) any appropriate restrictions on or requirements for use of the food.

For example, the processor of ginger root discussed in the example described in comment 6 above must be permitted to control "lead" as a hazard by disclosing to receiving facilities the lead content of the ginger root that it sells, e.g. in a certificate of analysis. The processor has no other way to control the lead content, as (a) it cannot cook or sift the lead out of the ginger root, and (b) it cannot know whether any particular level of lead poses a health risk since it does not know the purpose for which the ginger root will be used (e.g., lead levels that are perfectly acceptable and even low by normal standards might be excessively high in making candy for children). For further discussion and explanation, refer to comments #2, 9.3,and particularly 10.3 in AHPA's previously-submitted comments to the GMP-HA/PC Rule.

AHPA therefore proposes that § 117.135(c)(5) be renumbered, and new (5) be inserted as follows:

> (5) <u>For finished food that is a raw material, ingredient, or other non-packaged food, appropriately disclosing in the finished food's labeling the actual or potential presence or level of any actual or potential hazards present in the food which receiving facilities may need to consider in their hazard analysis, and/or stating any restrictions or other requirements for the finished food's safe use in or as packaged food;</u>

9. Comments regarding supplier programs

9.1 General comments

AHPA generally supports the outlined supplier program requirements, and appreciates that FDA has provided industry with a high degree of flexibility.

9.2 Comments regarding the definitions of "supplier" and "receiving facility"

In the supplemental notice of proposed rulemaking for the proposed GMP-HA/PC Rule, FDA proposes to define "receiving facility" and "supplier" as follows:

> *Receiving facility* means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.
>
> *Supplier* means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

AHPA is concerned that the definition of "receiving facility" implies the raw material or ingredient must be received directly from the "supplier" without any other companies intervening in the supply chain. Based on the Preamble, this is not what FDA intends the definition to imply.

AHPA therefore suggests the definition of "receiving facility" should be revised as follows for clarity:

> *Receiving facility* means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier, either directly or by means of one or more intermediary firms.

In addition, AHPA is concerned that the proposed definition of "supplier" is, unfortunately, not workable. With respect to farms, in many cases it is impossible to trace any given portion of RAC back to the farm from which it came, especially where farm cooperatives or consolidators are used or where non-produce botanicals are traded internationally. With respect to raw materials and ingredients that are processed foods, it is very common that the food passes through numerous hands on its way from the manufacturer to the end-user of the raw material/ingredient.

There is one fairly common business model which AHPA believes serves well to protect both food safety and the needs of industry. In this model, there is an intermediary between the "original source" (i.e., the manufacturer/processor or farm) of the food and the end-user of the food; this intermediary plays a key role in taking responsibility for meeting the needs of both. On behalf of the "original source" (which is commonly operating in a foreign country and is therefore limited in its access to US customers, ability to communicate in English, understanding of US laws and regulations, etc.) the intermediary will provide services such as education and training if needed; customer development and customer service; etc. On behalf of the "end user" the intermediary will provide services such as taking comprehensive responsibility to ensure the quality and regulatory compliance of the raw materials/ingredients provided to the customer (e.g., by qualifying potential manufacturers or farms; by performing audits; by sampling

and testing of shipments); obtaining technical or other information from the original source; etc. This "key intermediary" may be a farm cooperative, a US importer, or any other firm that is willing and able to assume the responsibilities required. The goods sold by the intermediary are often marketed under the intermediary's name, not the name of the original source. This arrangement has the added benefit of reducing the overall costs in the supply chain, as the "key intermediary" is able to perform the necessary quality assurance functions on large quantities of food and/or on behalf of multiple receiving facilities.

AHPA believes it essential, from a practical standpoint, to permit such intermediaries to function as the "supplier" of the food for purposes of Part 117, because in a very large number of cases the receiving facility will (a) not be given access to the identity of the original source (such information, even if known to the intermediary, is nonetheless often a closely-held business secret given the time, money and energy the intermediary must expend both to locate and qualify the sources and to develop customer relationships with end-users)[31]; (b) not have the expertise necessary to evaluate the operations or regulatory compliance of the original source; (c) not have the language fluency to interact with, or review documentation from, the original source in a meaningful way.

Therefore, AHPA proposes the definition of "supplier" be revised as follows:

> *Supplier* means <u>(i)</u> the <u>original</u> establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature<u>; or (ii) an intermediary that takes responsibility on behalf of the receiving facility to ensure the food sourced from the original establishment meets the requirements of this part</u>.

To be clear, AHPA envisions that if an intermediary serves as the supplier to the receiving facility by taking responsibility to ensure the safety of the food sourced from the original establishment, then the receiving facility's supplier program would need to focus on audits of the intermediary or other activities that verify that the intermediary is fulfilling its role properly.

Thus, in response to FDA's request for comment regarding how supplier verifications should be implemented in supply chains that involve multiple non-food-processing establishments between the receiving facility and the "original source" of the food (i.e., either a farm or a manufacturer/processor) and in which the "original source" is relied upon to mitigate the hazards, AHPA suggests that industry be provided with at least two options: (a) the receiving facility implements the supplier verifications, or (b) the receiving facility delegates responsibility for the supplier verifications to an entity farther upstream

[31] No matter what contractual agreements are in place to prohibit it, once the original source and the end user are known to each other it can be very difficult to prevent circumvention of the intermediary. It is difficult to enforce contracts in foreign jurisdictions, and it is expensive to enforce contracts in the US.

who is in a better position to effectively, efficiently, and economically perform the necessary supplier verification functions. FDA does not need to impose the supplier verification requirements in (b) on any particular intermediary entity (much less on all intermediary entities!); if option (b) is available under the Rule, AHPA believes there will be no shortage of firms willing to voluntarily assume responsibility to perform this function on behalf of their customers who are receiving facilities.

AHPA cautions, however, that even if allowances are made for an intermediary to take responsibility to ensure the safety of the food sourced from the original establishment, there will still be many circumstances in which the identity of the original establishment will NOT be able to be determined either by the receiving facility or by any intermediary more than one step removed from the original establishment. Therefore, it is critically important that the Rule be written in a manner that allows raw material/ingredient testing to serve as a preventive control (see comment 6 above).

9.3 Comments regarding § 117.136(a)(1)(i)

As discussed in comment 8.3 above, AHPA believes it important for the Rule to specify that raw material and ingredient vendors may control hazards by providing buyers with documentation of the existence and/or level of the hazard, such as in a Certificate of Analysis provided to receiving facilities. Thus, provision of such documentation constitutes "control before receipt of the raw material or ingredient."

With this in mind, AHPA believes § 117.136(a)(1)(i) should be revised as follows:

> Except as provided in paragraph (a)(1)(ii) of this section, the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient, <u>including when the receiving facility relies on the supplier's documentation described in</u> [new proposed, see comment 8.3 above] <u>§ 117.135(c)(5)</u>.

9.4 Comments regarding § 117.136(a)(1)(ii)(C)

With respect to proposed § 117.136(a)(1)(ii)(C), AHPA believes it impractical, unnecessary, and onerous to require the receiving facility to obtain "written assurance that the customer has established and is following procedures...that will significantly minimize or prevent the hazard" on an annual basis.

(a) The proposed Rule requires that the written assurance must identify the procedures the customer will use to significantly minimize or prevent the hazard, which raises the question of whether the receiving facility is required under the Rule to evaluate the adequacy of the customer's procedures. It is not at all clear that the receiving facility will be able effectively to do so; the customer may not be willing to provide sufficiently detailed information (i.e., by omitting confidential, proprietary, and/or trade

secret information) to enable a meaningful evaluation, and it may not be possible to fully evaluate adequacy without knowledge of the customer's prerequisite programs, equipment and facility design, etc.

The provision also raises concerns about the impacts of an FDA assertion or a court determination that the customer's procedures were inadequate. In such a case, the receiving facility may be alleged to have been "on notice" of the inadequacy of the customer's procedures based on the assurance's description of them, and therefore subject to enforcement action or civil liability stemming from an alleged failure to comply with Part 117 or otherwise. AHPA notes that established forms of an FD&C Act guaranty, such as those described in 21 CFR § 7.13, are forward-looking rather than backward-looking (i.e., they are provided by a vendor to a buyer, not by a buyer to a vendor). Therefore the receiving facility will not have the same legal protections from liability claims arising from the customer's acts, as the customer has for the receiving facility's acts. Given the potential barriers to conducting adequacy assessments, and this potential for legal exposure, FDA should (if the requirement to obtain written assurances is maintained in the final Rule) disclaim any implied or constructive requirement to evaluate a customer's procedures' adequacy. However, in the absence of such a requirement it is clear that the written assurance will not serve a function in protecting the public health and should therefore be omitted from the final Rule. AHPA strongly opposes the imposition of requirements that are mere paperwork exercises that yield no meaningful public health benefits.

(b) Many firms have hundreds or thousands of customers, so this provision represents an extremely large paperwork burden - especially if the receiving facility is required to evaluate the adequacy of the customer's procedures, either by regulation or in order to protect itself against liability claims.

(c) The proposed "identification of procedures" does not make sense for many hazards. For example, the customer can address the potential presence of pathogens or metal fragments through procedures such as appropriate heat treatment or sieving. On the other hand, many chemical contaminants (e.g., lead) are not controlled through easily described "procedures" but rather are controlled through product formulation (e.g., controlling the levels of contaminants in each ingredient depending on the proportion of the ingredient in the finished food), serving size, etc., and chemicals that require control in one context may not require control in others (e.g., based on whether a food's target consumer consists of adults or children). AHPA believes customers are unlikely to be willing to provide the receiving facility with confidential information about the customer's own hazard analysis with respect to sensitive topics (e.g., how much lead it has decided to allow in its finished products, or how its product formulation controls the level of lead in its finished food). Furthermore, in such cases the receiving facility will not even know whether the chemical contaminant constitutes an actual "hazard" for the purposes of the customer's finished food.

AHPA therefore suggests that § 117.136(a)(1)(ii)(C) should be revised as follows:

> The receiving facility relies on its customer to control the actual or potential hazard and provides documentation to notify its customer of the existence of the actual or potential hazard, in accordance with [new proposed, see comment 8.3 above] § 117.135(c)(5) ~~annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard~~.

Alternately, if FDA is insistent that written assurance must be obtained from the customer, AHPA believes such assurance should be required no more than once at the beginning of the relationship between the receiving facility and its customer, and must not implicitly or explicitly require the receiving facility to evaluate the adequacy of the customer's procedures. In this case AHPA suggests that § 117.136(a)(1)(ii)(C) should be revised as follows:

> The receiving facility relies on its customer to control the actual or potential hazard, provides documentation to notify its customer of the existence of the actual or potential hazard in accordance with [new proposed, see comment 8.3 above] § 117.135(c)(5), and ~~annually~~ obtains from its customer written assurance that the customer ~~has~~ will evaluate the hazard and if necessary will establish and follow ~~established and is following~~ procedures ~~(identified in the written assurance)~~ that will significantly minimize or prevent the hazard.

AHPA notes that according to proposed § 117.136(a)(1)(ii), supplier programs are not required in all circumstances. AHPA therefore proposes that §§ 117.136(a)(2) and (3) should be revised as follows:

> (2) The supplier program, if required, must be written.
> (3) The supplier program, if required, must include:

9.5 Comments regarding § 117.136(a)(5) and § 117.136(b)

AHPA finds § 117.136(a)(5) to be confusing since it seems to imply that § 117.136(b) discusses the "conduct" of verifications activities, but as written paragraph (b) only requires them to be "determined and documented." AHPA therefore suggests § 117.136(a)(5) be deleted and the following revisions to § 117.136(b) for clarity and for consistency with language proposed in comment 7.3 above:

> ~~(5) For some hazards, in some situations under paragraph (b) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented~~.
> (b) Determination ~~and documentation~~ of the appropriate verification activities or combination of verification activities and of the frequency at which each verification activity must be conducted in order to adequately assure the hazard is significantly

minimized or prevented. These determinations must be documented. In ~~determining and documenting the appropriate verification activities~~ making these determinations, the receiving facility must consider the following:
(1) The hazard analysis applicable to the raw material or ingredient received, including the nature of the hazard(s) requiring control~~, applicable to the raw material and ingredients~~;
(2) Where the preventive controls for those hazards are applied for the raw material ~~and~~ or ingredient~~s~~ – such as at the supplier or the supplier's supplier;
(3) The supplier's procedures, processes, and practices related to the safety of the raw material ~~and~~ or ingredient~~s~~;
(4) ~~Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an~~Any FDA warning letter or import alert relating to the safety of the food;
(5) The supplier's food safety performance history relevant to the hazards requiring control in the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards requiring control, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and
(6) Any other factors as appropriate and necessary~~. Examples of factors that a receiving facility may determine are appropriate and necessary are~~ such as storage and transportation practices.

9.6 Comments regarding § 117.136(c) and (f)

With respect to § 117.136(c)(1), AHPA is concerned that the proposed language requires the receiving facility to "conduct" the listed verification activities; it does not allow for, say, onsite audits to be conducted by an accredited third-party auditor either on behalf of the supplier or the importer, or sampling and testing to be performed by an independent laboratory or a third-party food certifier (such as NSF International) either on behalf of the supplier or the importer. AHPA strongly opposes a requirement for all verification activities to be conducted by the receiving facility itself. A requirement for receiving facilities to conduct on-site audits will be not only extremely expensive but also impractical for many receiving facilities due to language barriers, lack of technical expertise, etc. A requirement for receiving facilities to conduct food sampling and testing will be inappropriate because (a) many receiving facilities will not have in-house laboratories to conduct testing; (b) receiving facilities may not have the necessary expertise to decide appropriate test methods; and (c) there is no food safety reason to require duplicative test results by the supplier or receiving facility if an appropriate third party has already sampled and tested the food. AHPA therefore proposes the following revision to § 117.136(c)(1), and requests that similar changes be made wherever a requirement "to conduct" is mentioned in the Rule:

> (c) Supplier verification activities for raw materials and ingredients. (1) Except as provided in paragraph (c)(2) or (3) of this section, the receiving facility must conduct and document (or verify that a party has conducted and documented on behalf of yourself or the foreign supplier) one or more of the following supplier verification activities as determined by the receiving facility under paragraph (b) of this section, for each supplier before using the raw material or ingredient and periodically thereafter:

AHPA furthermore proposes the following revision to § 117.136(c)(1)(ii):

> (ii) Sampling and testing of the raw material or ingredient, which may be conducted by or on behalf of either the supplier or the receiving facility.

With respect to proposed § 117.136(c)(2)(i), AHPA remains concerned that it is not sufficiently clear what constitutes a hazard "for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans." AHPA comments on the originally-proposed Foreign Supplier Verification Program (FSVP) Rule addressed this point.[32] AHPA looks forward to additional guidance from FDA on this topic, as mentioned in the Preamble to the revised proposed FSVP Rule.

With respect to proposed § 117.136(c)(4), AHPA notes that revised proposed § 112.4(a) only applies to produce farms, and that proposed § 112.4(b) only applies to farms that are eligible for the qualified exemption in § 112.5. AHPA believes that non-produce farms (e.g., a farm that grows wheat or grows orris root for use in the manufacture of flavors) both small and large should be provided the same option as farms that are exempted under § 112.4. Based on statements in the Preamble to the FSVP Rule, AHPA believes that FDA does intend to afford the same option with respect to such farms, but fears this is not captured in the proposed language of the Rule because the proposed language is tied specifically to § 112.4. AHPA therefore proposes that § 117.136(c)(4) should be revised as follows:

> If a supplier is a farm that is not subject to the requirements established in part 112 of this chapter in accordance with § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, or is any farm that is not subject to part 112, the receiving facility does not need to comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

With respect to proposed § 117.136(f), AHPA believes these actions should be required only if the receiving facility is relying on the supplier to control the specific hazards found. AHPA therefore proposes that § 117.136(f) should be revised as follows:

> Supplier non-conformance. If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer

[32] See comment # 7.3 in AHPA's previously-submitted comments to the originally-proposed FSVP Rule.

or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as ~~significant~~ requiring control by the supplier, the receiving facility must take and document prompt action in accordance with § 117.150 to ensure that raw materials or ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, or Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

9.7 Comments regarding § 117.136(g)

AHPA proposes that § 117.136(g)(3) should be revised as follows, for conformity with changes to § 117.136(a)(1)(ii)(C) proposed above (two alternate forms, to mirror the alternate forms suggested above):

> ~~The annual~~ Any documentation provided to notify customers of the existence of actual or potential hazards in food provided to them by the receiving facility ~~written assurance that a receiving facility's customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard~~;

> ~~The annual~~ Any documentation provided to notify customers of the existence of actual or potential hazards in food provided to them by the receiving facility and the written assurance that ~~a~~ the receiving facility's customer will evaluate the hazard and if necessary will establish and follow ~~who is controlling a significant hazard has established and is following~~ procedures ~~(identified in the written assurance)~~ that will significantly minimize or prevent the hazard;

AHPA proposes that § 117.136(g)(4) should be revised as follows for clarity and accuracy:

> Documentation demonstrating that ~~products~~ raw materials and ingredients are received only from approved suppliers;

With respect to § 117.136(g)(6), AHPA notes that (a) when outside laboratories are used, the receiving facility will often not have access to information about the dates on which tests were conducted, but only to the dates on which the tests were reported; and (b) not every detection of a hazard will require a corrective action, for example if the hazard is one that the receiving facility's hazard analysis has determined does not require control. AHPA proposes that § 117.136(g)(6) should be revised as follows:

> Records of sampling and testing. These records must include:
> (i) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of the test(s) conducted, including the analytical method(s) used;
(iii) The date(s) on which the test(s) were conducted or their results reported;
(iv) The results of the testing;
(v) Corrective actions taken in response to detection of hazards, if necessary; and
(vi) Information identifying the laboratory conducting the testing.

AHPA proposes that § 117.136(g)(8) should be revised as follows:

(8) Records of other appropriate supplier verification activities based on the risk associated with the raw material, ingredient or supplier.

AHPA proposes that § 117.136(g)(11) should be revised as follows, to take into account the revision to § 117.136(c)(4) proposed above:

Documentation of an alternative verification activity for a supplier that is a farm described in § 117.136(c)(4) ~~that supplies a raw material or ingredient that is not subject to part 112 of this chapter,~~ including:

9.8 Other comments regarding supplier controls

In response to FDA's request for comment regarding how potential gaps in supplier controls should be addressed when a hazard in a food is controlled at a farm, and the food then passes through the hands of one or more firms that is not a manufacturer/processor and is not subject to supplier controls requirements, on its way to use by a consumer or retail establishment: AHPA suggests that any firm that sells directly to consumers or retail establishments might logically be required to have a supplier controls program in place. AHPA strongly supports this option rather than the original proposal of the Produce Safety Rule which would have required all produce farms to comply with Part 112 unless the farmer could document the identity of the commercial processor that would adequately address microbial hazards (a proposal which AHPA believes to be unworkable)[33].

In response to FDA's request for comment regarding the circumstances under which it may be necessary to use food sourced from an unapproved vendor on a temporary basis: AHPA believes there are a wide variety of circumstances in which this might be necessary, including but not limited to (a) supply interruptions or quality problems at an approved manufacturing facility due to equipment breakdown, natural or man-made disasters, bankruptcy, strikes, etc.; (b) supply interruptions or quality problems at an approved farm due to natural or man-made disasters, weather, labor shortages, etc.; (c) unexpected prolonged import delays due to dockworker or other strikes, the importer's loss of status under the new Voluntary Qualified Importer Program, shipments on hold pending sampling and testing by government

[33] See comments 3 and 6 in AHPA's previously-submitted comments to the originally-proposed Produce Safety Rule.

agencies, etc.; (d) shipments lost during transit due to containers overboard, trucking or rail accidents, theft, etc.; or (e) sudden increases in demand for ingredients due to an unexpectedly successful marketing campaign, product mention by a celebrity, etc. The types of verification activities that would be appropriate under these circumstances are highly dependent upon the nature of the food being sourced and the nature of the finished product and its manufacturing process, but AHPA believes they would typically include (a) sampling and testing the shipments received as appropriate; and (b) obtaining information about the source providing the shipments, to the extent immediately possible.

10. Comments on § 117.150 through § 117.165

In proposed § 117.150(a)(1)(ii), FDA lists two circumstances that require written corrective active procedures. AHPA notes that it is not clear whether this list is intended to be finite (i.e., written corrective action procedures are required in only these two circumstances) or not (i.e., there may be other circumstances that require written corrective action procedures). AHPA suggests this should be clarified by the insertion in § 117.150(a)(1)(ii) of "but are not limited to" after "must include," if that is what FDA intends.

In proposed § 117.150(c), FDA identifies circumstances that are exempted from the requirements of § 117.150(a) and (b). AHPA strongly supports these exemptions, and strongly supports the explicit identification of these circumstances in the Rule itself.

With respect to proposed § 117.160(b)(2), AHPA has a number of concerns. To begin with, AHPA believes there are a variety of circumstances in which the collection and evaluation of scientific and technical information is not necessary (e.g., the use of sieving or metal detectors to control physical hazards, or the use of ICP-MS analysis to control for the presence of lead). In addition, AHPA is extremely concerned that the requirement to "conduct studies" might be intended, or may be interpreted, to mean that firms are required to develop or validate analytical methods (either in general or for specific food matrices); AHPA believes any such requirement would be incur extreme costs and burdens without delivering commensurate public health benefits. AHPA therefore suggests the following revisions to proposed § 117.160(b)(2):

> Must, as appropriate to the hazard and the controls, include collecting and evaluating scientific and technical information (or, when such information is not available or is inadequate, conducting process validation studies) to determine whether the preventive controls, when properly implemented, will effectively control the significant hazards;

In addition, AHPA suggests the following revisions to § 117.160(b)(3):

> (3) Need not address:

(i) The food allergen controls in § 117.135(c)(2);
(ii) The sanitation controls in § 117.135(c)(3);
(iii) The raw material and ingredient testing in [new proposed] § 117.135(c)(4); ~~The supplier program in § 117.136; and~~
(iv) The labeling disclosures in [new proposed] § 117.135(c)(5);~~The recall plan in § 117.137.~~
(v) The supplier program in § 117.136; and
(vi) The recall plan in § 117.137.

With respect to proposed § 117.165(a)(4), AHPA greatly appreciates that overly-prescriptive timeframes for review of various preventive control records have been removed. However, AHPA is concerned that those identified in § 117.165(a)(4)(i) remain too prescriptive. For "monitoring," AHPA notes that certain types of monitoring will be conducted in connection with specific batches of product (e.g., monitoring of temperature during production of batch of product) and, for facilities that operate on a batch-production basis rather than a continuous-production basis, such records should be reviewed in connection with the completed batch (i.e., after all activities connected to the batch are complete, which may include weeks or months necessary for product testing, as explained in previous AHPA comments[34]) rather than within an arbitrarily short timeframe. With respect to "corrective actions," AHPA notes that certain types of corrective actions may require weeks or months to complete; these might include redesign of equipment, revision and revalidation of processing conditions, or chemical testing of potentially-affected food product. Thus, the records documenting the corrective action to be performed will be created at one point in time, but may not be finalized with documentation of completion of the corrective action until much later. Therefore, AHPA suggests that § 117.165(a)(4)(i) should be revised as follows:

> Records of monitoring and corrective action records within a week after the records are created, unless an alternate timeframe is justified.

With respect to proposed § 117.165(b)(2)(i), AHPA is concerned that the requirement for product testing procedures to "be scientifically valid" might be intended, or may be interpreted, to mean that firms are required to develop or validate analytical methods (either in general or for specific food matrices). AHPA believes any such requirement could impose extreme costs and burdens without delivering commensurate public health benefits. Firms should be permitted to rely on methods that are generally available. AHPA therefore suggests the following revisions to proposed § 117.165(b)(2)(i)

> Procedures for product testing must: (i) Be scientifically valid (however, firms are permitted to rely on generally available methods; firms are not required to develop or validate analytical methods either in general or for specific food matrices);

[34] See comment 10.12 in AHPA's previously submitted comments to the originally proposed GMP-HA/PC Rule.

11. Definition of "very small business"

In the supplemental notice of proposed rulemaking for the proposed GMP-HA/PC Rule, FDA proposes a revised definition of "very small business" as follows:

> *Very small business* means, for purposes of this part 117, a business that has less than $1,000,000 in total annual sales of human food, adjusted for inflation.

AHPA supports the change from "food" to "human food." AHPA also supports setting the dollar value threshold at $1,000,000 (if not higher) rather than $500,000 or $250,000. However, AHPA remains concerned that establishment of a dollar-denominated definition will place domestic firms at a disadvantage relative to foreign firms whose sales (a) are often denominated in currencies valued lower than the dollar and (b) often reflect much lower costs for land, labor, environmental compliance, etc.

AHPA therefore urges FDA to revise this definition and base it on an alternate measure, such as number of employees.

If FDA cannot substitute an alternate measure then AHPA requests that the sales of foreign very small businesses be calculated using an appropriate measure of purchasing power parity, if there is a straightforward way to do so.

AHPA furthermore notes that this proposed definition does not, like the definitions of very small entities proposed in other Rules, include a provision to average the firm's sales over a three-year period on a rolling basis. AHPA believes such a provision is essential since, in its absence, firms may be subject to significant changes in status from year to year (e.g., due to a short-term boost in sales). Furthermore, it is important that the definition clarify that the sales are to be evaluated retrospectively, not prospectively.

AHPA therefore proposes the following minimum changes to the proposed definition:

> *Very small business* means, for purposes of this part 117, a business that ~~has~~ had less than $1,000,000 in ~~total~~ average annual sales of human food during the previous three-year period (on a rolling basis from year to year), adjusted for inflation.

12. Comments regarding conflicts of interest

FDA has requested comment on circumstances in which persons should be excluded from performing supplier verification functions due to conflicts of interest.

To begin with, AHPA requests that in cases where supplier verification activities are performed by employees of a receiving facility or importer (as opposed to an independent third party), the Rule be clear that the "persons" to which any conflicts of interest provisions apply are the employees themselves, not the corporate entity which is or owns the receiving facility or importer. It is not uncommon in the food industry that a receiving facility or importer will have some shared financial interest in the supplier (e.g., partial ownership of one by the other, or both being owned by the same parent company). Therefore, prohibitions on conflicts of interest must not be written too broadly, otherwise they will preclude receiving facilities and importers from carrying out the very activities required of them by the GMP-HA/PC and FSVP Rules.

AHPA requests that, with respect to supplier verification activities conducted by a receiving facility or importer, conflict of interest provisions be limited to circumstances in which the individual employee performing the verification activity has a direct personal financial interest in or financial ties to the supplier (e.g., owns a substantial amount of stock directly in the supplier, or is personally paid directly by the supplier). Circumstances in which, for example, employees of the receiving facility or importer indirectly own stock in the supplier because they own stock in their own company, which in turn owns an interest in the supplier, or in which the employee is indirectly paid by the supplier because the supplier owns an interest in the receiving facility or importer, should not disqualify the employee from performing the verification activities.

AHPA also requests that, in crafting any conflicts of interest provisions, FDA take care to exclude circumstances in which the person performing the verification is blinded to the identity of the supplier. For example, a laboratory analyst performing ingredient testing should not be precluded from testing ingredients from a supplier, even if the analyst has a potential conflict of interest with the supplier, so long as the analyst is not aware of the identity of the supplier at the time the test is performed.

Furthermore, AHPA notes that conflict of interest provisions must not preclude a supplier from hiring an outside party to perform onsite audits, food certifications, or sampling and testing.

13. Other comments

13.1 Comments regarding required schedules

AHPA notes that in various places the proposed GMP-HA/PC Rule require various activities to be conducted on a specified schedule, such as annually or every two years. AHPA believes such requirements to be overly prescriptive. For example, it is not uncommon that a facility will process a particular food only every few years, or that an importer will import a particular food only every few years. In such circumstances a requirement to perform any given activity on an arbitrarily specified schedule is inappropriate, impractical, and excessively burdensome.

AHPA therefore requests that all such schedules specified in the GMP-HA/PC Rule and the FSVP Rule be removed entirely. If FDA cannot accommodate this request then such provisions need to be qualified, e.g. by addition of "unless otherwise justified."

13.2 Comments regarding proposed deletions from the list of "Exemptions for On-Farm Low-Risk Activity/Food Combinations"

FDA proposes to delete certain items from the list of activities in the small and very small business "Exemptions for On-Farm Low-Risk Activity/Food Combinations" as being unnecessary given proposed revisions to the definitions of "packing" and "holding."

AHPA requests that the list of activities in the final GMP-HA/PC Rule be sufficiently complete as to communicate clearly to exempt entities the full range of activities they are permitted to perform, even if this means the list will include provisions that are redundant to other sections of the Rule. For example, activities that are exempt as part of harvesting, packing, and holding should be specifically acknowledged in this list, even though this is not strictly speaking necessary in order for these activities to be exempted when performed by small and very small businesses.

For example, this section of the Rule could begin with language such as, "The following activities are exempt for all farms regardless of size because they are defined as farm activities:" and then go on to list harvesting, holding, and packing, either generally or with the same level of detail AHPA proposes in the suggested revised definitions provided herein.

AHPA believes that while unnecessary from a regulatory standpoint, such additions to the list will be extremely helpful in communicating clearly with the average reader.

13.3 Comments regarding Table 6 in the Preamble to the revised GMP-HA/PC Rule

AHPA notes that Table 6 ("Examples of Flexibility for Complying with the Requirements for Hazard Analysis and Risk-Based Preventive Controls in the Revised Requirements in Proposed Subpart C") is very helpful in elucidating FDA's thinking regarding various activities. AHPA requests that this Table 6 be expanded with additional examples and that it (or a similar one) be made prominently available on FDA's website wherever the public seeks out information regarding Part 117.

Conclusions

AHPA supports effective implementation of FSMA and believes that such implementation must be accomplished in a manner that minimizes the compliance costs and burdens that will be borne by the regulated industries and passed on to consumers.

AHPA appreciates the opportunity to provide comments on the supplemental notice of proposed rulemaking for the proposed GMP-HA/PC Rule. Our comments herein are intended to ensure the eventual final GMP-HA/PC Rule will meet the Congressional intent behind FSMA, maximize flexibility for compliance, and eliminate confusion for the affected domestic and international businesses.

AHPA staff and counsel will make themselves available at any mutually convenient time to address any of the topics addressed herein. Please feel free to contact us if clarification or further discussion is needed on the issues raised in these comments.

Respectfully submitted,

Michael McGuffin
President, American Herbal Products Association
8630 Fenton Street, Suite 918
Silver Spring, MD 20910
(301) 588-1171 x201

Anthony L. Young
General Counsel, American Herbal Products Association
Kleinfeld, Kaplan and Becker, LLP
1140 Nineteenth Street, N.W.
Suite 900
Washington, DC 20036
(202) 223-5120