DOCKET NO. FDA–2011–N–0921

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

STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

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. Packaging includes activities performed incidental to packaging the food, such as those listed as examples in the definition of "packing."

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. Definition of farm "ownership"

AHPA recognizes that the revised proposed Rule contains fewer provisions that depend on whether farms are "under the same ownership" or not. Nevertheless, there remain a few instances in which this

is important, and AHPA therefore reiterates its request, as stated in the original comments submitted to FDA regarding the proposed Produce Safety Rule, for the regulations to clarify what is meant by farm "ownership" for the purpose of determining whether a RAC is from a "farm under the same ownership."[24]

7. Definition of "covered activity"

In the supplemental notice of proposed rulemaking for the proposed Produce Safety Rule, FDA proposes a revised definition of "covered activity" as follows:

> *Covered activity* means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in this chapter. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

Insofar as FDA has stated in the Preamble to the original GMP-HA/PC Rule its intention to remove current Part 110 after the compliance date for all businesses to be in compliance with Part 117, AHPA believes the definition should refer to Part 117 rather than Part 110 (or both).

AHPA therefore proposes the following changes to the definition of "covered activity":

> *Covered activity* means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in this chapter. This part does not apply to activities of a facility that are subject to part 110 or part 117 of this chapter.

8. Definition of "very small business," "small business," and § 112.4(a)

In the supplemental notice of proposed rulemaking for the proposed Produce Safety Rule, FDA proposes a revised definition of "very small business" and "small business" as follows:

> (1) Very small business. For the purpose of this part, your farm is a very small business

[24] See Comment #9 of AHPA's previous comments to the originally-proposed Produce Safety Rule.

> if it is subject to this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $250,000.
>
> (2) Small business. For the purpose of this part, your farm is a small business if it is subject to this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

In addition, revised proposed § 112.4(a) provides:

> Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of produce (as "produce" is defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a "covered farm" subject to this part.

AHPA supports the change from "value of food" to "value of produce." However, AHPA remains concerned that establishment of dollar-denominated definitions and thresholds will place domestic farms at a disadvantage relative to foreign farms 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. Moreover, using dollar-value definitions and thresholds will cause farms of widely divergent size to be exempted vs. covered by various provisions of the Rule, due to the wide disparity in the value of produce crops.

AHPA therefore urges FDA to revise these definitions and thresholds and base them on an alternate measure, such as tonnage.

If FDA cannot substitute an alternate measure then AHPA requests that the sales of foreign farms be calculated using an appropriate measure of purchasing power parity, if there is a straightforward way to do so. Furthermore, if the definitions and thresholds remain tied to dollar values then AHPA urges FDA to include in the definitions an automatic adjustment for inflation, as Congress did in FSMA itself when setting dollar-denominated thresholds in connection with "qualified facilities" and "direct farm marketing." In the absence of such inflation adjustments, the full brunt of the Rule will extend to smaller and smaller farms over time, which could eventually put many small farms out of business.[25]

[25] AHPA recognizes that within the context of the "small business" and "very small business" definitions, the dollar thresholds are only relevant to establishing the timeframes for required compliance. However, since those timeframes are years in the future, and since the possibility of significant inflation between then and now cannot be excluded, it remains important to include inflation adjustments.

Finally, AHPA questions what precisely is meant by "on a rolling basis" (does it mean "rolling from year to year" or "rolling from month to month" or "rolling from day to day"?). AHPA recommends it should be clarified by specifying rolling "from year to year."

AHPA therefore suggests the following *minimum* changes to the current proposals (better yet would be to add adjustments for purchasing power parity; best would be to switch to a tonnage basis):

> (1) Very small business. For the purpose of this part, your farm is a very small business if it is subject to this part and, on a rolling basis from year to year, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $250,000, adjusted for inflation.
>
> (2) Small business. For the purpose of this part, your farm is a small business if it is subject to this part and, on a rolling basis from year to year, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $500,000, adjusted for inflation; and your farm is not a very small business as provided in paragraph (b)(1) of this section.
>
> § 112.4(a) Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of produce (as "produce" is defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000, adjusted for inflation (on a rolling basis from year to year), you are a "covered farm" subject to this part.

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 Produce Safety Rule. Our comments herein are intended to ensure the eventual final Produce Safety Rule will meet the Congressional intent behind FSMA, maximize flexibility for compliance, and eliminates 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,

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