**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**

**PROPOSED RULE for**
**STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION**

**November 22, 2013**

## Prefatory remarks

The Food and Drug Administration (FDA or the agency) on January 16, 2013 issued a proposed rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the proposed Produce Safety Rule or proposed Part 112). 78 FR 3504-3646. FDA states in its January 16 notice that this proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA also states in the notice that it is proposing these standards as part of its implementation of the FDA Food Safety Modernization Act (FSMA).

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 and dietary supplements.

AHPA's members are engaged in the commerce of herbs and herbal products, and some AHPA members are also engaged in farming operations. In the course of this commerce many AHPA members are engaged in activities that would be directly covered by the proposed Produce Safety rule. AHPA's members therefore have an interest in the proposed Produce Safety rule; these comments are therefore submitted on behalf of AHPA's members.

AHPA is also submitting on this date comments to FDA's proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (the proposed GMP HA/PC Rule or proposed Part 117; Docket No. FDA-2011-N-0920). Due to the complex interrelations between the two proposed rules, i.e., the proposed GMP-HA/PC Rule and the proposed Produce Safety Rule, the first five sections of these comments are reproduced verbatim in both sets of AHPA's comments, and the present comments reference herein certain comments submitted to the GMP HA/PC Rule and discuss certain provisions which relate to the GMP HA/PC Rule. Whenever the term "the proposed rule" is used in this document it means the proposed Produce Safety Rule; reference to the other proposed rule is always with the term "the GMP HA/PC Rule" or the term "Part 117."

In addition, in preparing these comments AHPA has found it appropriate to repeat certain information and positions in several different sections of the comments. Our purpose in doing so is not to be unnecessarily redundant but to ensure the repeated information and positions are appropriately considered in each of the relevant sections, even if separate FDA staff is assigned to review comments pertaining to different sections.

## 1. The broad and deep impact of the new regulations necessitates regulatory restraint

**NOTE: The following comments apply to both the proposed GMP-HA/PC and Produce Safety Rules and are reproduced verbatim in AHPA's comments to each.**

AHPA notes that proposed Part 112 and Part 117 are two of the most far-reaching regulations FDA has ever promulgated. They will impact the entire US food production system and millions, if not billions, of persons worldwide. They are likely to significantly increase costs and burdens throughout the food production system, and are therefore likely both to increase the prices paid by consumers and to reduce the range of choices available to the consumer. There is a very real risk that small-volume crops and products, as well as small companies, will be pushed entirely out of the marketplace, to the detriment of both producers and consumers.

AHPA therefore urges FDA to:

- Craft the regulations in a manner which maximizes the public health while scrupulously avoiding any and all burdens which are not strictly necessary to promote the public health;

- Be open to new ideas and be willing to jettison old ideas, when they are outdated or no longer appropriate.

Given the complexity of the proposed rules, the large and broad economic and cultural consequences at stake, and the significant revisions that AHPA believes, based on its own and others' comments, are necessary, AHPA urges FDA not to make the next step a final rule, but rather to publish a second set of proposed rules and invite additional comments specifically on those provisions which are newly-proposed or which changed significantly between the first proposed rule and the second.[1]

[1] AHPA understands FDA is operating under a court order to complete the final regulations by June 2015, and that FDA is appealing this order. Whether or not FDA's appeal is successful, AHPA believes there is adequate time between now and June 2015 for a second notice and comment period, so long as the comment period is kept relatively short. This should pose no problem for industry since most interested parties will have already analyzed and come to understand the issues and costs related to the rule, and therefore will be ready to submit comments promptly.

## 2. The same controls are neither necessary nor appropriate for non-RTE foods as for RTE foods

**NOTE: The following comments apply to both the proposed GMP-HA/PC and Produce Safety Rules and are reproduced verbatim in AHPA's comments to each.**

AHPA notes that a hazard which occurs early in the supply chain and/or early in the processing of a ready-to-eat (RTE) food does not pose an equal risk to the public health as the same hazard when it occurs at the end of the supply chain and/or at the end of processing an RTE food, because hazards early in the supply chain or manufacturing process are often mitigated by further processing.

This will be even more so the case once Part 117 goes into effect. Under current Part 110, the GMP rule to which food operations must currently adhere, many food processors simply assume the raw materials and ingredients they buy are safe for food use. In contrast, under Part 117 food processors will be required to proactively identify potential hazards in their raw materials and ingredients and take appropriate measures to control them.

Thus, under the existing Part 110 it makes sense for FDA to stringently monitor the safety of foods early in the supply chain, as contaminants present in raw or minimally processed agricultural commodities or other raw materials or ingredients may make their way into the retail food supply, affect a large number of downstream processors, and may cause widespread illness. However, under new Part 117 it should be possible, and AHPA believes it will be preferable, for FDA to relax its vigilance over foods early in the supply chain (other than covered produce which will be consumed without being subjected to an adequate microbial reduction step) and focus instead on ensuring that processors of RTE foods are effectively controlling hazards. And in fact new Part 117, if implemented as proposed, will place clear responsibilities on processors of RTE foods to effectively control any hazards that may be represented in the ingredients used to make these foods, so that FDA would be placing redundant and completely unnecessary regulatory burdens on companies in the early stages of the supply chain if it does not relax its vigilance in these stages.

For example, AHPA believes that much of the risk associated with microbes and other hazards that may be present in raw or minimally processed agricultural commodities or other raw materials or ingredients should be, or indeed can only be (as explained further below), mitigated through accurate disclosures in labeling or other commercial documentation. This will alert potential purchasers to the hazard which may exist and allow them to determine whether the goods offered for sale are suitable for their particular needs. Examples of such disclosures could be: (a) for pathogens and other microorganisms: a statement such as “NOTICE: Not grown in compliance with 21 CFR Part 112. Not for fresh or raw consumption. May require commercial formulation, processing, or both to adequately reduce microorganisms";[2] (b) for heavy metals: a sales specification disclosing the maximum levels of toxic

[2] See further discussion in our comment #9.23 regarding proposed § 117.80(b)(2).

metals the supplier allows to be present in the finished raw material/ingredient offered for sale, or a certificate of analysis disclosing the levels of toxic metals present in a particular lot or batch of raw material/ingredient; etc.

This disclosure would be analogous to the statements currently used in the transportation of food, in which food companies routinely notify trucking companies through a statement on the Bill of Lading for each shipment that the goods are food and must not be shipped with hazardous materials or poison. Trucking companies in turn are well aware of the importance and implications of this statement, and take care to arrange their shipments accordingly.

AHPA believes there would be many benefits to such an approach.

(a) Suppliers of raw materials and ingredients are often not in a good position to evaluate what will constitute a "hazard" in their products, because they do not know how each of their customers will treat or process the raw materials/ingredients, nor how the final product will be formulated, packaged, and sold. Some manufacturing processes employed by downstream customers will have no effect on levels of contaminants, but others may serve to remove contaminants and mitigate hazards,[3] and still others may serve to concentrate contaminants and increase hazards.[4] Raw material/ingredient suppliers furthermore have no control over what the serving size, packaging, storage conditions, or target consumers of the eventual finished food will be; which other ingredients at what levels will be combined into that finished food; or what the contaminant levels in those other ingredients will be. Thus, the appropriate specifications for raw materials and ingredients needed to protect the public health can only be determined by the final RTE food processor, not by raw material/ingredient suppliers. See our comments to § 117.130(c) (i.e. our comment #10.3 to the GMP-HA/PC rule) for more information on these difficulties.

(b) Under the new Reportable Food Registry regime, distributors of raw or minimally-processed agricultural commodities have sometimes been forced to recall their products from the marketplace when they are found to contain pathogens. This has the effect of pressuring such distributors to subject their agricultural commodities to effective microbial reduction treatments prior to sale. However, as discussed at length elsewhere in our comments, AHPA believes indiscriminate sterilization of botanical materials early in the supply chain is actively detrimental to the quality of the food supply, as such anti-microbial treatment removes an important marker of proper post-harvest handling and storage. See our comments to § 117.80(b)(2) (i.e. our comment # 9.23 to the GMP-HA/PC rule) for further information.

[3] For example, various refining, extraction, and purification processes used in the manufacture of bulk ingredients often serve to remove chemical contaminants.

[4] For example, removal of water often serves to concentrate chemical contaminants.

(c) By focusing its attention on companies which process and/or package RTE food, FDA will be able to deploy its enforcement resources most effectively. The only juncture at which a contaminant can be determined to be a hazard which presents a definite public health risk is at the point where an RTE food materializes. Prior to that point, the hazard and its attendant risks are hypothetical and uncertain.

(d) A reduced sensitivity to hypothetical hazards early in the supply chain, if those hazards are being effectively controlled later in the supply chain, will reduce the number of potentially needless food recalls. AHPA notes that in recent years millions of dollars of food have been recalled annually. AHPA questions, in the case of raw or minimally-processed agricultural commodities intended for further commercial processing, to what extent such recalls actually prevent foodborne illness even under the current regulatory regime, given that many contaminated ingredients are decontaminated by further processing, and studies of the distribution of specific contaminated ingredients have rarely linked them to increased foodborne illness; see our comments § 117.80(b)(2) (i.e. our comment # 9.23) for further information.[5]

(e) Focusing attention and responsibility for controlling hazards on processors and packagers of RTE foods will reduce the adverse economic impacts of the new rules, by avoiding the unnecessary and expensive duplication of efforts throughout the supply chain.

(f) Allowing microbial risks to be mitigated through labeling will facilitate a drastic reduction in the economic impact of the Produce Safety Rule.

AHPA does not mean to suggest that companies which manufacture, process, pack, or hold foods early in the supply chain should be relieved of their responsibility to take appropriate measures to avoid the contamination or degradation of the foods in their care. To the contrary, AHPA believes it essential for such companies to protect the foods they sell, as through proper plant construction and maintenance; control of temperature and, where applicable, humidity; proper cleaning and sanitation; etc.

Rather, what AHPA means to suggest is that suppliers should be permitted to mitigate hazards through written disclosure to their customers of potential hazards and that other provisions of Subpart C should be limited or softened with respect to raw materials and ingredients for further commercial processing.

AHPA recognizes that under current legal interpretations it is illegal to distribute food which is known to be adulterated with pathogens; that FDA is required to take appropriate action when alerted through a Reportable Food Report that a contaminant exists in the food supply; and that FDA's policies are constrained by various other requirements of the FDCA. Nevertheless, AHPA believes adjustments can

[5] AHPA recognizes that, when a microbiologically contaminated ingredient has been sold to a manufacturer whose process includes an adequate kill step, the ingredient is not required to be recalled from that manufacturer. AHPA supports this practical approach. Nevertheless, under the current regulations and commercial practices the contaminated ingredient may have been sold to companies who do not use such a kill step or who are unsure of the microbiological effect of their processing, making it often necessary to conduct at least a partial recall.

be made to the proposed rule to accommodate the realities of the food ingredient supply chain, and AHPA makes suggestions to this end throughout our comments.

# 3. Wherever possible, food processors rather than farmers should ensure the biological safety of food

**NOTE: The following comments apply to both the proposed GMP-HA/PC and Produce Safety Rules and are reproduced verbatim in AHPA's comments to each.**

### 3.1 Wherever possible, FDA should avoid burdening farmers and should rely on food processors rather than farmers to ensure biological safety

AHPA understands the need to improve the safety of fresh produce sold in the US, since fresh produce is typically delivered straight from the farm to the final end user (e.g. consumer or restaurant) without any processing and is often consumed raw.

However, AHPA urges FDA to avoid creating new burdens for farmers wherever possible and consistent with the goals established by FSMA. AHPA believes that the currently proposed Produce Safety and GMP-HA/PC regulations are unnecessarily broad, unclear, and/or burdensome to farmers in various respects, and that FDA should adjust them appropriately. AHPA will explain elsewhere in our comments the details of these concerns and will recommend appropriate adjustments.

First, though, AHPA would like to explain various reasons why FDA should strive to minimize the impact of Parts 112 and 117 on farmers, and wherever possible should look to food processors (including those who only package a raw agricultural commodity (RAC) for retail sale) rather than farmers to ensure food safety.

### 3.2 Farmers are generally ill-equipped to comply with either Part 112 or 117

AHPA notes that both Part 112 and Part 117[6] will affect both farmers who grow and/or harvest produce and those who grow and/or harvest other edible crops,[7] especially if the current proposals are if not revised along the lines AHPA will recommend elsewhere in our comments.

More than a third of the world's population (i.e. several billion people) is engaged in agriculture. Most of these farmers are impoverished and poorly educated, and most live in rural or remote locations with weak infrastructure and impaired access to modern information and technologies. Most have little access to capital. Huge percentages of farmers are women and children (as young as 5 to 7 years of age), who have even less access to education and financial services. Furthermore, in many countries there is little government assistance to farmers. In the current economic climate, government budgets are

[6] For example, if changes are not made to FDA's proposed definition of "harvesting," many farms will become "farm mixed-type facilities" subject to Part 117. See AHPA's comments regarding the definition of "harvesting."

[7] For example, if changes are not made to FDA's proposed definition of "produce," many RACs used as or in production of spices, dietary ingredients, and food additives will be covered by Part 112. See AHPA's comments below regarding the definition of "produce."

stretched thin even in rich countries, and many countries exhibit a "profound and prolonged lack of investment in agriculture."[8]

It is true that most farmers' crops are not sold into the US, and therefore most farmers will not be affected by Part 112 and/or Part 117. However, the farmers who supply to the US will still be a very large number, easily millions. AHPA believes it to be a Herculean task to attempt to educate millions of illiterate, impoverished farmers worldwide even as to the existence of the US regulations, never mind for them to fully understand the regulatory requirements. Actual implementation of the requirements, even those which need little capital expenditure such as recordkeeping, will be truly impossible for at least the foreseeable future.

For comparison, AHPA notes that even in here in the US, where local, state, and federal agencies have been striving for decades to provide excellent food sanitation education, and where the population is literate, relatively economically secure, and has ample access to information and training, as of 1998 only 60% of full service restaurants were in compliance with FDA food safety recommendations;[9] and after all, these recommendations are much simpler and cheaper to implement than either Part 112 or Part 117 will be. If 50 years of food safety education is not sufficient to achieve widespread compliance with basic food safety procedures in the US, AHPA doubts that widespread upgrades to farm practices and infrastructure among millions of peasants worldwide can be achieved in any reasonable timeframe.

Furthermore, AHPA would like to point out that most farmers have no way to know whether their crop ends up being sold in the US marketplace, and therefore will have no way to know whether they are required to comply with the US regulations (assuming they are somehow made aware of their existence). While the supply chains for fresh produce are relatively short, those for other botanical commodities are often long and complicated, with numerous intermediaries (local buyers, traders, and brokers) between the farmer and the processor or user. Even for fresh produce, AHPA believes the farmer often has no idea where his crop ends up, because the crops are frequently sold through cooperatives or other intermediaries. The opacity of these supply chains normally prevent the farmer from knowing where his crops are used or by whom, and likewise neither the processor nor end user normally has access to information about the identity of the farmer.

Finally, even within the US itself where farmers are literate, relatively economically secure, and have reasonable access to infrastructure and information (e.g. via agricultural extension services), AHPA believes the proposed rules will be difficult to implement if a primary location for implementation is on

[8] This quote and much of this information are from FAO Statistical Yearbook 2013, World Food and Agriculture. Food and Agriculture Organization of the United Nations, Rome, 2013. http://www.fao.org/docrep/018/i3107e/i3107e01.pdf, accessed 09/26/13.

[9] Food and Drug Administration (FDA). 2004. Healthy People 2010 Progress Review: 2004 Challenges, Barriers, Strategies and Opportunities. Healthy People 2010 Focus Area Data Progress Review. Focus Area 10: Food Safety Challenges, Barriers, Strategies and Opportunities. http://www.fda.gov/Food/FoodScienceResearch/HealthyPeopleInitiative/ucm236488.htm, accessed 11/22/2013.

farms. There is a real risk the new regulations will put many US farmers out of business. According to recent IRS data, two-thirds of US farmers already operate at a loss.[10] The new regulations will not only increase their operating costs, they are also likely to reduce the international price competitiveness of US farm products since AHPA believes there will inevitably be greater enforcement of the new regulations on US farms compared to those in foreign jurisdictions.

### 3.3 Food processors are the appropriate entity to ensure the biological safety of food wherever possible

Wherever possible, ensuring microbiological and other biological safety will be more appropriately and reliably accomplished by the food processor than by the farmer.

Food processors tend to have better access to capital, infrastructure, and information than farmers do, and they are more easily identified and influenced by governments and customers.[11] They are therefore more likely to have the resources and motivation necessary to improve their operations. They are also far fewer in number than farmers, which reduces the scope of the education and compliance burden, and are in better position to know and/or control whether their products are sold into the US market.

AHPA furthermore believes that many food processors will prefer to address biological hazards themselves, rather than relying on entities farther up the supply chain (e.g. farmers, distributors, brokers, traders, or RAC processors) to do so. This approach has a number of advantages:

(a) It will provide the food processor with first-hand knowledge and proof that any biological hazards have been mitigated.

(b) For ingredients which are not purchased directly from the farm, food processors may find it impractical or even impossible to identify the farmer to confirm the farmer's compliance with Part 112 and/or (in the case of farm mixed-type facilities) Part 117.

(c) For produce purchased directly from the farm, food processors may find it expensive or impractical to conduct or require audits to monitor the farm's compliance with Part 112 and/or Part 117.

(d) Knowledgeable food processors often prefer to purchase dry botanical ingredients in unsterilized form, since the microbial count serves as a useful marker of proper on-farm and subsequent handling practices. Improper cultivation, harvest, post-harvest handling, and/or drying of botanical ingredients

[10] Department of the Treasury, Internal Revenue Service (IRS). 2012. *Individual income tax returns 2010. Publication 1304 (Rev. 08/2012)*. Table 1.4: All returns: Sources of income, adjustments, and tax items, by size of adjusted gross income.

[11] For example, all food processors are required to register their facility with FDA; in contrast, there is no comparable registry of farms, at either the local, state, or federal level.

can compromise quality and increase microbial contamination and microbial toxins to unacceptable levels; sterilization can be used to hide these problems. AHPA emphasizes that this is considered extremely important by many food processors. Indiscriminate sterilization of botanical materials at early stages of the supply chain will remove crucial information which knowledgeable food processors rely on to judge the quality and integrity of the ingredients they buy, and will therefore be actively counterproductive.[12]

Due to the factors above, AHPA believes any safety problems which may exist in botanical crops will more properly be, wherever possible,[13] addressed by the food processors rather than by the farmers. Existing Parts 111, 113, 114, and 120 currently require, and Part 117 will require, commercial processors and packagers to take whatever steps are necessary to ensure food safety, either through control of raw materials, use of microbial reduction steps,[14] or other means. To attempt to force the farmers in addition to the commercial processor to ensure microbial safety through compliance with Part 112 and/or Part 117 would be both duplicative and less likely to succeed.[15]

[12] See further discussion in our comment #9.23 regarding proposed § 117.80(b)(2).

[13] In some cases it will not be possible: For fresh raw foods prepared without an adequate microbial reduction step, Part 112 compliance by the farmer will remain necessary to ensure microbiological safety. However, as described elsewhere in our comments, AHPA believes this requirement should emanate backward to the farmer from specific downstream users, rather than being assumed to be necessary in all or most cases.

[14] For example, under current Part 111, manufacturers who purchase unsterilized botanical ingredients often send the ingredient out for microbial reduction (e.g. steam sterilization) prior to use, if their own manufacturing process does not include a kill step.

[15] For more information, see our comments regarding (a) rethinking the underlying assumptions of the Produce Safety rule and (b) the proposed commercial processing exemption.

# 4. Comments on the definitions of "farm" and "mixed-type facility"

**NOTE: The following comments apply to both the proposed GMP-HA/PC and Produce Safety Rules and are reproduced verbatim in AHPA's comments to each.**

### 4.1 Overview of AHPA's comments

FDA proposes in both the proposed GMP-HA/PC and Produce Safety Rules a definition of "farm" and a definition of "mixed-type facility," and the latter includes a definition of "farm mixed-type facility." AHPA believes the proposed definitions inadvertently include as farm activities the packing and/or holding of certain processed foods.

AHPA furthermore believes the proposed definitions are confusing and fail to communicate, in a clear and unambiguous manner, which manufacturing/processing, packing, and holding activities will remain within the farm definition vs. which will necessitate facility registration.

AHPA makes various recommendations to improve the definitions.

### 4.2 The proposed definition of "farm" inadvertently includes as farm activities the packing and/or holding of certain processed foods

The proposed definition of a farm states it includes "(i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised or consumed on that farm or another farm under the same ownership." The use of the general word "food" in this subparagraph indicates that under the currently proposed definition, this provision is not limited to raw agricultural commodities.

This means, for example, that the following packing and/or holding activities would still qualify as "farm" activities according to the proposed definition:

- A farm grows millet, which is harvested and sent to a separate company to be ground into bulk powder (millet meal), then is returned to the original farm to be packaged and/or held for distribution into commerce outside the farm or group of co-owned farms.[16]

- A farm grows peanuts, which are harvested and sent to a separate company to be processed into peanut butter with no other ingredients, which is then returned to the original farm to be

[16] See AHPA's comments to the Produce Safety Rule regarding farm ownership, where AHPA proposes the following definitions: (a) *Farm owner* means the individual, family, corporation, collective, or other entity responsible for managing a farm operation which produces one or more raw agricultural commodities; (b) *Farms under the same ownership* or *co-owned farms* mean all farms that have the same farm owner. For brevity, AHPA proposes "co-owned farm" be used throughout the Rule.

packaged and/or held for distribution into commerce outside the farm or group of co-owned farms.

- A farm grows apples, which are harvested and sent to a separate company to be processed into applesauce with no other ingredients, which is then returned to the original farm to be packaged and/or held for distribution into commerce outside the farm or group of co-owned farms.

AHPA believes this is probably not what FDA intended, and doubts that in practice FDA would inspect such a farm solely under Part 112, because this outcome is inconsistent with the Organizing Principles articulated in each of the preambles to both the proposed GMP-HA/PC and Produce Safety rules.[17] The First Organizing Principle states that the basic purpose of farms is to produce RACs and that RACs, as opposed to processed foods, are the essential products of farms. In the Third Organizing Principle FDA states, "A farm that chooses to transform its RACs into processed foods should be considered to have chosen to expand its business beyond the traditional business of a farm, thereby opting to become a farm mixed-type facility...."

Thus, it seems clear the provision in subparagraph (i) should be limited to raw agricultural commodities, otherwise the regulated industry will not understand FDA's intention. This necessitates additional changes to the definition, which are described in the next section of this comment and which AHPA believes are also desirable in their own right.

### 4.3 The proposed "farm" definition is confusing

AHPA finds proposed subparagraph (i) of the farm definition to be quite confusing, as it mixes together sourcing of RACs by the farm (i.e. growing and raising of RACs) with subsequent usage of the RACs (i.e. consumption on the farm), which makes it difficult to comprehend and envisage all the implications and ramifications of the provision. It was not until AHPA had read the entire preambles to both the Produce Safety and the GMP-HA/PC Rules, and had spent many hours considering the statements therein, before AHPA began to grasp precisely what FDA intended by it. Indeed, AHPA notes that even FDA's own staff appears to have been confused by this provision.[18]

[17] The Organizing Principles are described somewhat differently in the two preambles, but in both these are presented as principles "regarding classification of activities on-farm and off-farm," and the language used in the two proposed rules is nearly identical. When referred to in AHPA's comments we therefore mean the Organizing Principle(s) as presented in the preambles to either of the proposed rules.

[18] The FDA document "FSMA Facts: I Have a Farm - Does the Proposed Preventive Controls Rule Affect Me?" indicates that a farm is a "farm mixed-type facility" if it "manufactures, processes, packs or holds food that is not grown, raised, or consumed" on the farm or any farm under the same ownership (i.e. if the growing, raising, and consumption are not all three conducted on the farm then the farm is a farm mixed-type facility). This is inconsistent with the Fifth Organizing Principle, which states that "packing, or holding food...FROM ANY SOURCE [emphasis added] for consumption on the farm remains within the farm definition," and with subparagraph (1) of the "farm" definition, which does not limit food used in packing and holding operations on a farm only to the food grown, raised AND consumed on the farm or a co-owned farm;

After due consideration, AHPA believes FDA to intend the following to remain within the farm definition:

(a) A farm which packs and/or holds food, where all of said food is grown on the farm or a co-owned farm (irrespective of whether the food is also consumed on the farm or a co-owned farm).

(b) A farm which packs and/or holds food, where all of said food is raised on the farm or a co-owned farm (irrespective of whether the food is also consumed on the farm or a co-owned farm).

(c) A farm which packs and/or holds food, where all of said food is consumed on the farm or a co-owned farm (irrespective of whether the food is also grown and/or raised on the farm or a co-owned farm, or indeed whether some or all of the food is purchased from a grocery store or food warehouse or other source).

AHPA arrived at these conclusions through consideration of the plain English meaning of the word "or" in the phrase "grown, raised, or consumed" along with close reading of the Organizing Principles, in particular the Fourth and Fifth Organizing Principles.

The Fourth Organizing Principle indicates that the special classification of on-farm activities "should only apply to RACs grown or raised on the farm itself or on other farms under the same ownership because the essential purpose of a farm is to produce its own RACs, not to handle RACs grown on unrelated farms for distribution into commerce....[A]ctivities farms may perform on others' RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce." It goes on to indicate that when a farm opts to perform activities outside the farm definition it becomes a farm mixed-type facility.

The Fifth Organizing Principle indicates "manufacturing/processing, packing, or holding food -- whether RACs or processed foods, FROM ANY SOURCE [emphasis added] -- for consumption on the farm [remains] within the farm definition because otherwise farms could not feed people and animals on the farm without being required to register under section 415 of the FD&C Act." AHPA strongly supports this organizing principle.

AHPA believes FDA intends the Fifth Organizing Principle to take precedence over the Fourth, i.e. the Fourth Organizing Principle should apply only when the RAC is subsequently sold or distributed outside

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rather, it requires only that the food be grown, raised OR consumed on the farm or a co-owned farm. It is also inconsistent with subparagraph (2) under the "farm" definition which does not limit food used in manufacturing/processing on a farm only to the food grown, raised, AND consumed on the farm or a farm under the same ownership; rather, it requires only that the food be consumed on the farm or a co-owned farm. Chart 1 of the same document also indicates that any farm which receives food that is not grown, raised, or consumed on the farm or a co-owned farm is automatically a "farm mixed-type facility." Again, this is a logical contradiction to the definitions provided in the proposed rule and to the Fifth Organizing Principle.

the farm or group of farms. This is evidenced by the Fourth Organizing Principle's repeated use of the qualifier "distributed into commerce." AHPA strongly supports giving primacy to the Fifth Organizing Principle over the Fourth. Manufacturing, processing, packing, or holding food from any source for consumption on the farm or a co-owned farm has little relevance to the safety of the American public, due to the extremely limited distribution of the food, so little benefit will be realized by encumbering either FDA or the farm with the requirements of Part 117.

To clarify what FDA intends by the farm definition, AHPA suggests the subparagraphs of the farm definition should be rearranged so that subparagraph (i) deals solely with sourcing of RACs to the farm and subparagraph (ii) deals solely with consumption of the RACs; see our detailed markup farther below.

**4.4 The proposed "mixed-type facility" definition is unclear**

The proposed rule defines a "mixed-type facility" as "an establishment that engages in both activities that are exempt from registration...and activities that require the establishment to be registered," and defines a "farm mixed-type facility" as "an establishment which grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered."

At first, it was not clear to AHPA what FDA meant by "other activities within the farm definition" and "activities which require the establishment to be registered." After reading the preambles to the two proposed rules and considering the statements therein, AHPA believes the phrase "other activities within the farm definition" is meant to include the activities in subparagraphs (i) and (ii) of the "farm" definition, and the phrase "activities which require the establishment to be registered" is meant to include any manufacturing, processing, packing, or holding of food except as described in (i) and (ii) of the "farm" definition. AHPA suggests the definition should be revised to clarify this, as per our detailed markup of the definitions provided below.

**4.5 AHPA's suggestions regarding the definitions**

AHPA believes it crucial for the definitions to be self-explanatory in their own right. It should not be necessary to read the preamble, much less multiple preambles, in order to understand basic definitions provided in the text of the rule. Also, the definitions should not state or imply that packing or holding of certain processed foods remains within the farm definition if in fact FDA will not honor that exemption from Part 117 during actual inspections.

AHPA therefore suggests the definition of "farm" should be modified as follows:

> *Farm* means a facility in one general physical location devoted to the growing and/or[19] harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes and is limited to:
>
> (i) Facilities that pack or hold ~~food~~ raw agricultural commodities, provided that all food used in such activities is grown~~,~~ or raised ~~or consumed~~ on that farm or ~~another farm under the same ownership~~ a co-owned farm[20]; and
>
> (ii) Facilities that manufacture/process, pack, or hold food, provided that all food used in such activities is consumed on that farm or ~~another farm under the same ownership~~ a co-owned farm.

AHPA furthermore suggests the definition of "mixed-type facility" should be modified as follows:

> *Mixed-type facility* means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition (i.e. manufacturing, processing, packing, or holding food as enumerated in the "farm" definition), but also conducts activities that require the establishment to be registered (i.e. any manufacturing, processing, packing, or holding of food outside what is enumerated in the "farm" definition)."

[19] AHPA notes that not all farms are engaged in both growing (in the sense of actively cultivating) and harvesting crops. Some operations produce RACs through wildcrafting, as discussed at length in footnote 22 below, as well as our comments to the Produce Safety Rule regarding the definition of "produce" and regarding farm "ownership."

[20] See AHPA's comments to the Produce Safety Rule regarding farm ownership, where AHPA proposes the following definitions: (a) *Farm owner* means the individual, family, corporation, collective, or other entity responsible for managing a farm operation which produces one or more raw agricultural commodities; (b) *Farms under the same ownership* or *co-owned farms* mean all farms that have the same farm owner. For brevity, AHPA proposes "co-owned farm" be used throughout the Rule.

# 5. Comments regarding the definition of "harvesting"

**NOTE: The following comments apply to both the proposed GMP-HA/PC and Produce Safety Rules and are reproduced verbatim in AHPA's comments to each.**

### 5.1 Overview of AHPA's comments

AHPA believes the proposed definition of "harvesting" to be inappropriately narrow and insufficiently clear.

AHPA believes the definition of "harvesting" must make clear that any activity which is traditionally performed by the farmer to prepare a RAC for packing, storage, transportation, and subsequent use as food falls within the definition of "harvesting," at least as long as it does not transform the usual raw agricultural commodity (RAC) into a different commodity.

This may include a much broader range of activities than the examples FDA lists in the proposed definition, which appear to be predicated solely on harvest of fresh produce and animals. Most edible botanical RACs are not produce and involve additional harvest activities such as cutting, slicing, peeling, freezing, heating, and fermenting (to name a few) to prepare the RAC for packing, storage, transportation, and subsequent use as food.

Furthermore, FDA's policy position on "heat treatment" requires refinement; in its current form it is impractical and contradicts a number of FDA's own policy positions. If not adjusted, the policy on heat treatment will inappropriately sweep vast numbers of farms into the "farm mixed-type facility" category, thereby drastically increasing the burden both on millions of farmers and on FDA.

AHPA also suggests that FDA use the same logic it used to exclude soybeans from the produce category (i.e. they are not produce because they are not typically grown for fresh consumption) when defining "harvesting" for other commodities traded in more than one form: all activities traditionally used by farmers to prepare the form normally traded in the US should remain within the "harvesting" definition, rather than being defined as "food processing" activities, even if technically the activities serve to transform a less-common RAC into the normal RAC sold in the US.

AHPA suggests appropriate changes to the definition of "harvesting," with emphasis on distinguishing between produce and animals (for which the scope of harvesting

activities is relatively narrow) and non-produce[21] botanicals (for which the scope of harvesting activities is broader).

### 5.2 Summary of the proposed definition and notes regarding FDA's intent

FDA proposes to define "harvesting" as follows: "*Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally performed by 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 the farm on which they were grown or raised, or another farm under the same ownership. 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, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting."

In FDA's Second Organizing Principle for distinguishing farms vs. farm mixed-type facilities, FDA states "activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of 'farm.'...This is the case even if the same activities off-farm would be considered to be manufacturing/processing."

Furthermore, the preamble includes the table "The Effect of Activities on RACs That Are Foods," which represents the joint policy interpretation of FDA and EPA regarding which activities transform a RAC into a processed food vs. which do not. Specifically, in this table it is stipulated that "Application of pesticides," "Drying for the purpose of storage or transportation," and "Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant" do not change the status of an RAC into a processed food.

AHPA will discuss further below how the proposed definition of "harvesting" is at odds with these policy positions.

### 5.3 Problems with the proposed definition

AHPA is concerned that the proposed definition of "harvesting" is inappropriately narrow and appears be predicated only on the harvest of fresh produce and animals, when in fact the vast majority of edible RACs do not fall into either of those categories.

[21] 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 comments regarding the definition of the word "produce."

To begin with, the general description given of "harvesting" does not capture the full spectrum of activities inherently necessary in the harvest of RACs. The proposed definition stipulates that "activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and *preparing them for use as food*" [emphasis added] remain farm activities (i.e. do not transform the farm into a farm mixed-type facility with all that entails). But as FDA noted in the Second Organizing Principle, there are also activities performed to prepare the RAC for "*packing, holding and transporting*" [emphasis added], which FDA states should also remain within the scope of farm activities. AHPA strongly agrees with this, and recommends FDA state it in the definition.

Next, the proposed "harvesting" definition goes on to provide a number of examples of activities (e.g. trimming, shelling, etc.) which, when performed on a farm, are part of "harvesting" and therefore do not transform the farm into a farm mixed-type facility. However, these examples fail to include various activities which are frequently performed by the farmer in the harvest of non-produce botanical RACs intended for human consumption, as discussed farther below. Nearly all non-produce botanical RACs are either wildcrafted or are grown on small farms, meaning the number of potential "facilities" involved in growing and/or harvesting these crops numbers at least in the tens of millions, and those selling in the US number at least in the millions.[22] Per our comments to the Produce Safety Rule regarding the definition of "produce," AHPA believes these farmers are exempt from Part 112 since they do not grow produce; AHPA furthermore believes they should be exempt from Part 117, not only for consistency with FDA's existing policies which stipulate that "activities traditionally performed to prepare the crop for use as food" remain within the farm definition, but also because it would be a clearly impossible task for FDA to regulate them as "farm mixed-type facilities"[23] even assuming it were possible to identify which farms are supplying these RACs to the US.[24] Therefore, it is important the definition be revised to

[22] As discussed elsewhere in our comments, AHPA estimates the number of commercial wildcrafters in the US alone to be as many as 1 million; in non-industrialized countries an even higher percentage of the population participates in wildcrafting. Furthermore, AHPA estimates the number of small farmers in the US alone who grow non-produce botanical edible crops to be at least in the tens if not hundreds of thousands. This is based on USDA data from 2007 which puts the number of small farms in the US at 1,995,133, of which roughly 33% of the ca. 1.3 million farms with revenues under $10,000; roughly 12% of the ca. 500,000 farms with revenues between $10,000 and $99,999; and roughly 7% of the ca. 100,000 farms with revenues from $100,000 to $250,000, for a total of around 500,000 small farms, were engaged in production of "other crops." ("Other crops" includes everything other than animals, grains, oilseeds, fruits, nuts, vegetables, and horticulture.) AHPA has no numerical estimate of how many wildcrafters and small farmers perform additional harvest activities besides gathering the crop (e.g. drying, cutting, fermenting, etc.), but knows it to be fairly common.

[23] As discussed at length in section 3 above, educating tens of millions of non-produce botanical farmers and wildcrafters, many of whom are peasants and/or illiterate, in countries all over the world to comply with either Part 112 or 117 is obviously not possible in any reasonable timeframe. It will be difficult enough to educate produce farmers to comply with Part 112, and they are both much fewer in number and more easily identified (since the supply chain for fresh produce is inherently much shorter and simpler). See also our comments to proposed § 112.2(b).

[24] In practice, there is often no way for a foreign non-produce botanical farmer to know whether his RAC eventually makes its way into the US market. Likewise, the processor of the RAC often has no information about

encompass these other activities so the farms which perform them remain clearly within the "farm" definition.

AHPA notes that most farmers have no prior experience with regulation by FDA. It would therefore be wise for FDA to make the rule as clear and straightforward as possible, to educate the farmers and avoid confusion. Relegating key information to separate policy documents will be wholly counterproductive; rather, the key information should appear in the rule itself, otherwise large numbers of farmers and/or their downstream customers may erroneously conclude they fall into the "farm mixed-type facility" category and may therefore incur significant unnecessary expenses; or, in order to avoid the expense of being a "farm mixed-type facility," farmers may alter their normal harvest practices in deleterious ways.

AHPA notes that FDA's proposed definition of "produce" contains extensive explanatory information, and believes the definition of "harvest" should likewise include as much explanation as necessary to communicate accurately and comprehensively which activities fall into the definition vs. those which do not.

### 5.4 Most edible botanical RACs are not produce

FDA acknowledges in its proposed definition of "produce" that it does not include "food grains" such as "barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans." As noted in AHPA's comments to the Produce Safety Rule regarding the definition of "produce," there are other categories of botanical RAC which likewise are not produce, such as algae and dried legumes as well as RACs used as or for spices, colorants, flavorings, dietary ingredients, and excipients.

These non-produce botanical RACs include thousands of items and, to AHPA's knowledge, represent the majority of edible RACs traded worldwide, both by number of commodities and by dollar value.[25] As a result, it is quite important the definition of "harvesting" take into account the practices necessary for production of these RACs, and to explain in clear terms FDA's policy with respect to those practices; otherwise millions of farmers worldwide will not recognize the activities they routinely perform to be encompassed by the definition.

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the identity of the farmers who originally grew the crop. The supply chains involved are too long and complicated, with various local buyers, traders, brokers, cooperatives, and distributors between the farmer and the processor.

[25] To AHPA's knowledge there are at least several thousand plant species used as spices, dietary ingredients, and for technical purposes in the manufacture of food, while the plant species used as fresh produce number only in the dozens or perhaps hundreds. In terms of dollar value, data from International Trade Centre (http://www.intracen.org/exporters/statistics-export-product-country/) indicate international trade in fruits and vegetables (including nuts and peanuts, in fresh, dried, frozen, and preserved form) totaled $157 million in 2012, while crude non-produce botanicals (excluding non-human and non-food uses) totaled $254 million and processed non-produce botanicals (e.g. flours, meals, extracts, etc.) totaled $36 million.

### 5.5 Non-produce botanical RACs require additional harvest activities

Non-produce botanical RACs are overwhelmingly traded in dried form, and this drying is often performed by the farmer rather than at a centralized facility. This drying may be accomplished with air, heat, sunlight, or other means; it serves to facilitate storage and transportation and does not create a distinct commodity from the RAC.[26] According to the FDA/EPA joint policy interpretation discussed in the preamble(s), such drying does not transform the RAC into a processed food.

In addition to drying, the following activities are common in the harvest of non-produce botanical RACs:

(a) Peeling. Peeling may be necessary to isolate the desired commodity from other parts of the plant, for example in harvesting slippery elm (for which the desired plant part is the inner bark), mace (for which the desired plant part is the leathery aril), bergamot orange (for which the desired plant part is the fruit peel), or cocoa (for which the desired plant part is the seed and accompanying pulp).

(b) Cutting, slicing, or other size reduction. Cutting, slicing, or other size reduction may be necessary both to facilitate peeling and/or drying and to facilitate handling, packing, and storage. This is especially true of roots, bark, stems, and other plant parts that may occur (depending on the species and age of the plant) in large, unwieldy, or irregular sizes and shapes, or where the botanical is mucilaginous.

(c) Freezing. Brief freezing of the material may be used to kill the plant tissues; this serves to prevent further development (e.g. of seeds), disrupt cellular structures, and/or initiate various enzymatic processes. For example, vanilla pods must be killed after picking, and freezing is one of the options growers use to accomplish this. A temporary freeze step may also facilitate long-term storage (e.g. by killing insects).

(d) Wet or dry heat treatment. Dry heat (either with sunlight or artificial heat) is often used to speed drying and minimize microbial growth. In addition, wet or dry heat may be used to kill the plant tissues, thereby preventing further development, disrupting cellular structures, and/or facilitating various enzymatic processes. For example, some vanilla growers kill the pods using hot water. Heat treatments may also improve the safety of the RAC (e.g. by reducing the microbial load), or facilitate long-term storage of the commodity (e.g. by deactivating enzymes,[27] reducing the microbial load, and/or killing insects).

[26] In the preamble to the GMP-HA/PC rule, FDA gives the following examples: (a) Drying of grapes to create raisins creates a distinct commodity from the RAC, therefore raisins are processed foods. (b) Drying of grains, nuts, legumes, grasses, hops, rice, beans, and corns does not create a distinct commodity; the dried commodity remains a RAC.

[27] Whether heat serves to facilitate enzymatic reactions or to deactivate enzymes depends on the temperature and duration of exposure as well as the particular crop involved.

(e) Water treatments (e.g. steaming, soaking, boiling, scalding). These activities may be a necessary step in preparing the RAC for packing, storage, and/or food use. They may serve to soften woody or fibrous plant parts to facilitate cutting, slicing, flattening, or straightening of the RAC. They may also facilitate isolation of the desired plant part (e.g. peeling outer plant structures from a seed or bark from a root). In combination with heat, they may improve the safety of the RAC (e.g. by reducing the microbial load) or facilitate long-term storage of the commodity (e.g. by deactivating enzymes, reducing the microbial load, and/or killing insects). After the water treatment, the material is dried in preparation for storage and transport.[28]

(f) Aging or fermenting. Certain non-produce RACs are traditionally stored for a period of time, either in wet or dry condition, prior to leaving the farm. For example, the spice "allspice" is produced by picking the unripe, green berries of the *Pimenta dioica* tree, then piling them in heaps to ferment prior to drying in the sun. Similarly, vanilla beans are fermented ("sweated"), then after drying they are aged ("cured" or "conditioned") for several months before they are ready for sale. Cocoa and many other commodities are also commonly aged and/or fermented by the farmer prior to sale.

AHPA notes the above list is not a complete list of all activities which farmers traditionally perform during harvest of a non-produce botanical RAC. The activities which may be traditionally used are numerous and diverse, and a complete list is not possible. Furthermore, it is not uncommon for these steps to be performed by small farmers themselves, rather than at a centralized collection center.

Since these and other activities are traditionally used by farmers in the production of non-produce RACs, they are part of the harvest of the crop, and the activities involved must remain within the "farm" definition. They should not be deemed "food processing" and thereby transform the farm into a "farm mixed-type facility"; to do so would not only be confusing and inconsistent with existing FDA policy, but more importantly would impose enormous costs both on the farming sector and on FDA. Furthermore, as discussed elsewhere in our comments, AHPA does not believe regulating these activities as "food processing" is necessary to protect the public health, since these non-produce RACs will all be subject to the GMP-HA/PC Rule at later stages of the food production chain. (See our comments to § 117.80(b)(2) for discussion of how best to mitigate microbial risks in raw materials and ingredients used in food processing.)

AHPA therefore believes the definition of "harvesting" must make clear that any activity which is traditionally performed during or after gathering the crop to prepare the RAC for packing, storage, transportation, and subsequent use as food falls within the definition of "harvesting" at least as long as it does not transform the usual RAC (i.e. the one most commonly traded in the US) into a different commodity.

[28] Other preparatory steps may be performed either before or after drying, depending on the circumstances.

**5.6 Additional comments regarding heat treatments**

In the preamble(s) FDA discusses what it means by "treating" a crop and the circumstances under which "treating" remains within the farm definition or not. FDA considers two specific types of "treating," namely pesticide treatment and heat treatment.

Regarding pesticide treatment, FDA states it would "classify pesticide treatments of a farm's own RACs or a farm mixed-type facility's own RACs for the purpose of safe or effective storage to be holding within the farm definition rather than manufacturing/processing outside the farm definition. An example of such activity is fumigating a farm's own raw nuts to prevent insect infestation and damage during the potentially long storage period of the nuts. FDA is aware that such treatments are traditionally performed by farms and may be a practical necessity for the preservation of some crops during storage, and such treatments do not transform a RAC into a processed food. Thus, these treatments fit the proposed definition of 'holding' applicable to farms and farm mixed-type facilities with respect to their own RACs."

FDA goes on to say it would "classify pesticide treatment of a farm's own RACs or a farm mixed-type facility's own RACs for the purpose of removing the crop from the growing area and preparing it for use as food to be harvesting. An example of such activity is washing a crop in water containing an antimicrobial chemical after removing the crop from the growing area....If an antimicrobial chemical was...intended to reduce the microbial load on the crop itself as a safety measure...[this] would now be classified within the farm definition rather than be classified as manufacturing/processing outside the farm definition....FDA is aware that such treatments are traditionally performed by farms and that they are part of preparing the crop for safe use as food, and such treatments do not transform a RAC into a processed food. Thus, these treatments fit the proposed definition of 'harvesting' applicable to farms and farm mixed-type facilities with respect to their own RACs."

However, regarding heat treatment, FDA states that delivering a heat treatment "has been, and would continue to be, classified as manufacturing/processing outside the farm definition." AHPA strongly objects to the notion that heat treating inherently falls outside the farm definition. It may be so for fresh produce and for animal crops, but it cannot be true for non-produce botanical RACs.

As outlined in our comments above, various wet or dry heat treatments are traditionally performed during the harvest of non-produce botanical food RACs, either for purposes of isolating the desired plant part, drying, safety, or storage. With respect to the first of these, FDA has already acknowledged elsewhere (such as in the joint FDA/EPA policy position) that activities that facilitate isolation of the desired plant part do not transform a RAC into a processed food. With respect to the latter three applications, the use of wet or dry heat is directly analogous to use of pesticide and antimicrobial chemicals discussed by FDA in the preamble as "harvesting" activities, i.e. it serves either to improve safety by reducing the microbial load or to facilitate long-term storage; therefore these applications of

wet or dry heat should be classified in precisely the same manner as those applications of pesticide chemicals.

For FDA to take any other position will automatically convert millions of farms around the world into "farm mixed-type facilities," thereby imposing huge unnecessary costs on both FDA and the farmers. Furthermore, it is counterproductive for FDA to disincentivize use of wet or dry heat treatments for these purposes, as they are often preferable to use of pesticides from an environmental, consumer safety, employee safety, marketing (e.g. "organic"), and regulatory compliance point of view.[29]

**5.7 Comments regarding multiple RACs derived from the same plant material**

AHPA does not disagree that activities which transform one RAC into another commodity should generally be characterized as food processing rather than harvesting. However, AHPA believes that in order to draw this line appropriately, the "harvesting" definition should encompass all the activities traditionally performed by farmers to yield the RAC normally or most commonly sold in the U.S., rather than only those activities necessary to yield the very first RAC it is possible to produce after gathering the crop.

For example, after gathering the unripe fruit of *Piper nigrum*, a small part of the peppercorns may be sold in fresh or dried green form ("green peppercorns"), but the vast majority are dried after fermentation ("black peppercorns"). The primary item which enters commerce and is eventually traded in the U.S. is the black peppercorn, and the fermentation and drying activities involved in preparing it for food use should be considered part of the harvest of black pepper.

Similarly, after gathering the ripe fruit of *Piper nigrum*, a small part of the peppercorns may be sold in fresh or dried red form. (These are known as "red peppercorns," although many "red peppercorns" are derived not from *Piper nigrum* but from other species.) However, the vast majority of ripe *Piper nigrum* berries are soaked in water (an activity sometimes called "maceration" or "fermentation") until the fleshy outer layer of the fruit disintegrates, after which they are washed and sun dried to yield the RAC "white peppercorns." The primary item which enters commerce and is eventually traded in the U.S. is the white peppercorn, and the soaking and drying activities involved in preparing it for food use should be considered part of the harvest of white pepper.

These are just two examples of many botanical crops which are sometimes traded in one form but are normally traded only after additional activities are performed. For such crops, AHPA believes all harvesting activities traditionally used by farmers to create the normal article of commerce should remain within the farm definition, i.e. they should be harvesting activities rather than food processing

[29] If all heat treatments automatically force farmers into the "farm mixed-type facility" category, they may find it cheaper to switch to use of chemicals to reduce microbial loads and facilitate long-term storage. This poses a problem insofar as (a) the chemicals and/or the manner in which they are used may not be safe or environmentally friendly, and (b) many crops have no tolerance established for such chemicals.

activities. In at least one case FDA appears to have already followed a similar line of reasoning, insofar as the proposed definition of "produce" states that soybeans, which primarily enter commerce in dry, shelled form, are *not* produce despite the fact that a small percentage of soybeans are sold as a green vegetable in undried, unshelled form (edamame). AHPA strongly encourages FDA to adopt this as a general guiding principle and articulate it explicitly. AHPA believes, as a practical matter, it would be both unworkable and pointless to attempt to regulate these farmers as "farm mixed-type facilities."[30]

### 5.8 AHPA's suggestions regarding the definition

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

> "Harvesting" applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised, ~~and~~ preparing them for use as food, and preparing them for packing, holding, and/or transportation. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. 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. For raw agricultural commodities which are animals or produce, common examples of harvesting activities include but are not limited to g~~G~~athering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, ~~and~~ cooling, and treating (e.g. against pests) raw agricultural commodities grown on a farm or a co-owned farm[31] ~~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. For botanical food commodities which are not produce, harvesting may include (a) activities (e.g.

[30] As with other non-produce botanical crops, any safety problems created on the farm will more properly be addressed by the commercial processors and packagers rather than by the farmers. Commercial processors and packagers must comply with Part 117 and will need to take whatever steps are necessary to ensure food safety, either through control of raw material sourcing, use of microbial reduction steps, or other means. To attempt to force the farmers additionally to comply with Part 117 would be both redundant and unlikely to succeed. See related discussions in our comments on proposed § 112.2(b).

[31] See AHPA's comments below regarding farm ownership, where AHPA proposes the following definitions: (a) *Farm owner* means the individual, family, corporation, collective, or other entity responsible for managing a farm operation which produces one or more raw agricultural commodities; (b) *Farms under the same ownership* or *co-owned farms* mean all farms that have the same farm owner. For brevity, AHPA proposes "co-owned farm" be used throughout the Rule.

peeling) which isolate the desired commodity from other parts of the plant; (b) cutting, slicing, or other size reduction to facilitate handling, drying, and/or packing; (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 drying with sunlight or forced heat) to kill the plant tissue, improve safety (e.g. by reducing microbial loads or by speeding drying), and/or to facilitate long-term storage (e.g. by reducing moisture content, deactivating enzymes, reducing microbial loads, and/or killing insects); (f) aging or fermentation (sometimes known as curing or conditioning), when these are a traditional part of preparing the crop for use as food; and (g) other activities traditionally used by farmers to prepare a raw agricultural commodity for packing, storage, transportation, and use as food, so long as these are performed on raw agricultural commodities grown on the farm or a co-owned farm.

**Note: Hereinafter our comments pertain primarily to the proposed Produce Safety Rule, and are not duplicated in our comments to the GMP-HA/PC Rule.**

## 6. FDA can dramatically reduce the cost and burdens of the Produce Safety Rule by rethinking one basic assumption

FDA's proposed Produce Safety rule is predicated on the assumption that all covered produce will be required to be compliant with Part 112 unless the farmer identifies the commercial processor who will be responsible for reducing any associated microbial risks.

AHPA suggests that besides being often unnecessary and/or unworkable as explained in our comments below to the commercial processing exemption, this approach is not the most efficient or effective way to implement the new rule; it unnecessarily increases the scope and cost of the burden, and places a requirement to control the supply chain on entities (i.e. farmers) who are ill-equipped to enforce such control.

A better approach would be to move the burden of determining whether Part 112 compliance is necessary from the beginning of the supply chain, i.e. the farmer, to the end of the supply chain, i.e. the person who sells covered produce to retailers such as grocers, or the final food processor in the supply chain.

Thus, AHPA proposes that FDA invert the underlying assumption of the Produce Safety rule: Rather than assuming that all covered produce must comply with Part 112 until the farmer proves otherwise, FDA should write the rule in a manner which assumes that no covered produce must comply with Part 112 unless the need for such compliance is established through delivery to an end user who will not process it with an adequate microbial reduction step. This would have a number of clear benefits.

(a) As noted above, this is a much more practical approach since it avoids burdening the farmer with a requirement to find out information he often has no access to, and to control the supply chain in a manner he is not equipped to enforce. The end user is the only entity with both the necessary information to know whether Part 112 compliance is necessary to ensure microbiological safety and, if so, the market power to enforce that requirement.

(b) It will make the regulations consistent with longstanding commercial expectations that it is the customer's responsibility to determine, in making purchasing decisions, whether an item is suitable for its intended use. Vendors are not customarily expected to ensure the items they offer for sale are suitable for every conceivable intended use; rather, it is incumbent upon purchasers, who are after all the entity which knows the detailed circumstances of the intended use, to understand what is needed and determine whether a given item will be appropriate.

(c) It will allow the food industry to target its resources much more effectively and will dramatically reduce the economic footprint of the rule. Rather than requiring large numbers of farmers needlessly to comply, only those farmers actually selling into the fresh or minimally processed produce markets will be required to comply.

(d) It will tremendously enhance enforcement of the rule, since (a) every end user and/or their immediate prior source would be enlisted in the effort to ensure compliance, and (b) federal and state agencies would be able to focus their attention on those farms that actually merit inspection. Furthermore, to AHPA's knowledge, the only way for federal or state agencies to identify farms for inspection will be to work backward through the supply chain in this manner; there is no registry of farms, and it would be clearly inefficient for inspectors simply to drive around rural areas until a potential produce farm is spotted.[32]

### 6.1 Disclosures provided in commercial documentation are the most practical way to control distribution

AHPA believes the simplest way to ensure that covered produce which was not grown in compliance with Part 112 is directed to the appropriate end users is through disclosures provided in commercial documentation accompanying the sale of the produce.

That is to say, the Produce Safety and GMP-HA/PC rules should be written in a manner which:

(a) Includes a provision allowing for disclosure of the non-compliant status of covered produce grown on a covered farm in a manner which does not comply with Part 112, in commercial documentation accompanying the sale of the covered produce, as an alternative to the farmer being required to document the identity of the commercial processor who adequately processes the produce. Specifically, AHPA suggests the following statement be provided in commercial documentation accompanying the sale by a covered farm of covered produce which was not grown in compliance with Part 112. (See our comments to § 117.80(b)(2) of the proposed GMP-HA/PC Rule, as well as below.)

> NOTICE: Not grown in compliance with 21 CFR part 112. Not for fresh or raw consumption. May require commercial formulation, processing, or both to adequately reduce microorganisms.

[32] As discussed in our comments regarding the commercial processing exemption, many farms grow produce crops for non-food purposes, and neither state nor federal inspectors have any authority to inspect such farms under FSMA.

(b) Requires persons supplying covered produce to retail operations[33,34] to ensure the produce thus supplied is either compliant with Part 112 (as evidenced by the lack of the above notice in the commercial documentation accompanying the sale) or is sourced from a farm that is exempt from Part 112. This person, depending on the circumstances, might be the farmer himself or it might be a cooperative, distributor, or other intermediary (see our comments to § 117.93 of the GMP-HA/PC Rule); and

(c) Requires food processors who prepare food for retail sale without an adequate microbial reduction step, to ensure the covered produce they buy is compliant with Part 112.[35] (See our comments in section 2 above regarding RTE vs. non-RTE food, and in the GMP-HA/PC Rule our comments to § 117.80(b)(2), § 117.130(c), and § 117.93, as well as our suggested new § 117.135(d)(2) and § 117.135(d)(6).) In some circumstances this food processor might be a farm mixed-type facility; it might also be a food processor which simply packages produce for retail sale. It would also include food processors who prepare fresh-cut produce, fresh salads, and other uncooked or minimally processed items. The food processor might buy the produce directly from the farmer, in which case they will be able to determine directly the status of the farm, or they might buy it from an intermediary, in which case the intermediary will have to provide proper notice if the covered produce they offer for sale was not grown in compliance with Part 112.

AHPA notes some form of requirement to document the status of covered produce will almost certainly be implemented by large parts of the produce distribution industry, even if FDA does not require it by regulation, because grocery chains and other retailers will not want to accept liability for selling covered produce which is not compliant with Part 112. Many such companies have already implemented enhanced produce safety requirements for their vendors, such as Wegmans[36] and Safeway.[37] Thus, for

[33] Cooperatives and other intermediaries will be subject to FDA regulation due to their warehouse operations. Therefore FDA can create requirements for persons who supply covered produce to grocery stores and similar retailers.

[34] The burden to ensure covered produce is sourced from a Part-112-compliant farm might also be placed on the retailer. Sec. 204(d)(6)(G) of FSMA explicitly permits FDA to require grocers to maintain records documenting the farm that was the source of a "high risk" food, so FDA has the option to declare all covered produce to be "high risk" and then require grocers to maintain records of the identity of the farm that supplied the produce.

[35] It would be inappropriate for such processors to buy from a farm that is exempt from Part 112, since in that case there would not be adequate assurance of microbiological safety, and the food processor would therefore not be in compliance with part 117.

[36] http://www.foodsafetynews.com/2013/09/wegmans-to-require-best-food-safety-practices-from-all-produce-growers/#.UlQvQBDuBkc, accessed 10/08/13.

[37] http://suppliers.safeway.com/usa/forms/Produce_Vendor_Food_Safety_Verification_Program.pdf, accessed 10/08/13.

FDA to implement such a requirement by rulemaking would create a uniform playing field throughout the fresh produce industry.

AHPA furthermore notes the provision suggested in (b) above will not create a new burden for the food processor, because these considerations will already be part of the food safety evaluation required by the GMP-HA/PC rule. Part 117 will require the food processor to evaluate their processes and products and create a food safety plan to ensure, among other things, the microbiological safety of their products, and if the processing does not include an adequate microbial reduction step then logically the processor will need to evaluate the Part 112 compliance of covered produce in any event. Many such food processors, such as Fresh Express,[38] have already implemented enhanced produce safety requirements for their vendors, and these requirements will no doubt be harmonized with Part 112 once it goes into effect.

As an alternative to disclosures communicating the Part 112 status of a given shipment of covered produce, FDA might require commercial documentation of the shipment to include the identity and Part 112 status of the farm itself. AHPA does not favor this option, but if such a burden is imposed, FDA should place it on the buyer/user, who will be in position to enforce requirements on their vendors, rather than on the farmer. The text of FSMA demonstrates that Congress itself considers the end user more likely to have access to traceability information than the farmer. Sec. 204(d)(6)(G) of FSMA explicitly permits FDA to require grocers routinely to maintain records of the farm that was the source of certain types of food; in contrast, Sec. 204(f)(1) only permits FDA to request farmers to identify the immediate subsequent recipient of the farmer's food, even under the extreme circumstances of a foodborne illness outbreak. AHPA considers this to reflect Congress' accurate understanding of the practical realities of the produce supply chain, and urges FDA to consider these same realities. It is impractical for farmers to be expected to know or control the downstream users of their produce.

### 6.2 Relevant suggested changes to Part 112

In view of the above, AHPA recommends the following change to the definition of "covered produce":

> Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop. Covered produce does not include produce sold with the following statement on the commercial documentation accompanying its sale: " NOTICE: Not grown in compliance with 21 CFR part 112. Not for fresh or raw consumption. May require commercial formulation, processing, or both to adequately reduce microorganisms."[39,40]

[38] http://www.freshexpress.com/our-promise/food-safety, accessed 10/08/13.

[39] See our comments on the exemption for commercial processing regarding the need to include "formulation" as well as "processing."

### 6.3 Relevant suggested changes to Part 117

In view of the above discussion, AHPA has made a number of suggested revisions to Part 117. See our comments in the GMP-HA/PC Rule our comments to § 117.80(b)(2), § 117.130(c), and § 117.93, as well as our suggested new § 117.135(d)(2) and § 117.135(d)(6).

Also in view of the above discussion, AHPA suggests the following changes to § 117.80(b)(2):

> (i) Raw materials and ingredients used in the plant as, or in preparation of, ready-to-eat food must either not contain levels of undesirable microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated. Except as otherwise required under more-specific food regulations or unless otherwise specified in the firm's food safety plan under 21 CFR § 117.112, compliance with this requirement may be verified by any effective means, such as examination of the supplier's specifications or test results; purchase of the materials under a supplier's guarantee or certification; or laboratory analysis.
> (ii) If microorganisms of public health concern are a hazard in the food which will not be adequately controlled by processing, formulation, or other means, use of the following is prohibited in ready-to-eat food:
> (A) any covered produce (as defined in 21 CFR part 112) for which commercial documentation accompanying the sale includes the following notice: "NOTICE: Not grown in compliance with 21 CFR part 112. Not for fresh or raw consumption. May require commercial formulation, processing, or both to adequately reduce microorganisms."; and
> (B) any raw material or ingredient in which microorganisms of public health concern are a hazard and whose labels or labeling include the following notice:-"NOTICE: Not processed to reduce microorganisms of public health concern. May require commercial formulation, processing, or both to adequately reduce microorganisms."

AHPA also suggests that § 117.93 be revised as follows.

> § 117.93 Warehousing and distribution.
> (a) Storage and transportation of food must be under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and the container.

[40] See also our additional suggested changes to "covered produce" below.

(b) No food whose labels, labeling, or commercial documentation accompanying the sale contain the following notice may be sold or otherwise distributed to any commercial user except a commercial processor: "NOTICE: Not grown in compliance with 21 CFR part 112. Not for fresh or raw consumption. May require commercial formulation, processing, or both to adequately reduce microorganisms."

AHPA suggests that a new paragraph (2) added to § 117.135(d), and subsequent paragraphs be renumbered, as follows. This is for consistency with our proposed § 117.80(b)(2) and § 117.93.

§ 117.135 (d) Preventive controls must include, as appropriate:
(1) Process controls....
(2) Raw material and ingredient controls. (i) Raw material controls and ingredient controls must include those raw material and ingredient specifications or other requirements which must be met to significantly minimize or prevent hazards that are reasonably likely to occur. Except as otherwise required under more-specific food regulations or unless otherwise specified in the firm's food safety plan under 21 CFR § 117.112, compliance with the specifications or other requirements may be confirmed through certificates of analysis or other commercial documentation accompanying the shipment; testing; vendor audits; or other appropriate means.
(ii) Where the hazard analysis identifies the presence of microorganisms of public health concern as a hazard that is reasonably likely to occur and that will not be adequately reduced through the formulation or manufacturing/processing of the finished food or by other means, raw material and ingredient controls must preclude use of goods whose labels, labeling, or other commercial documentation include either of the following notices:
(A) "NOTICE: Not grown in compliance with 21 CFR part 112. Not for fresh or raw consumption. May require commercial formulation, processing, or both to adequately reduce microorganisms."; or
(B) "NOTICE: Not processed to reduce microorganisms of public health concern. May require commercial formulation, processing, or both to adequately reduce microorganisms."

AHPA suggests the following addition to proposed § 117.135(d) with respect to raw materials and ingredients intended for further processing. This is intended to address the issues raised in our comments to § 117.130(c), and for consistency with our proposed § 117.80(b)(2) and § 117.93:

§ 117.135 Preventive controls for hazards that are reasonably likely to occur.
For hazards indentified in the hazard analysis as reasonably likely to occur:
(d) Preventive controls must include, as appropriate:...

(6) Inclusion of the following statement in labels or labeling accompanying the sale of raw materials and ingredients which have not been adequately processed to reduce microorganisms of public health concern: "NOTICE: Not processed to reduce microorganisms of public health concern. May require commercial formulation, processing, or both to adequately reduce microorganisms."[41]

[41] This paragraph will be number (6) if FDA accepts our suggestion to include new paragraph (2); otherwise it will be paragraph (5).

# 7. Comments regarding the definitions of "produce," "fruit," and "vegetable" and the proposed scope of the rule

## 7.1 Overview of AHPA's comments

AHPA believes the proposed definitions of "produce," "fruit," and "vegetable" and the proposed inclusions and exclusions do not accurately capture the spectrum of commodities intended either by Congress or by FDA to fall within the scope of the proposed rule.

Congress intended FDA to promulgate regulations to improve the safety of fresh produce sold in the United States, and FDA in preparing the proposed rule clearly had fresh cultivated produce in mind. However, the proposed definitions, as currently written, would encompass a wide variety of non-produce botanical crops used for human consumption, such as those used as or in production of spices, flavors, colorants, dietary ingredients, and excipients.

Furthermore, although it is logical to exempt fruits and vegetables that are rarely consumed raw and/or are routinely cooked by the end user prior to consumption, and this is clearly FDA's intent in the draft, the proposed definitions and exclusions do not actually exempt many such crops. Also, the proposed definition of "vegetable" inadvertently excludes various crops which are sold as produce. Finally, wildcrafted foods should be exempted entirely from the rule, as they are rarely consumed raw and furthermore were not part of FDA's deliberations in creating the rule and the resulting requirements are wholly unworkable in that context.

AHPA makes various recommendations to improve the definitions.

## 7.2 Current proposed definitions and scope of the rule

FDA has proposed the following definitions:

"Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the

crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans."

In addition to the above definitions, the proposed rule states that the following food is covered by the rule:

§ 112.1 "(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part....(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:...Fruits and vegetables such as almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon...."

The proposed rule also stipulates that the following produce is not covered by the rule:

§ 112.2(a)(1) "Produce that is rarely consumed raw, specifically the produce on the following exhaustive list – arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams."

### 7.3 Comments regarding the word "produce" and the phrase "fruits and vegetables"

The words "fruit" and "vegetable," if defined technically or academically, could encompass virtually all botanical structures on the planet, whether harvested or not and whether used as food or not. In botany the word "fruit" means "a part of a flowering plant that derives from specific tissues of the flower, one or more ovaries, and in some cases accessory tissues"[42] and the broadest meaning of the term "vegetable" is used to "designate members of the plant kingdom."[43]

[42] http://en.wikipedia.org/wiki/Fruit, accessed on 09/08/13.

[43] http://en.wikipedia.org/wiki/Vegetable, accessed on 09/08/13.

However, it is clear that neither Congress nor FDA intends the Produce Safety rule to be applied so broadly. In the context of food, "fruit" generally means "the fleshy seed-associated structures of a plant that are sweet or sour and edible in the raw state,"[44] and "vegetable" is defined as "an edible plant or its part, intended for cooking or eating raw."[45]

In normal American usage the phrase "fruits and vegetables" refers to various leafy or fleshy foods of botanical (or sometimes fungal) origin which are (a) sold in macroscopically identifiable form (i.e. whole or cut form, as opposed to powder form); (b) commonly found in the produce, frozen food, and/or canned food sections of retail markets,[46] and (c) are commonly eaten as-is or used as a quantitatively significant (as opposed to the *de minimis* amounts used of items such as spices) component of a meal prepared in the home kitchen (as opposed to use primarily in industrial processing).

Furthermore, the word "produce" is commonly understood to refer to food crops which are sold in fresh or minimally processed form.[47] Thus the intersection between "fruits and vegetables" and "produce" includes only those fruits and vegetables which are sold (or at least potentially sold) in fresh whole or cut form in the produce aisle of retail stores.

AHPA believes that neither the word "produce" nor the phrase "fruits and vegetables," nor even the combination of "produce" and "fruits and vegetables" (much less "fruits and vegetables" as a synonym for "produce," which is how the phrase is used in FSMA), includes all RACs of botanical origin, even if said RACs are ultimately intended for human consumption. For example, they do not include:

- RACs used as or for colorants, such as *Bixa orellana* seed (annatto extract) or *Tagetes erecta* flower (Aztec marigold meal);
- RACs used as or for industrial excipients, such acacia sap (gum arabic) or cotton fiber (microcrystalline cellulose);
- RACs used as or for dietary ingredients, such as *Mahonia aquifolium* root (Oregon grape) or *Solidago canadensis* flower (goldenrod);
- RACs used as or for drugs, such as *Digitalis lanata* leaf (digoxin) or *Papaver somniferum* latex (opium);

[44] http://en.wikipedia.org/wiki/Fruit, accessed on 09/08/13.

[45] http://en.wikipedia.org/wiki/Vegetable, accessed on 09/08/13.

[46] Juices are sometimes also considered part of "fruits and vegetables."

[47] http://www.thefreedictionary.com/produce, accessed on 09/08/13, defines the noun "produce" as "farm products, especially fresh fruits and vegetables, considered as a group." http://www.merriam-webster.com/dictionary/produce, accessed on 09/08/13, defines the noun "produce" as "agricultural products and especially fresh fruits and vegetables as distinguished from grain and other staple crops." http://en.wikipedia.org/wiki/Produce, accessed on 09/08/13, states that "the term "produce" often implies that the products are fresh and generally in the same state as where they were harvested."

- RACs used as or for grains or pseudograins (unless in fresh or minimally-processed whole or cut vegetable form, e.g. sweet corn), such as *Triticum aestivum* (wheat) or *Amaranthus caudatus* (amaranth);
- RACs used as or for spices (unless in fresh or minimally-processed whole or cut vegetable form, e.g. fresh chilis), such as *Cuminum cyminum* seed (cumin), *Illicium verum* fruit (star anise), or *Rhus coriaria* fruit (sumac);
- RACs used as or for flavorings (unless in fresh or minimally-processed whole or cut vegetable form, e.g. fresh peppermint), such as *Iris germanica* root (orris flavor), *Sorghum bicolor* stalk (sorghum molasses), or *Acer saccharum* sap (maple syrup).

AHPA believes that Congress in the text of FSMA used the word "produce" and the phrase "fruits and vegetables" in a manner consistent with the common American usage described above. If Congress had intended "produce" or "fruits and vegetables" to have specialized meanings, rather than the meanings established by normal American usage, Congress would have provided definitions. Specific instances of Congress's use of the terms "produce" and "fruits and vegetables" confirm this interpretation. For example, new Sec. 418(m) established by FSMA states that FDA may "exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in...the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing...." This clearly indicates that the category "fruits and vegetables" is not synonymous with "raw agricultural commodities." Furthermore, new Sec. 419(e)(1) states FDA "shall publish, after consultation with...various types of entities engaged in the production and harvesting or importing of fruits and vegetables that are raw agricultural commodities...updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce under this section"; this sentence uses "fresh produce" as a synonym for "fruits and vegetables that are raw agricultural commodities," thereby emphasizing the law's focus on food in fresh form.

AHPA notes that FDA in drafting the proposed rule appears to have envisioned a similar scope. For example, FDA repeatedly references "fresh" ("fresh produce," "fresh herbs," "fresh fruits and vegetables," "fresh-cut") in the preamble to the proposed rule. FDA also repeatedly references USDA's list of "vegetables" under the Perishable Agricultural Commodities Act (PACA); PACA applies only to fresh fruits and vegetables. USDA's list of "Fresh Fruits and Vegetables Covered Under [PACA]" includes fresh fruits, vegetables, and culinary herbs likely to be found in the produce aisle of a grocery store, and does not include other RACs such as spices or dietary ingredients. Similarly, USDA's list of vegetables at http://www.choosemyplate.gov/food-groups/vegetables.html, which FDA references, includes items likely to be found in the produce aisle but not other RACs. The industry guidance documents referenced by FDA, such as http://postharvest.ucdavis.edu/producefacts/ and http://www.producemarketguide.com/, likewise focus on foods consumers expect to find in the produce section of a grocery store and do not include spices, colorants, etc.

Furthermore, FDA's proposed definition of "vegetable" includes only "herbaceous" (i.e. non-woody) plants, thereby explicitly excluding a huge number of (non-fruit) crops used to produce spices (e.g.

juniper "berry" (a pseudofruit), clove bud, mace aril, cinnamon bark), dietary ingredients (magnolia bark or flower, uva ursi leaf, chaste tree flower), flavors (sassafras leaf or root, neroli flower), and excipients (sterculia gum, cotton fiber).

Finally, AHPA notes that the "produce" considered in the Qualitative Assessment of Risk upon which FDA relied in drafting the proposed rule included various fresh or minimally-processed (fresh cut or, in the CDC data, juiced) fruits and vegetables as well as a small number of culinary herbs (basil and parsley). As above, the "produce" did not include crops used primarily as or for spices, colorants, flavorings, dietary ingredients, or excipients (except for a few crops sold in fresh vegetable form, i.e. fresh basil, parsley, and "hot peppers" or chilis).

### 7.4 Problems with the proposed definitions and scope

As discussed above, AHPA believes it can be clearly concluded that both Congress and FDA intend the Produce Safety rule to apply to various leafy or fleshy food crops of botanical (or sometimes fungal) origin which are commonly sold in macroscopically identifiable form (i.e. whole or cut form, as opposed to e.g. powder form) in the produce section of retail markets, and are commonly consumed as-is or used as a quantitatively significant component of a meal prepared in the home kitchen; and that crops used for other purposes (e.g. spices, colorants, flavorings, dietary ingredients, or excipients, as well as drugs) are intended to be excluded from the rule.

However, the proposed definitions and inclusions/exclusions are written in a manner which is not coextensive with this scope. The proposed rule states that it applies to all "food that is produce" except for the defined list given in § 112.2(a)(1), and the definition of "produce" includes all edible fruits, edible herbaceous plants, and edible fleshy fungal fruiting bodies with the exception of seed grains.

### 7.5 Detailed comments on the definition

To begin with, the proposed definition is overly broad because it fails to take into account the key concepts that produce is (a) commonly sold at retail in fresh whole or cut form (although the same crop may also be sold in frozen, canned, or juiced form); and (b) consumed as-is or used as a quantitatively significant component of a meal prepared in the home kitchen. Edible crops which do not meet these criteria, such as those used as or for spices, colorants, dietary ingredients, etc., should not be encompassed in the definition.

Secondly, AHPA is concerned with the unqualified use of the word "herbs" in the definition of "vegetable." The Merriam-Webster dictionary defines "herb" as "(1) a seed-producing annual, biennial, or perennial that does not develop persistent woody tissue but dies down at the end of a growing season; (2) a plant or plant part valued for its medicinal, savory, or aromatic qualities."[48] The category of

[48] http://www.merriam-webster.com/dictionary/herb, accessed on 09/08/13.

"herbs" is therefore very large, much broader than the small number of herbs typically found in the produce aisle of a grocery store. To avoid confusion, AHPA believes "herbs" requires appropriate qualifiers (e.g. "fresh culinary herbs").[49]

Thirdly, FDA's use of the word "herbaceous" in the definition of "vegetable" appears to be inappropriate. The word "herbaceous" can refer to a plant which does not develop a persistent woody stem,[50] or it can refer to the leafy or non-woody part of a plant.[51] By specifying that "vegetable" includes only "herbaceous plants," FDA is excluding various foods such as rosemary, sage, bay leaf, and nopales which are derived from woody plants but which are nevertheless sold as fresh produce. AHPA believes this to be unintentional, as evidenced by the fact that "oregano" is included in the proposed list of covered produce despite being a woody plant. Therefore, AHPA believes FDA intends "vegetable" to include edible "herbaceous plant parts" as well as edible "herbaceous plants."

Fourthly, it is unclear whether FDA intends algae to be included or excluded from the rule. In modern taxonomic usage, "algae" are considered a separate kingdom from "plants," but historically algae were considered a type of plant, and indeed even today Google returns "a simple nonflowering plant" as the first search result for the query "define alga." AHPA believes that algae should properly be excluded from the rule, insofar as (a) algae are not sold in fresh form in American grocery stores; (b) algae are not commonly included in the category "produce" by USDA or industry groups;[52] (c) algae do not appear to have been included in the "produce" considered in FDA's Qualitative Assessment of Risk; and (d) the proposed rules appear to have been developed with terrestrial, rather than oceanic, crops in mind. If FDA intends to promulgate regulations covering ocean-grown vegetables, AHPA believes separate rulemaking is in order due to the practical and technical differences in oceanic vs. terrestrial cultivation. Therefore, AHPA suggests the definition of "produce" should specify an exclusion for algae.

[49] In the preamble, FDA states "Herbs are generally consumed in combination with other foods (for example, in salads or as garnishes) rather than consumed as distinct servings, but they nonetheless satisfy the dictionary definition of 'vegetable.'" However, the Merriam-Webster definition FDA cites in this connection is overly broad, and merely satisfying it is not sufficient to merit inclusion in the scope of the rule.

[50] http://www.thefreedictionary.com/herbaceous+plant, accessed on 09/08/13, defines "herbaceous plant" as "a plant lacking a permanent woody stem."

[51] http://www.merriam-webster.com/dictionary/herbaceous, accessed on 09/08/13, gives one definition of "herbaceous" as "having the texture, color, or appearance of a leaf." http://www.thefreedictionary.com/herbaceous, accessed on 09/10,13, gives one definition as "green and leaflike in appearance or texture." http://dictionary.reference.com/browse/herbaceous, accessed on 09/10/13, gives one definition as "not woody."

[52] However, USDA's PACA list does inexplicably include nori, which to AHPA's knowledge is always sold in dry form and is not a perishable food.

Fifthly, AHPA notes that dry legumes are commonly sold at retail to consumers, and require extensive boiling by the consumer prior to consumption.[53] This serves as "processing that adequately reduces the presence of microorganisms of public health significance," although it is not "commercial" processing and therefore does not qualify for the exclusion in § 112.2(b)(1). Furthermore, there are dozens if not hundreds of such dry legumes sold in the marketplace - Canary beans, Adzuki beans, Cranberry beans, Rattlesnake beans, San Luis peas, etc., far more than the handful listed in § 112.2(a)(1). Since these crops should certainly be excluded from the rule, but FDA desires § 112.2(a)(1) to be as defined a list as possible and it is not practical to list every variety of dry legume, AHPA suggests that "dry legumes" be exempted from the rule by defining "produce" in a manner that excludes the entire category.[54]

### 7.6 Further comments regarding exclusions

AHPA notes that a key feature of "produce" as normally understood in American English is that it is delivered to the end user in fresh whole or cut form. In contrast, crops used primarily as or for spices, colorants, flavorings, dietary ingredients, and excipients typically undergo various industrial processing steps prior to retail sale, such as size reduction (e.g. grinding, milling, crushing), extraction or other chemical refinement, sterilization (as by heat, solvents, steam, or irradiation), packaging, and various other steps.[55,56] Such commercial processing even if limited to packing for retail sale, is or will be subject to the requirements of Part 111 (dietary supplement GMPs) and/or Part 117 (general GMP-HA/PC rules

[53] AHPA notes that FDA has partially addressed the issue of legumes by attempting in the definition of "produce" to define "grains" to include legumes such as soybeans. AHPA believes that lumping together grains and legumes is scientifically inaccurate, creates confusion in the definition (for example, why would soybeans, which are sometimes consumed in fresh cooked form, be defined as a "grain," while other shelled beans (e.g. kidney beans) are defined as "produce that is rarely consumed raw"?), and creates problems insofar as grains and legumes differ both in agriculture and in culinary use. (For example, legumes can both be harvested when green and consumed fresh, or harvested when mature and consumed after extensive cooking; whereas the latter is the only commercial option for grains.) Lumping them together also creates various inconsistencies between the rules; for example proposed § 117.5(h)(1) lists "dried beans and peas" as an example of "intact fruits and vegetables," whereas the proposed "produce" definition excludes soybeans (and presumably many other beans, although the precise scope of the "grains" category is unclear) from "fruits and vegetables."

[54] See additional information in our comments regarding proposed § 112.2(b).

[55] As discussed elsewhere in our comments, AHPA notes that RACs used in these industries are commonly traded in dried form, and that many of the RACs require peeling (e.g. to remove the inner bark of slippery elm or to separate the aril from the seed of nutmeg), cutting, or slicing in order to isolate the desired plant part and facilitate drying, packing, and storage. These steps are therefore an inherent part of the "harvesting" process for these commodities, and do not by themselves transform the commodity into a processed food.

[56] Some dried spices are sold at retail in whole form, but typically these are retail packaged at a facility other than the farm where the crop was harvested; as such, the packaging operation would be subject to the GMP-HA/PC Rule.

for foods).[57] Part 111 requires, and Part 117 will require, the manufacturer or packager to establish appropriate controls to ensure the safety of their products and prevent adulteration. As a result, it is not necessary for these crops to be additionally subject to the Produce Safety rule in order to protect public health.[58]

Furthermore, it is clear that FDA has not, as is required by FSMA, made a determination that these classes of RACs are ones for which the Produce Safety standards would minimize the risk of serious adverse health consequences or death, since neither the preamble nor the Qualitative Risk Assessment evaluates any safety risks related to non-produce[59] botanical food crops. Therefore, the proposed rule should be written in a manner which clearly excludes these RACs.

AHPA acknowledges that § 112.2(a)(3) excludes "produce that is not a raw agricultural commodity," which AHPA reads to mean that, for example, dried sliced tomatoes, garlic powder, or blackberry syrup would be regulated as a processed food under the new GMP-HA/PC Rule, rather than under the Produce Safety Rule. However, while on the farm, the Produce Safety rule would obviously apply to the tomatoes, garlic, or blackberries used to make these items (at least insofar as the exemption in § 112.2(b) would apply), which begs the question of whether the Produce Safety rule will similarly apply to crops used as or for spices, colorants, flavorings, excipients, or dietary ingredients (i.e., under current proposed Part 112 these crops would require documentation of the identity of the commercial processor in order to qualify for exemption). AHPA believes that the definitions as currently written could lead to the erroneous conclusion that it does.

AHPA further acknowledges that § 112.2(b)(1) provides an exclusion for produce that receives "commercial processing that adequately reduces the presence of microorganisms of public health significance" provided the farm keeps documentation "of the identity of the recipient of the covered produce that performs the commercial processing." However, AHPA believes this requirement will often

[57] AHPA notes that botanicals used in dietary supplements will frequently be subject to both rules: Part 117 will typically apply to manufacture and packing of the dietary ingredient, and Part 111 will apply to manufacture and packing of the dietary supplement.

[58] As discussed elsewhere in our comments, AHPA is aware that the American Spice Trade Association recently (March 2011) published guidance to aid its members in ensuring the cleanliness of spices. AHPA believes parts of the ASTA guidance to be more aspirational than practical (for example, the recommendations for improving farm practices represent laudable goals, but AHPA doubts their widespread implementation can be achieved in anything short of decades), but it does include the (usually sufficient) advice to include a microbial reduction step somewhere in the process. AHPA believes the prompt subsequent drop in Reportable Food Reports and recalls related to pathogen contamination in spices, to the extent it is not due to chance, is probably due use of such microbial reduction steps rather than to sudden widespread changes in farming practices. Such quick response to the guidance proves the willingness and ability of the processed food industry to take care of these problems without the need for FDA regulation at the farm level.

[59] 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.

be difficult or impossible to implement, especially for RACs traded in dried form, as discussed elsewhere in our comments; as a result, many farmers will be unable to avail themselves of this exclusion. Even if able to do so, these farmers should not be burdened with unnecessary documentation, but rather should be entirely excluded from the regulation through appropriate adjustments to the definitions and/or scope.

### 7.7 Comments regarding the exclusion for produce that is rarely consumed raw

AHPA strongly supports exempting "produce that is rarely consumed raw" from the rule. FDA has not made a determination that fruits and vegetables that are cooked by the consumer prior to consumption are RACs for which the Produce Safety standards would minimize the risk of serious adverse health consequences or death; AHPA doubts there would be evidence or data to support such a conclusion.

However, AHPA is concerned that the "exhaustive" list of "produce which is rarely consumed raw" given in § 112.2(a)(1) is not, in fact, an exhaustive list of all such food crops; nor does AHPA believe it is possible to compile an exhaustive list. There are hundreds of food crops which are commonly sold as produce and are cooked by the consumer prior to consumption. Many of these are sold as specialty items and in ethnic stores; many are only available regionally; and many rotate seasonally and/or may become newly fashionable (such that a one-time program of visiting stores to identify an "exhaustive" list would nevertheless fail to capture all such food crops).

AHPA feels strongly that neither ethnic consumers nor the broader American public should needlessly suffer higher prices for, or potentially even be denied access to these ingredients (e.g. if for some reason the crop cannot be grown in compliance with Part 112). Many of them are essential to the proper reproduction of ethnic cuisines; many of them represent heritage or antique foods or varieties;[60] and many offer an unusual eating experience. To take a simple example, the category "winter squash" contains far more than the two examples listed by FDA; it also includes dozens of other varieties such as Kabocha, Buttercup, Spaghetti, Hubbard, Delicata, Boston Marrow and Tohono O'odham.

AHPA believes it impossible for this paragraph to be a defined list; it can only be a list of examples.

### 7.8 Wildcrafted RACs should be excluded from the rule

FSMA requires the produce safety regulations promulgated by FDA to "provide sufficient flexibility to be applicable to various types of entities in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities."

[60] These may offer benefits both to the consumer (e.g. an unusual taste or texture) and to the farmer (e.g. suitability to a particular climate or bioregion, such as the highly drought-tolerant Pima Orange beans of the American southwest).

Produce and non-produce botanical food crops are both cultivated and wildcrafted. However, the current proposed rule was clearly written only with cultivated, rather than wildcrafted, produce in mind; this is evident from the types of provisions contained in the rule (many of which are wholly impracticable in the context of wildcrafting, such as those requiring control of agricultural water and animal manure, and monitoring for animal intrusion) as well as from the lack of any discussion of wildcrafting in the preamble, the Qualitative Assessment of Risk, or the Preliminary Regulatory Impact Analysis, and from FDA's belief that the proposed rule did not necessitate an Environmental Impact Analysis. Furthermore, it is clear that FDA has not, as is required by FSMA, made a determination that wildcrafted foods are a class of RAC for which the proposed Produce Safety standards would minimize the risk of serious adverse health consequences or death, since neither the preamble nor the Qualitative Risk Assessment evaluates any safety risks related to wildcrafted food crops.

AHPA estimates that up to 1 million individuals in the US depend on wildcrafting for some or all of their income, based on data from Robbins 2008.[61] AHPA believes in non-industrialized countries an even higher percentage of the population participates in wildcrafting. The total number of commercial wildcrafters worldwide is undoubtedly at least tens of millions of households.

Wildcrafting is labor-intensive, so although millions of people are engaged in it, wildcrafted foods represent only a tiny fraction of the US food supply. For example, blueberries are probably the most commonly wild harvested fresh fruit in the US, yet in 2012 wild Maine blueberries represented only 16% of the total US blueberry crop by tonnage, and only 0.2% of the total US fruit and nut harvest.[62]

[61] This study found that 17.8% of the population in 4 New England states had engaged in the harvest of non-timber forest products (NTFPs) in the past year. The current population of these states includes 7.855 million adults over 18 years old (U.S. Census Bureau: 2012), so this data would indicate that 1,398,000 adults in these states have recently engaged in wild harvesting. The study found that 61.5% of harvesters (860,000 adults based on the current population) had harvested food items; another 7.8% had gathered “medicinal/dietary supplement” articles (currently 109,000 adults; respondents could identify more than one NTFP type so some of this latter group may also have identified food articles). The study also found that 1.2% of the NTFP harvesters sold the harvested NTFPs and that another 2.1% sold product they made with the harvested articles. Thus not less than 10,300 adults in these 4 states can be assumed to be commercial wildcrafters of foods (1.2% of 860,000) and this number could be as high as 28,400 if the commercial sale of products made from these wild foods is also included (3.3% of 860,000). [If wildcrafted medicinals/supplements are also included, without any accounting for duplication, these numbers would be 11,600 (selling the harvested article as is) and 32,000 (also selling goods made from the NTFPs), respectively.] Extrapolating these calculations to the entire United States (current adult population over 18 = 240 million) would estimate that at least 315,000 Americans adults are commercial wildcrafters of foods, and that as many as 978,000 obtain some economic benefit from selling wildcrafted NTFPs as foods, medicines, or dietary supplements or as ingredients for these products. Since New England is not the most prolific source of non-timber forest products in the U.S. (by dollar value, at least, the Pacific Northwest and Appalachia are the largest U.S. sources), these numbers may be quite conservative.

[62] USDA Noncitrus Fruits and Nuts Preliminary Survey 2012.

Furthermore, less than 1% of wild blueberries are sold in fresh form, while the remainder are processed;[63] of the portion sold fresh, many are undoubtedly cooked prior to consumption.

Since wildcrafted produce is rarely consumed at all in the US, by logical extension it is rarely consumed raw. As such, AHPA believes wildcrafted foods should be added as an exclusion in § 112.2(a)(1). Furthermore, AHPA believes most commercial processors and consumers are aware that wildcrafted foods inherently contain biological risks and are careful to cook them thoroughly.

If FDA eventually makes a determination that wildcrafted foods are a class of RAC for which regulations promulgated under Sec. 419 would minimize the risk of serious adverse health consequences or death, FDA should engage in separate rulemaking specific to wildcrafted produce.

### 7.9 AHPA's suggested revisions to the definitions, inclusions, and exclusions

In consideration of the above, AHPA suggests the following revisions to the definition of "produce":

> "Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and fresh culinary herbs. A fruit is the fleshy sweet, sour, or savory edible reproductive body of a seed plant (such as apple, orange, and tomato) or a tree nut (such as ~~apple, orange,~~ walnut and almond) such that fruit means the harvestable or harvested part of a plant ~~developed~~ which develops from a flower and is commonly sold as food at retail markets in the United States in fresh whole or cut form. A vegetable is the leafy or fleshy edible part of an herbaceous plant (such as cabbage or potato), the ~~or~~ fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part, or the edible green part of a woody plant (such as rosemary, sage, or nopales), such that vegetable means the harvestable or harvested part of ~~any~~ a plant or fungus ~~whose~~ which is a ~~fruit,~~[64] ~~fleshy fruiting bodies,~~ seed~~s~~, root~~s~~, tuber~~s~~, bulb~~s~~, stem~~s~~, ~~leaves~~leaf, ~~or~~ flower ~~parts are~~,

[63] USDA U.S. blueberry production and utilization (cultivated and wild), selected States, 1980-2012; available at http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1765, accessed 09/25/13.

[64] AHPA recommends deleting "fruit" from the definition of "vegetable," otherwise there is redundancy between the definition of "fruit" and the definition of "vegetable." If FDA intends to retain "fruit" in the definition of "vegetable" then FDA should clarify in the definition of "fruit" that it refers to a *sweet or sour* edible reproductive body while in the context of "vegetable" the word "fruit" refers to a *savory* edible reproductive body, and should also move "tree nuts" such as "almond" to the "vegetable" category. However, AHPA believes it simpler and more effective for regulatory purposes simply to delete "fruit" from the definition of "vegetable." For additional clarity, AHPA proposes specifying that "fruit" can be either sweet, sour, or savory and proposes adding "tomato" and "walnut" as an additional examples.

or fleshy fruiting body[65] and is commonly sold as food[66] at retail markets in the United States in fresh whole or cut form;[67] ~~and~~ vegetable includes mushrooms, sprouts, and fresh culinary herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, wild rice, rye, wheat, amaranth, quinoa, buckwheat, or cotton seed~~, and soybeans~~.[68] Produce does not include algae or dry legumes (such as beans, lentils, and peas). Produce does not include food crops used as or in the production of spices, dietary ingredients, or food additives such as colorants, flavorings, or excipients, except for items which are commonly sold as food at retail markets in the United States in fresh whole or cut form (such as fresh mint or fresh hot peppers)."

AHPA recommends the following revisions to § 112.1:

"(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part....(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes but is not limited to[69] ~~all of~~ the following:...Fruits and vegetables such as almonds, apples, apricots, aprium, ~~asian~~ Asian pears, avocados, babaco, ~~bamboo shoots,~~[70] bananas, Belgian endive, blackberries,

[65] AHPA recommends moving "fleshy fruiting body" to the end of the list of plant parts because it is likely to be the one with which the reader is least familiar, and is therefore more likely to cause confusion if it occurs early in the list.

[66] It is important to specify "as food," otherwise the definition would include items such as fresh decorative flowers.

[67] AHPA believes it important to stipulate that the "harvestable or harvested" plant part must itself be commonly sold in fresh whole or cut form, otherwise certain crops will inappropriately be subject to the rule even when the plant part harvested is not in fact produce. For example, the crop *Coriandrum sativum* may be grown either to harvest cilantro (i.e. fresh produce), coriander root (i.e. fresh produce which is rarely consumed raw), or coriander seed (i.e. a spice or flavoring which is not produce). Similarly, celery may be grown either to harvest the stalk (i.e. fresh produce), root (i.e. fresh produce which is rarely consumed raw), or seed (i.e. a spice or flavoring which is not produce).

[68] Soybeans are not normally considered a grain; they are a legume, along with other types of beans, and should be addressed as such. Furthermore, soybeans are commonly sold in fresh form as edamame; however edamame is rarely consumed raw and should be included in § 112.2(a)(1).

[69] See comments below regarding use of the word "includes."

[70] Bamboo shoots are rarely consumed raw and should be included in § 112.2(a)(1).

blueberries, broccoli, cabbage, cantaloupe, carambola (star fruit), carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive (chicory leaf), garlic, grapes, ~~green beans~~[71], guava, fresh culinary herbs (such as basil, chives, cilantro, mint, ~~oregano,~~[72] and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and ~~persian~~ Persian), cultivated agaricus mushrooms,[73] nectarine, onions, papaya, passion fruit, peaches, pears, ~~peas,~~[74] peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions (green onions), ~~snow peas,~~[75] spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon...."

AHPA recommends the following revisions to § 112.2(a)(1):

"Produce that is rarely consumed raw in the United States,[76] ~~specifically~~ such as the produce on the following ~~exhaustive~~ list – acorns, amaranth greens (en choy),[77] arrowhead, arrowroot, artichokes, asparagus, bamboo shoots, bay leaf, beets, beet greens, bitter melon, fresh black-eyed peas, bok choy, boniato, breadfruit, ~~brussels~~ Brussels sprouts, burdock root (gobo), cactus pear, cassava (yuca), celeriac (celery root), chayote, chestnuts, fresh chick-peas, chicory root, choy sum, collard greens, coriander

[71] Green beans are rarely consumed raw and should be included in § 112.2(a)(1). To the extent that consumers may add defrosted frozen green beans directly to salads without cooking, it should be the responsibility of the frozen food manufacturer to control microbial risks, the same as for sweet corn which is already listed in § 112.2(a)(1).

[72] Oregano is rarely consumed raw and should be included in § 112.2(a)(1). To the extent that oregano is purchased in dried form, it should be the responsibility of the spice processor/packager to control microbial risks.

[73] Other cultivated mushrooms, such as shiitake and oyster, as well as all wild-harvested mushrooms, are rarely consumed raw and should be included in § 112.2(a)(1).

[74] If FDA retains peas in the current paragraph they should be modified with the word "fresh" to distinguish from dry peas, which are always boiled before consumption. However, fresh peas are also rarely consumed raw and should be included in § 112.2(a)(1). To the extent that consumers may add defrosted frozen peas directly to salads without cooking, it should be the responsibility of the frozen food manufacturer to control microbial risks, the same as for sweet corn which is already listed in § 112.2(a)(1).

[75] Snow peas are rarely consumed raw and should be included in § 112.2(a)(1).

[76] There are fruits and vegetables that are commonly eaten raw in their home country but not in the US.

[77] AHPA notes that the naming of ethnic produce is problematic, insofar as many items have no common English name; the same ethnic name may apply to more than one species; and ethnic names may vary between ethnic communities. If FDA insists the § 112.2(a)(1) list must be exhaustive rather than illustrative, AHPA believes it necessary to provide a comprehensive list of ethnic names and synonyms, correlated with Latin binomial and plant part along with common English name where possible.

root, crabapples, cranberries, curry leaf, edamame (fresh soybeans), eggplant, elderberries, false banana, fresh fava beans, fiddlehead ferns, figs, gai choy, gai lan, galangal, ginger root, green beans, kale, ~~kidney beans,~~ kohlrabi, lemongrass, ~~lentils,~~ lily bulb, fresh lima beans, long beans, lotus root, Malabar spinach, malanga (corms and leaves), marjoram, moringa (drumsticks; whole plant), mustard greens, nettles, nopales, oca, okra, olives, oregano, palm hearts, parsley root, parsnips, fresh peas, peanuts, ~~pinto beans,~~ plantains, potatoes, pumpkin, quince, ramps, rhubarb, rosemary, rutabaga, sage, sago, salsify, sea beans (salicornia), snow peas, sugarbeet, sweet corn, sweet potatoes (leaves and tubers), Swiss chard, sugarcane, taro (corms and leaves), tatsoi, thyme, turmeric, turnips (leaves and tubers), ulluco tuber, water caltrop, water chestnuts, water spinach, non-agaricus or "wild" cultivated mushrooms (such as shiitake and oyster), wild-harvested mushrooms,[78] other wild-harvested foods, winter melon (ash gourd), winter squash (such as acorn and butternut squash), and yams."

[78] "Wild" (i.e. non-agaricus) and wild-harvested mushrooms are never or almost never eaten raw. For example Wikipedia states, "Some wild species are toxic, or at least indigestible, when raw. As a rule all wild mushroom species should be cooked thoroughly before eating." http://en.wikipedia.org/wiki/Edible_mushroom, accessed 09/26/13. The Mycological Society of San Francisco website states "With a few exceptions...we do not recommend that mushrooms be eaten raw." http://www.mssf.org/cookbook/part_1.html#cwwcm, accessed 9/25/13.

# 8. Comments regarding the definition of "covered produce" and proposed § 112.2(b)

## 8.1 Overview of AHPA's comments

Proposed § 112.2(b) is too narrow; it provides exemptions for commercial processing in accordance with 21 CFR Parts 113, 114, or 120, but not other parts of 21 CFR. AHPA discusses why commercial processing in accordance with Parts 111 or 117 serves the purpose of protecting the public health. If FDA maintains the requirements for the identity of the commercial processor to be documented, these Parts should be added to § 112.2(b) as providing eligibility for covered produce to be exempt from Part 112.

The requirement in § 112.2(b) for farmers to document the identity of the commercial processor will be frequently unnecessary. For example, farmers can preclude their harvest from being used as fresh produce by planting species or varieties which are unsuitable for fresh use, or by harvesting a plant part or harvesting at a stage of maturity which is inconsistent with use of the crop as fresh produce.

Proposed § 112.2(b) will be frequently unworkable, since the farmer often will not know the identity of the commercial processor. This is especially true for botanical RACs which are used as or in production of spices, flavors, colorants, dietary ingredients, or excipients, which are typically traded in dry form and involve long, complex supply chains; this should be addressed through revision of the definition of "produce" as recommended elsewhere in AHPA's comments. But it is also true that produce farmers often do not know the end user of their crop.

Furthermore, many farmers do not operate under contract to a specific processor and therefore cannot know the identity of the commercial processor, if any, until after the harvest is sold. Finally, it should be clarified that the rule does not apply to the cultivation of produce crops for non-food purposes, such as soil improvement, phytoremediation, planting seed, nursery stock, decorative flowers or foliage, biofuels, perfumery, or pharmaceuticals.

AHPA makes appropriate recommendations below to the definition of "covered produce" and to § 112.2(b) to address the above concerns.

## 8.2 Summary of the proposed definition of "covered produce" and proposed § 112.2(b)

Covered produce is defined in the proposed Produce Safety Rule as "produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term 'covered produce' refers to the harvestable or harvested part of the crop."

Proposed § 112.2(b) provides that produce which "receives commercial processing that adequately reduces the presence of microorganisms of public health significance" are exempt from Part 112, provided the farmer keeps "documentation in accordance with the requirements of subpart O...of the identity of the recipient of the covered produce that performs the commercial processing." The proposed rule states that examples of such commercial processing include "processing in accordance with the requirements of parts 113, 114, or 120 of [21 CFR], treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining or distilling produce into products such as sugar, oil, spirits, or similar products."

### 8.3 Commercial processing in accordance with Part 111 or Part 117 should qualify for exemption in most cases

As discussed elsewhere in our comments, AHPA believes FDA should remove the default assumption that all covered produce is required to comply with Part 112 until proven otherwise. AHPA believes covered produce should not be assumed to be required to be Part 112 compliant unless delivered to an end user who will not adequately process it. Any biological risks which may occur in non-compliant covered produce should be mitigated through disclosures in commercial documentation accompanying the sale of the produce, which will preclude delivery to retail users or purchase by inappropriate commercial processors (i.e. those whose process does not include a kill step). For more information, see our comments above on rethinking the underlying assumptions of the Produce Safety rule.

However, in the event FDA proceeds to implement the proposed rule without altering the underlying assumption that all produce must be Part 112 compliant by default, AHPA finds the proposed exemption to be unnecessarily narrow. AHPA believes commercial processing in accordance with Part 111 or Part 117 should also qualify for the exemption, especially if the farmer provides notice where appropriate if it was not grown in compliance with Part 112. Part 111 requires, and Part 117 will require, the manufacturer or packager to evaluate proactively the risks associated with their products and establish appropriate controls to ensure the safety of their products and prevent adulteration. These may include controls on raw material sourcing (such as requiring vendors to comply with particular safety programs or sampling and testing of ingredients prior to use), use of microbial reduction steps (either within their own facility or by sending raw materials to another company for sterilization), finished product sampling and testing, and/or other effective means. So long as they are properly informed as to the status of any noncompliant covered produce offered to them for sale, such commercial processors will be able to make appropriate decisions as to the purchase and processing of said produce.

Part 111 requires dietary supplement manufacturers to implement specifications and controls for their ingredients, manufacturing processes, and finished products to ensure the identity, purity, strength, and composition of their products and ensure they are free from contaminants that may adulterate or lead to adulteration of the products, including microorganisms of public health concern. In response to the regulations, supplement manufacturers have implemented strict specifications and testing programs to

ensure their ingredients are free from harmful species or levels of microorganisms, as well as procedures to control microbiological hazards, such as steam treatment of ingredients prior to use. There is ample evidence that dietary supplement manufacturers are using effective means to ensure the microbiological safety of their products. The CDC website lists no multistate outbreaks of foodborne illness[79] linked to dietary supplements, and a recent CDC analysis of foodborne illnesses from 1998-2008 did not find any measurable percentage of outbreaks to be attributable to supplements.[80] In addition, CDC's Foodborne Outbreak Online Database[81] lists no dietary supplement as the source of a microbiological foodborne illness during the years 1998-2011, and AHPA is aware of no dietary supplement products for which a serious adverse event report (SAER) pertaining to gastrointestinal illness has been submitted to FDA.[82] AHPA acknowledges there are occasional recalls of dietary supplements due to pathogen contamination, but there have been none so far in 2013[83] and AHPA expects the frequency to continue to drop as supplement manufacturers proceed with implementation of the new dietary supplement GMPs and as their ingredient suppliers implement the proposed GMP-HA/PC regulations in Part 117.

Part 117 will require food processors and packagers to maintain a food safety plan, perform a hazard analysis, institute preventive controls to mitigate hazards, monitor those controls, and verify the controls are effective; the hazards to be addressed include microorganisms of public health concern. These steps are very similar to the HACCP requirements of Part 120. Once implemented, the requirements of Part 117 will force companies to identify and control any microbiological hazards which may be a concern for their products.

Based on recent history, AHPA expects the food processing industry will take the necessary steps to come into compliance with the new Part 117. For example, the American Spice Trade Association (ASTA) published voluntary guidance in March 2011 to aid its members in ensuring the cleanliness of spices. The ASTA guidance includes many excellent recommendations; some of these are more aspirational

[79] http://www.cdc.gov/outbreaknet/outbreaks.html, accessed on 09/24/13.

[80] "Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by using Outbreak Data, United States, 1998–2008." Painter, J.A. et al. Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 19, No. 3, March 2013.

[81] http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx, accessed on 09/24/13.

[82] AHPA has access to data from 2008-2009; 2008 is the first year in which SAERs were required by law to be submitted to FDA, while after 2009 FDA has not fulfilled FOIA requests for such data. In the 2008-2009 data there were four reports of gastrointestinal illness associated with nutrition bars containing peanut butter contaminated by Peanut Corporation of America; AHPA believes these to be foods, not dietary supplements, as they are currently sold with Nutrition Facts on their labels.

[83] Based on review of recalls at http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/default.htm, accessed on 09/25/13.

than practical, especially those directed toward farmers,[84] but the guidance also includes steps importers, processors, and/or packagers can easily implement to take control of the microbiological quality of their products, such as the recommendation to include a microbial reduction step somewhere in the processing of the spice.

Publication of the guidance was followed by a significant drop in Reportable Food Reports related to pathogen contamination in spices (from 25 during 09/2010 to 09/2011, to 8 during 09/2011 to 09/2012). Furthermore, since 09/2012[85] there have been only two recalls related to pathogens in spices, and no reports in CDC's Foodborne Outbreak Online Database of illnesses linked to spices. To the extent these low numbers are not due to chance, AHPA believes they are probably due to increased attention to microbial kill steps by the spice industry. Such quick response to the guidance proves the willingness and ability of the food processors to take care of these problems. AHPA expects the food processing industry to be even more motivated to comply with Part 117, since it will be legally enforceable rather than voluntary.

## 8.4 The proposed requirement to identify the commercial processor will be frequently unnecessary and unworkable

Proposed § 112.2(b) requires the farmer to keep "documentation in accordance with the requirements of subpart O...of the identity of the recipient of the covered produce that performs the commercial processing" in order to qualify for exemption from Part 112. AHPA believes this requirement will be frequently unnecessary and/or unworkable, and that the intended application (or lack of applicability) of the rule to various circumstances requires clarification.

### 8.5 The proposed requirement to identify the commercial processor will be frequently unnecessary

The requirement to document the identity of the commercial processor will be frequently unnecessary because the farmer himself often has the means to control whether or not his crop is or will be used as fresh produce subject to Part 112. These controls include:

- Species or variety planted. Different species or varieties of the same plant may be used for different purposes. For example, the *Apium graveolens* variety cultivated for celery root (produce rarely eaten raw) is different from the variety cultivated for celery stalks (produce frequently eaten raw), and the *Foeniculum vulgare* variety grown for fennel seed (a spice, not fresh produce) is different from the variety grown for fennel bulb (produce frequently eaten

[84] The ASTA guidance presents many laudable goals which it will be wise for the farming industry to work toward in the long term. However, as discussed elsewhere, the majority of farmers worldwide are impoverished, many are illiterate, many live in remote areas without access to modern technology, and many have little access to government assistance. They are therefore ill-prepared, at least currently, to implement controls over agricultural water, modernize their facilities, or make other improvements recommended in the ASTA guidance.

[85] As of 09/24/13.

raw). Similarly, the orange species *Citrus bergamia* is grown not for the fruit (which is unpalatable for use as fresh produce) but rather for the fruit peel (used to make flavors, fragrances, and marmalade). If FDA proceeds with the rule written in a manner that defaults to an assumption of required Part 112 compliance, the rule should be written in a manner that minimizes the recordkeeping burden, and imposes no other burden, on farmers of celery root, fennel seed, Bergamot orange, and similar RACs that are exempt either because they are not produce or because they are rarely eaten raw, even when closely related species or varieties may be grown for covered produce.

- Harvest. Farmers decide which plant part to harvest and when, and these decisions often preclude use of the crop as fresh produce subject to Part 112. For example, stalk celery is harvested for use as fresh produce when it is young, tender, and mild-flavored; by the time the plant goes to seed so that celery seeds (a spice or flavoring) can be collected, the stalks have a strong unpleasant flavor and are tough and fibrous. The same is true of *Coriandrum sativum*: the farmer may gather the young plants as cilantro (fresh produce), or may wait to collect the coriander seeds (a spice or flavoring), by which time the leaves are unpalatable. Similarly, peas and beans intended for use as a green vegetable are harvested when they are young and tender, while those intended for use as a dry legume are harvested after they are mature and starchy. If FDA proceeds with the rule written in a manner that defaults to an assumption of required Part 112 compliance, the rule should be written in a manner that minimizes the recordkeeping burden, and imposes no other burden, on farmers of celery seed, coriander seed, dry legumes, and similar RACs that are exempt either because they are not produce or because they are rarely or never eaten raw, despite the fact that the same plant may also be grown for covered produce.

### 8.6 The proposed requirement to identify the commercial processor will be frequently unworkable

The requirement to identify the commercial processor will be unworkable, especially insofar as FDA may apply Part 112 to crops which are not produce (i.e. if FDA does not revise the proposed definition of "produce" in accordance with our comments elsewhere[86]). Non-produce botanical RACs are normally traded in dry form (i.e. drying is part of the harvest of the RAC, not a food processing step) and such RACs usually involve long and complicated supply chains. The farmer who grows a spice or other non-produce RAC normally sells it to a local buyer, who then sells it to a trader who sells it in the international market; the farmer has no way even to know what country it ends up in, never mind which specific company ends up processing it.

Even for fresh produce, AHPA believes the farmer often has no idea where his crop ends up, because the crops are frequently sold through cooperatives or other intermediaries. Some such intermediaries may

[86] AHPA's suggested revisions would exclude edible botanical RACs which are algae or dry legumes, or are used as or in production of spices, colorants, flavorings, dietary ingredients, and excipients.

supply only the retail market, but others supply both retailers and commercial processors. AHPA believes it will be necessary for cooperatives and other intermediaries to establish systems for segregating Part-112-compliant produce (suitable for retail or other consumption without an adequate kill step) from non-compliant produce (suitable only for commercial processing with an adequate kill step), and for tracking each type of produce from farm to end user. Indeed, some such systems already exist,[87] although participation costs money. However, it must be borne in mind that use of such tracking systems stems from the demands not of farmers but of large end-users,[88] who have the leverage (through their buying decisions) to enforce new requirements on the supply chain. It is not something the farmer can force his customers to implement. Therefore, many farmers will not be in position to identify the end-users of their harvests.[89]

Also, this requirement would be unworkable insofar as FDA may expect farmers who choose to grow a produce crop not in compliance with Part 112 to have proof of the intended commercial processor on hand during the middle of the growing season. Many farmers grow their crops on speculation, i.e. without a contract in place for sale of the harvest; therefore the identity of the customer is not known until after the harvest. FDA must bear in mind that if inspection of a farm finds its current crop to be out of compliance with Part 112, a lack of documentation as to the identity of the commercial processor for the crop cannot be taken as *prima facie* evidence of wrongdoing by the farmer. A farmer who grows his produce crop without complying with Part 112 will have a narrower range of prospective customers for his harvest, insofar as use without an adequate kill step would be excluded, but he will still be legally able to sell the harvest to an appropriate commercial processor[90] or to use it for any non-food purpose.

Furthermore, AHPA would point out that crops grown for food are also frequently grown for various non-food purposes, such as soil improvement (e.g. nitrogen fixation); phytoremediation; planting seed; nursery stock; decorative flowers or foliage; biofuels (e.g. sugarcane); perfumery; and pharmaceuticals (e.g. mint as a source of menthol, which can also be grown as a fresh culinary herb). FDA should therefore recognize that not every farm which grows these crops will be subject to FDA jurisdiction, and FDA must not expect a farmer to account for the commercial food processor of every part of his harvest.

These concerns will be largely moot if FDA accepts AHPA's suggestion to rethink the Produce Safety Rule to allow non-compliant covered produce to be sold with an appropriate notice provided in commercial

[87] See for example http://w4.icix.com/industries/food-and-beverage, accessed 10/08/13.

[88] For example, Safeway's produce safety program requires traceback and trace-forward systems for certain types of produce. http://suppliers.safeway.com/usa/forms/Produce_Vendor_Food_Safety_Verification_Program.pdf, accessed 10/08/13.

[89] See additional discussion in AHPA's comments above on rethinking the assumptions underlying the Produce Safety Rule.

[90] An "appropriate" commercial processor would be one who processes the produce with an adequate kill step. AHPA notes that under the current proposed Part 112, the farmer would be required to document the identity of the commercial processor.

documentation. Failing that, some of the above concerns will be addressed if FDA accepts AHPA's recommended changes to the definition of "produce"; others can be most easily addressed through clarifications to the definition of "covered produce" and adjustments to § 112.2(b).

**8.7 AHPA's suggestions regarding the definition of "covered produce" and § 112.2(b)**

AHPA emphasizes that the most practical solution would be to write the Produce Safety Rule in a manner which allows non-compliant covered produce to be sold with an appropriate notice provided in commercial documentation, as discussed elsewhere.

In addition, in view of the complexities above, AHPA believes the definition of "covered produce" requires significant clarification as follows:

> Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop. Covered produce does not include produce sold with the following statement on the commercial documentation accompanying its sale: "NOTICE: Not grown in compliance with 21 CFR part 112. Not for fresh or raw consumption. May require commercial formulation, processing, or both to adequately reduce microorganisms." Additionally, covered produce does not include a farmer's crop which is precluded from use as fresh produce by planting a species or variety unsuitable for use as fresh produce (e.g. which is unpalatable or tough) or by harvesting the crop in a manner that renders it unsuitable for use as fresh produce (e.g. harvesting at a different time than is suitable for fresh produce, or harvesting a plant part other than the one used as fresh produce). Covered produce does not include a farmer's crop or portion of a crop when it is grown for soil improvement or remediation; for use as planting seed, nursery stock, or decorative flowers or foliage; for production of biofuels, perfumery, or pharmaceuticals; or for other non-food purposes.

In addition, AHPA suggests the following revisions to § 112.2(b):

> (b) Covered produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (b)(2), and (b)(3) of this section) under the following conditions:
> (1) The following statement is contained in commercial documentation accompanying the sale of the covered produce: "NOTICE: Not grown in compliance with 21 CFR part 112. Not for fresh or raw consumption. May require commercial formulation, processing, or both to adequately reduce microorganisms." ~~receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of parts 113, 114, or 120 of this chapter,treating with a validated process~~

~~to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining or distilling produce into products such as sugar, oil, spirits, or similar products;~~
(2) You must establish and keep documentation in accordance with the requirements of subpart O of this part, of the ~~identity of the recipient of the covered produce that performs the commercial processing~~ commercial documentation containing the notice described in paragraph (b)(1) of this section; and
(3) The requirements of this subpart and subpart Q of this part apply to such produce.

If FDA insists the rule must require farmers to document the identity of the commercial processor, AHPA suggests the following revisions to § 112.2(b):

(b) Covered produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (b)(2), and (b)(3) of this section) under the following conditions:
(1) The covered produce (i) ~~receives commercial processing~~ is commercially formulated and/or processed[91] to ~~that~~ adequately reduce~~s~~ the presence of microorganisms of public health significance or (ii) is inherently precluded from use as covered produce due to the species or variety planted, plant part harvested, or stage of maturity at harvest. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of parts 111, 113, 114, 117, or 120 of this chapter, such as treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), ~~and~~ or processing such as refining or distilling produce into products such as sugar, oil, spirits, extracts, or similar products;
(2) You must establish and keep documentation in accordance with the requirements of subpart O of this part, of (i) the identity of the recipient of the covered produce that performs the commercial processing described in paragraph (b)(1) of this section or (ii) the reason the harvest is inherently precluded from use as fresh produce, i.e. the species or variety planted, plant part harvested, or stage of maturity at harvest; and
(3) The requirements of this subpart and subpart Q of this part apply to such produce.

[91] AHPA notes that product formulation can serve to adequately reduce microorganisms of public health significance, either alone or in combination with process steps such as heat or pressure. For example, the microbiological quality of mayonnaise and other egg products, as well as many acidified foods, are often controlled solely through product formulation (e.g. use of acid or preservatives) rather than through heat. To preclude any confusion as to whether use of a formulation validated to kill pathogens is sufficient to qualify for the exemption, "product formulation" should be explicitly included in the language.

## 9. Comments on farm "ownership"

The regulations need to clarify what is meant by farm "ownership" for the purpose of determining whether a RAC is from a "farm under the same ownership." AHPA believes Congress intended this phrase to include RACs produced by the same entity on various pieces of land. However, AHPA believes that while the Congressional intent is clear, the use of the term "ownership" is ambiguous in the context of farming operations.

- In the US and around the world, it is common for farmers to rent land on which to grow their crops.

- In the case of wildcrafted botanicals or hunted animals, it is common for the RAC to be collected from public lands and from private lands not owned by the collector or hunter.

- In many areas of the world, and to some extent even in the US, it is common for crops to be grown communally or collectively.

AHPA believes that the entity (individual, family, corporation, collective, or other entity) which manages the farming operation and controls the distribution of its output should be designated the "owner" irrespective of the land use arrangements, irrespective of the farming practices, irrespective of whether the work is performed by individuals who are "employees" in the usual sense of the word, and irrespective of how the proceeds from the farming operation are distributed among the people involved.

To define it in any other way would lead to perverse outcomes as described in the hypothetical examples below.

Example 1: Farmer A owns 5 acres of land and Farmer B rents 5 acres of land. Both farmers grow nutmeg spice and perform the tasks of growing, harvesting, peeling (to remove the aril from the rest of the seed), drying, packing, and storing the nutmeg, all of which activities are necessary to produce the RAC "nutmeg." It would make no sense for Farmer A to be designated a "farm" (since all of the activities are performed on land that he owns) while Farmer B is designated a "farm-mixed type facility," "food processing facility," or "food warehouse" (simply because he rents the land on which the activities are performed). Furthermore, to do so would put Farmer B at a significant disadvantage to Farmer A, since Farmer B would be required to incur significant new expenses in order to comply with Part 117.

Example 2: Farmers A and B each own 5 acres of land and Farmer C holds permits to collect from public lands. All three farmers are in the American ginseng trade. Farmer A grows his plants in shade-covered fields and performs the tasks of growing (including sowing, tilling, cultivating, fertilizing, etc.), harvesting, cutting, drying, packing, and storing the roots, which produces the RAC "American ginseng root." Farmer B practices a different type of cultivation and grows his plants in the understory of the forest on his property, which produces the RAC known in the herbal trade as “woodsgrown American ginseng root”

or “wild-simulated American ginseng root”; he performs the tasks of seeding, harvesting, cutting, drying, packing, and storing the roots. Farmer C collects roots from public lands and performs the tasks of seeding (wildcrafters commonly re-seed the plant they collect in order to ensure sustainability, and in fact this practice is usually required under state regulations), harvesting, cutting, drying, packing, and storing the roots. Again, it makes no sense for the three farmers to be treated differently based on their land ownership, and to do so would put Farmer C at a significant disadvantage to the others, since he would be required to incur significant new expenses in order to comply with part 117. Furthermore, FDA has no authority to make distinctions based on various types of farming practices, as it would do if it tried to classify Farmers B and C differently from Farmer A based on the difference in cultivation method; nor would it make any sense, nor does AHPA believe the Congress would have intended, to classify the same item as an RAC when grown on a farm and a processed food when it is collected in the wild.

Example 3: Farmer A is a man and his family who farm 10 acres of land, Farmer B is a corporation which farms 100 acres of land, Farmer C is a collective which farms 50 acres of land wherein the crop is grown in large fields and each member of the collective works in those fields, Farmer D is a collective which farms 50 acres of land wherein each member of the collective is assigned a small area which he or his family is personally responsible for tending. (AHPA notes that many variations on the theme of Farmer C and Farmer D exist in the world. AHPA believes that often the arrangements can be rather free-form, with members lending a hand wherever needed, even if each small area is officially assigned to a particular person or family.) Each of these farmers grows cinnamon bark and performs the tasks of growing, harvesting, peeling away the bark (i.e. the article of commerce), cutting into large pieces (to facilitate subsequent drying, handling and packing), drying, packing, and storing the bark, all of which activities are necessary to produce the RAC "cinnamon bark." Farmer A shares the farming proceeds among his family. Farmer B shares the farming proceeds among its employees and shareholders by way of paychecks (which may be based on the amount of work contributed, the volume or quality of RAC produced or harvested, job description, seniority, etc.) and distribution payments. Farmers C and D each shares the farming proceeds (in the forms of both money and RAC) among its members by whatever criteria are deemed appropriate (e.g., based on need, amount of work contributed, size of family, volume or quality of RAC produced or harvested, social hierarchy, etc.). In each case, it would make no sense for FDA to regulate any of these farmers differently simply because of differences in the financial arrangements between the individuals involved; nor does FDA have the authority to investigate the financial or employment relationships between the parties involved in the farming operation, or to make distinctions based on differences in farming practices or work-sharing arrangements.

Example 4: Farmer A is a family which produces 10 different RACs on one 5-acre parcel of land and 1 other RAC on a separate but adjoining 3-acre parcel of land, all of which land the family owns. Farmer B is a corporation which produces 3 different RACs on several large (1000s of acres) areas of land in several states, some of which land is owned by Farmer B, some of which is rented from private owners, and some of which is rented from the government. Farmer C is a collective which produces 25 different RACs on various parcels of land around a small city; each parcel produces a variety of different RACs. In each case, it would make no sense for FDA to regulate any of these farmers differently simply because of

differences in the geographic location of the growing areas or on the number or configuration of RACs grown.

Therefore, AHPA suggests that the "owner" of a farm should be interpreted as the entity that directs its operation. AHPA proposes that the following definitions be established:

> *Farm owner* means the individual, family, corporation, collective, or other entity responsible for managing a farm operation which produces one or more raw agricultural commodities.
>
> *Farms under the same ownership* or *co-owned farms* mean all farms that have the same farm owner.

AHPA also strongly recommends that FDA ensure the final rule does not inadvertently or inappropriately disadvantage one ownership type, as described in the above examples, over another.

# 10. Other comments

### 10.1 Comments regarding "includes"

In the preamble to the GMP-HA/PC Rule, FDA proposes to "replace the phrase 'includes, but is not limited to' with 'includes,' because the use of the word 'includes' indicates that the specified list that follows is not exclusive. The phrase 'but is not limited to' is unnecessary."

AHPA strongly disagrees with this proposed change and believes such a change will make regulations much less clear and much more confusing.

The word "includes" is inherently ambiguous. For example, one popular online resource states "Some writers insist that *include* be used only when it is followed by a partial list of the contents of the referent of the subject....This restriction is too strong. *Include* does not rule out the possibility of a complete listing."[92]

AHPA notes that FDA's own usage of "includes" in the proposed GMP-HA/PC Rule and Produce Safety Rule demonstrates the confusion that would result from an automatic presumption that the list which follows is not exclusive.

For example, FDA has proposed the following definition of "farm":

> *Farm* means a facility 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:
>
> (i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised or consumed on that farm or another farm under the same ownership; and
>
> (ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

AHPA believes the list (i) and (ii) in this definition is intended to be complete, i.e. any farm performing food-related activities other than those listed in (i) and (ii) will no longer meet the definition of "farm" but rather will be a "farm mixed-type facility." If this is not what FDA intends then AHPA is extremely confused about the intended scope of the Produce and GMP-HA/PC Rules.

AHPA believes examples such as this demonstrate that "includes" can be and often is, despite FDA's statement to the contrary, used to introduce a list which is complete. AHPA therefore encourages FDA to use "includes, but is not limited to" wherever the list which follows is not intended to be exhaustive, to make it clear to the

[92] http://www.thefreedictionary.com/include, accessed 11/13/13.

reader that other list items may exist. Alternately, FDA might replace "includes, but is not limited to" with "such as," as the latter always clearly indicates the following list is not complete.

Correspondingly, wherever FDA intends a specified list to be complete, AHPA encourages FDA to use the phrase "includes and is limited to" or "is limited to." This will make it clear to the reader that no other items are intended to be comprised by the list.

**10.2 Comments regarding paragraph headings**

AHPA opposes FDA's use of headings in the form of questions in the proposed Produce Safety Rule. The "question" format (e.g. "What are the requirements for personnel?") is both wordy and patronizing, and makes it more difficult to scan the rule quickly to find a desired section.

AHPA requests FDA to use simple, short, clear headings which briefly capture the topic of each section, as was done in the proposed GMP-HA/PC Rule.

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