**DOCKET NO. FDA–2011–N–0920**

**BEFORE**

**THE UNITED STATES OF AMERICA**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**FOOD AND DRUG ADMINISTRATION**

# COMMENTS OF THE

# AMERICAN HERBAL PRODUCTS ASSOCIATION

**ON**

**PROPOSED RULE for**
**CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD**

**November 22, 2013**

## Prefatory remarks

The Food and Drug Administration (FDA or the agency) on January 16, 2013 issued a proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (the proposed GMP-HA/PC Rule or proposed Part 117). 78 FR 3646-3824. This proposed rule would amend FDA's existing regulation for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food to add requirements for facilities that are required to register with FDA under FDA's current food facility registration regulation under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The proposed rule would also revise certain of the definitions in FDA's current food facility registration regulation to clarify the scope of the exemption from registration requirements provided by the FD&C Act for "farms." FDA states in its January 16 notice that it is taking this action as part of its announced initiative to revisit the CGMPs since they were last revised in 1986 and to implement new statutory provisions in the FD&C Act.

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 GMP-HA/PC rule. AHPA's members therefore have an interest in the proposed GMP-HA/PC 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 Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (the proposed Produce Safety Rule or proposed Part 112; Docket No. FDA-2011-N-0921). 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 Produce Safety Rule and discuss certain provisions which relate to the Produce Safety Rule. Whenever the term "the proposed rule" is used in this document it means the proposed GMP-HA/PC Rule; reference to the other proposed rule is always with the term "the Produce Safety Rule" or the term "Part 112."

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) 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) for further information.

(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

[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.

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 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.

[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.

# 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 to the Produce Safety Rule 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 full service restaurants, AHPA doubts that widespread upgrades to farm practices and infrastructure among millions of peasant farmers 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

[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.

believes the proposed rules will be difficult to implement if a primary location for implementation is on 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; rather, it requires only that the food be grown, raised OR consumed on the farm or a co-owned farm. It is also inconsistent

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 the farm or group of farms. This is evidenced by the Fourth Organizing Principle's repeated use of the

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.

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 in footnote 22 below, as well as in 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 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 to the Produce Safety Rule 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

[22] As discussed elsewhere in our comments, AHPA estimates the number of commercial wildcrafters in the US alone to be at least 300,000 adults and possibly nearly 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 large numbers 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

definition be revised to 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) below 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 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

[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.

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. 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

[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 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.

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 GMP-HA/PC Rule, and are not duplicated in our comments to the Produce Safety Rule.**

## 6. Comments regarding the definitions of "qualified facility"

AHPA applauds Congress's and FDA's intent to ensure that the Part 117 rules are not overly burdensome for small businesses, for example by exempting "qualified facilities" from some of the requirements. However, when creating this exemption, FSMA was unclear about how to determine whether a facility is a qualified facility, and the current proposed rule provides insufficient clarity on this issue. Accordingly, we request that FDA to revise the proposed regulations that describe how to calculate sales for determining qualified facility eligibility.

The current proposed rule provides, in part:

> *Qualified facility* means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:
>
> (1) During the 3-year period preceding the applicable calendar year, the average monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
>
> (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Thus, whether a facility meets the qualified facility criteria depends on a calculation of sales. However, given certain other proposed regulatory definitions, it is not clear how to calculate "sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate."

The proposed rule provides the following definitions, which are modeled on the language in FSMA:

> *Affiliate* means any facility that controls, is controlled by, or is under common control with another facility.
>
> *Facility* means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

> *Subsidiary* means any company which is owned or controlled directly or indirectly by another company.

Furthermore, 21 CFR 1.227(b)(2) defines a "domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act" in relevant part as follows:

> *Facility* means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States....

Thus, facilities appear to be defined as buildings or other structures, while subsidiaries are business organizations. (It is possible that "establishment" could be interpreted as a business entity, but this is not obvious, as "establishment" also normally implies the existence of a structure or building.)

Accordingly, a facility cannot have or be a subsidiary because it is not a business entity or a person and, as a building or structure, cannot own or directly control any business entity. Further, in that a building cannot control or be controlled by another building, the only way that a facility can be an affiliate of another facility is if both facilities are under common control. AHPA acknowledges that the proposed regulatory definitions of "qualified facility," "affiliate," and "subsidiary" generally track the statutory definitions. However, as discussed above, those definitions likewise fail to account for the legal differences between a piece of property (i.e., a facility) and a business entity or person.[32]

Applying the proposed definitions therefore renders redundant or meaningless much of the direction that, when calculating sales to determine qualified facility eligibility, one must include "the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate." In fact, when applying the relevant definitions, the calculation technically may include only sales of the facility in question and of other facilities that are under common control. General principles of construction include avoiding interpretations that render words or phrases redundant or meaningless and that produce absurd results.[33] Since a literal interpretation of the proposed rule's definition of "qualified facility" would arguably do both, we ask that FDA consider

[32] See 21 USC § 350g(l)(1), (4)(A), (4)(D).

[33] E.g., Sprietsma v. Mercury Marine, 537 U.S. 51, 63 (2002) (interpreting "law" narrowly, in part, because a broad interpretation could include regulations, thereby rendering the express reference to "regulations" superfluous); Mackey v. Lanier Collection Agency & Serv., Inc., 486 U.S. 825, 837 (1988) (rejecting interpretation of provision that made it redundant with another provision); Public Citizen v. Department of Justice, 491 U.S. 440, 454 (1989) ("Where the literal reading of a statutory term would 'compel an odd result,' . . . we must search for other evidence of congressional intent to lend the term its proper scope").

amending the proposed definition of "qualified facility" to clarify what sales to include in determining whether a facility so qualifies.

In so clarifying, FDA might use as a model the FDCA provisions that govern eligibility for a waiver of the new drug application user fee for a small business's first human drug application.[34] Determining eligibility for that provision's definition of "small business" requires counting the employees of both the applicant company and its affiliates. For purposes of the waiver provision, the term "affiliate" means "a business entity that has a relationship with a second business entity if, directly or indirectly —

(A) one business entity controls, or has the power to control, the other business entity; or
(B) a third party controls, or has the power to control, both of the business entities."[35]

Thus, whether a company qualifies as a small business depends on the number of employees of the companies that are under common control or ownership with the company and any companies that own or are owned by the company.

Similarly, we propose that the Final Rule define "qualified facility" to direct that the sales counted include:

(1) the sales of the facility;
(2) the sales of any other facility under common control or ownership with the facility;
(3) the sales of any other facility owned or controlled by any subsidiary of any business entity that owns or controls the facility; and
(4) if any business entity that owns or controls the facility is a subsidiary of a third party, the sales of any other facility owned or controlled by that third party.

This approach would implement FSMA consistent with Congress's and FDA's apparent intent to include in the calculation sales by facilities owned or controlled by the facility's owner as well as those owned or controlled by subsidiary and affiliated entities. Congress could not have intended the unclear and unworkable result which appears to be produced by a literal application of the statutory definitions. As the agency tasked with interpreting and implementing FSMA, FDA should issue regulations that carry out the obvious intent of Congress. No stakeholder can reasonably question what Congress attempted to do in crafting the "qualified facility" exemption, and therefore no stakeholder should object to regulations that implement the statute accordingly and the FDA's interpretation of FSMA in this regard should be accorded "Chevron deference."[36]

[34] See 21 USC § 379h(d)(4).

[35] 21 USC § 379g(11).

[36] See Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

Additionally, for the purposes of applying the definition, we request that FDA set at 51% the threshold for determining whether a company owns or controls a facility or another company, i.e. a company will be said to own or control a facility or another company if it holds a 51% or greater interest in the facility or company.

AHPA therefore proposes the following revisions to the definition of "qualified facility":

> *Qualified facility* means ~~(when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate)~~ a facility that is a very small business as defined in this part, or a facility to which both of the following apply:
>
> (1) During the 3-year period preceding the applicable calendar year, the average monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
>
> (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.
>
> For purposes of these calculations, the sales to be counted include (a) the food sales of the facility; (b) the food sales of any other facility under common control or ownership with the facility; (c) the food sales of any other facility owned or controlled by any subsidiary of any business entity that owns or controls the facility; and (d) if any business entity that owns or controls the facility is a subsidiary of a third party, the food sales of any other facility owned or controlled by that third party.

# 7. Comments regarding other definitions

### 7.1 Comments regarding the definition of "cross-contact"

The proposed definition of cross-contact is "the unintentional incorporation of a food allergen into a food."

AHPA notes that the safety risks associated with the presence of major food allergens are, by law, mitigated through disclosure of the allergen on product labels. Cross-contact is a problem, therefore, only for products whose labels do not disclose presence of the allergen.

For example, no safety risk occurs if a product made with milk powder, and labeled to disclose the presence of milk, is "contaminated" with traces of whey from a nearby processing operation.

AHPA furthermore believes the evaluation of hazards related to allergens should not be open-ended, but rather should be limited to the major food allergens identified by law.

AHPA therefore suggests the definition be revised as follows:

> *Cross-contact* means the unintentional incorporation of a major food allergen into a food where the presence of that allergen is not disclosed on the label of the finished food.

### 7.2 Comments regarding the definition of "microorganisms"

For clarity, AHPA recommends the following change to the definition of "microorganisms":

> *Microorganisms* means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites ~~and includes~~, including but not limited to[37] species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

### 7.3 Comments regarding the definition of "packing"

For clarity, AHPA recommends the following change to the definition of "packing":

> *Packing* means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes packaging and other packing-related activities traditionally performed by farms to prepare raw agricultural

[37] See AHPA's comments on use of "including" vs. "including but not limited to."

> commodities ~~grown or raised on the same farm or another farm under the same ownership~~ for storage and transport, when the commodities involved are grown or raised on the same farm or a co-owned farm[38]; but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

In the absence of this change, the packing definition is confusingly vague and largely redundant to other definitions; for example "trimming the outer leaves" would technically meet the definition of "packing" (since such trimming facilitates more efficient packing) despite being already covered by the definition of "harvesting." Also, the word "packaging" should be explicitly included to make clear that packing produce into retail product-contact containers, when performed on the farm, does not transform the farm into a farm mixed-type facility.[39]

**7.4 Comments regarding the definition of "pest"**

See our comments in connection with proposed § 117.35(c) below, in our comment #9.12.

**7.5 Comments regarding the definition of "rework"**

AHPA suggests the following revision to the definition of "rework," for clarity:

> *Rework* means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or, in the case of food removed from processing for insanitary conditions, that has been successfully reconditioned by reprocessing and that is suitable for use as food.

**7.6 Comments regarding the definition of "small business"**

The proposed rule defines a "small business" as "a business employing fewer than 500 employees."

AHPA generally supports this definition. It is the smallest of the food manufacturing small business size standards promulgated by the Small Business Administration in 13 CFR § 121.201, which range from 500 employees to 1000 employees depending on the type of food. AHPA knows of no justification for

[38] 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.

[39] The definition of "packing" in the proposed Produce Safety Rule states that on-farm packing may include packaging.

defining the term in any other manner, unless it were to make the threshold higher (i.e. either 750 employees or 1000 employees, the other size thresholds established by SBA in 13 CFR § 121.201 for food manufacturing).

However, AHPA suggests the definition should be revised to clarify whether employees at subsidiary or affiliate companies should be included in the total; AHPA assumes FDA intends for such persons to be included. Also, the definition should be revised to clarify that only persons actually employed by the firm in question are counted toward the total.[40]

AHPA therefore recommends the following change to the definition of "small business":

> *Small business* means, for purposes of this part 117, a business employing fewer than 500 persons, including those employed at subsidiaries or affiliates of the business, but not including those employed by unrelated firms such as subcontractors or vendors.

### 7.7 Comments regarding the definition of "very small business"

The proposed rule offers three possible definitions of "very small business":

> **Option 1 for definition of "Very small business"**
> *Very small business* means, for purposes of this part 117, a business that has less than $250,000 in total annual sales of food, adjusted for inflation.
> **Option 2 for definition of "Very small business"**
> *Very small business* means, for purposes of this part 117, a business that has less than $500,000 in total annual sales of food, adjusted for inflation.
> **Option 3 for definition of "Very small business"**
> *Very small business* means, for purposes of this part 117, a business that has less than $1,000,000 in total annual sales of food, adjusted for inflation.

AHPA finds none of these options to be appropriate.

To begin with, food manufacturing margins are typically quite slim; the average net margin for large, publicly-traded food processors is in the range of 4-5%.[41] To AHPA's knowledge the average net margin

[40] It may seem obvious that the number of a firm's employees does not include persons employed by a separate company. However, AHPA is aware that employees of FDA have from time to time stated that when a facility subcontracts work to another firm, the employees of that other firm count toward the number of personnel employed by the facility. For example, a CFSAN official made this statement in industry question-and-answer sessions after the dietary supplement regulations were published. AHPA finds this to be an erroneous and unsupportable interpretation, and FDA subsequently conceded the point, but not before causing great confusion among the regulated stakeholders. The definition should be written in a manner that precludes such confusion.

[41] http://csimarket.com/Industry/industry_Profitability_Ratios.php?ind=505; http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/margin.html; both accessed 10/15/13.

for small companies is even lower, since they do not have the economies of scale, leverage over vendors, wide range of customers, use of forward contracts and other hedges to stabilize commodity prices, and other advantages enjoyed by large companies. Assuming therefore a 2-3% average net margin, even setting the definition of "very small business" at the highest threshold proposed by FDA ($1,000,000) would require small companies with profit margins of as little as a few thousand dollars per year to comply with the new rule.[42] AHPA believes such firms will be unable to afford the new required expenses out of their existing cash flow; will likely be unable to raise prices to increase their cash flow; and therefore ultimately will be driven out of business by the Rule.

Furthermore, AHPA notes that Part 117 will apply to businesses globally, many of which operate in countries having currencies valued much lower than the dollar. Therefore, if "very small business" is defined based on annual revenues, many small foreign firms (which will be largely exempt from the rule due to the low dollar value of their annual revenues) would operate at a huge advantage to American firms of comparable number of employees or comparable annual production volumes. AHPA doubts this outcome would be consistent with the intent of Congress and believes it would be unfair to domestic business.

AHPA therefore urges FDA to define "very small business" on the basis of number of employees rather than a dollar amount of revenue. AHPA suggests defining "very small business" as a company which is 5x smaller than "small business."

AHPA recommends the following definition of "very small business":

> *Very small business* means, for purposes of this part 117, ~~a business that has less than $1,000,000 in total annual sales of food, adjusted for inflation~~ a business employing fewer than 100 persons, including those employed at subsidiaries or affiliates of the business, but not including those employed by unrelated firms such as subcontractors or vendors.

**7.8 Comments regarding the definition of "lot" and new definitions of "batch" and "production code"**

The proposed rule defines "lot" as "the food produced during a period of time indicated by a specific code." AHPA finds this definition to be too prescriptive and inflexible.

The proposed definition is predicated on the assumption that the timeframe of production is the most logical way to identify a lot. This may be true in some production environments, such as those that operate continuously, but it is emphatically not true in others. Many food processors, especially smaller ones, operate on a batch production basis rather than a continuous production basis.

[42] A profit margin of 2% on $1,000,000 is $20,000; however, 2% is only an average. Many companies have net profits much smaller than this.

Also, AHPA believes it important for the regulations to clarify the purpose of the "specific code" associated with the lot (i.e. that it should allow the production history of the associated food to be determined), and to define "production code" since this term is used in the regulation [e.g. § 117.305(f)(4)].

AHPA therefore recommends the definition of lot be modified, and that definitions for "batch" and "production code" be added to § 117.3, as follows:

> *Lot* means a batch, or a specific identified portion of a batch; or, in the case of food produced by a continuous process, a specific identified amount of ~~the~~ food produced during a specified period of time, or in a specified quantity, on a specified equipment line. ~~indicated by a specific code.~~
>
> *Batch* means a specific quantity of a food that is produced during a specified time period during a single cycle of manufacture.
>
> *Production code* (also known as a *lot number* or *batch number*) means a unique and distinctive group of letters, numbers, and/or symbols from which the manufacturing and packaging history of the associated lot or batch of food can be determined.

# 8. Comments regarding the exemptions in § 117.5(g) and (h)

Proposed § 117.5(g) provides a list of exemptions from Subpart C for small and very small businesses engaged in on-farm packing and/or holding of certain foods when those foods are not grown, raised, or consumed on the same farm or farm mixed-type facility or co-owned farm or farm mixed-type facility (henceforth "FFMTF" for short).

Proposed § 117.5(h)(1) provides a list of exemptions from Subpart C for small and very small businesses engaged in on-farm manufacturing/processing of certain foods when performed on RACs which are grown, raised, or consumed on the same FFMTF.

Proposed § 117.5(h)(2) provides a list of exemptions from Subpart C for small and very small businesses engaged in on-farm manufacturing/processing of certain foods when those foods are not grown, raised, or consumed on the same FFMTF.

These lists of exemptions were created in response to FSMA Sec. 103(c)(1)(C), which directs FDA to perform a science-based risk analysis (RA) of (i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on the same farm or a co-owned farm, as such packing and holding relates to specific foods, and (ii) specific types of on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on the same farm or a co-owned farm; and FSMA Sec. 103(c)(1)(D), which states "In promulgating the regulations under subparagraph (A), the Secretary shall consider the results of the science-based risk analysis conducted under subparagraph (C), and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act (as added by this section), including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act (as added by section 201), or modify the requirements in such sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk."

Below, AHPA discusses various aspects of the draft RA and the three lists of exemptions; identifies language in proposed § 117.5(g) and § 117.5(h) which should be clarified; and makes suggestions for revision of each of the three lists.

### 8.1 The goal is to identify low-risk, rather than no-risk, activities and foods

To begin with, AHPA notes that some of the items listed in § 117.5(g) and § 117.5(h) are known to entail a certain, albeit low, degree of risk. For example, fresh intact fruits and vegetables (e.g. greens and melons) are occasionally contaminated with pathogens. Nevertheless, AHPA agrees with the RA that packing and holding of these items are low risk activities since packing/holding is not likely to significantly increase nor decrease the level of risk, and supports the proposed inclusion of these food/activity combinations in the § 117.5(g) list.

Similarly, "coating of nuts with seasonings" involves a certain low level of risk, since both nuts and seasonings are occasionally known to be contaminated with pathogens; the same can be said of "chopping of raw peanuts and raw tree nuts" and "grinding/milling/cracking/crushing raw peanuts and raw tree nuts." Yet the RA found these to be low risk food/activity combinations, and the § 117.5(h) lists propose to include them; and AHPA agrees with their inclusion. AHPA notes that FSMA directs FDA to identify "low-risk," as opposed to "no-risk" or "risk-free," food/activity combinations.

However, the RA then fails to include as "low-risk" various food/activity combinations that AHPA does not believe entail any higher degree of risk than those described above. These will be discussed in our comments further below.

AHPA believes the RA should identify as "low-risk" all food/activity combinations which meet a consistent low level of risk, and the § 117.5(g) and § 117.5(h) lists derived from the RA should be revised to include all such low-risk food/activity combinations.

**8.2 The low-risk activity criteria developed in the RA should be applied consistently**

The draft RA creates two criteria for identifying low-risk activities. An activity is defined to be low-risk if it meets either one of the two criteria.

(1) Low-risk activity is "performed on, or during production of, a food that has inherent controls for foodborne pathogens, provided that the food does not require preventive controls to significantly minimize or prevent other types of hazards (e.g. a chemical hazard such as mycotoxins)." In this context, the RA defined inherent controls to mean that "in making the food the hazard is controlled, and it is highly unlikely that the food will be made in a way that the hazard is not adequately addressed."

(2) Low-risk activity "(a) is not reasonably likely to introduce (or increase the potential for) a hazard for which there is a reasonable probability that use of, or exposure to, the food will cause serious adverse health consequences or death to humans (a SAHCOD hazard)," and "(b) does not significantly minimize or prevent a SAHCOD hazard." To be low-risk, the RA considered that an activity must satisfy both of these criteria.

However, the RA does not apply these two criteria carefully and consistently, which leads to illogical results. These will be discussed in our comments further below.

**8.3 A definition should be provided for "low moisture food," and moisture levels should be taken into account more consistently in the draft RA**

To help ensure the regulation is written in a clear, understandable, and unambiguous manner, AHPA believes FDA should provide a definition of "low moisture food" as follows.

> *Low moisture food* means any food, whether in liquid, solid, or semisolid form, having a water activity lower than 0.85.

This proposed definition is consistent with FDA's definition of "potentially hazardous food,"[43] the definitions applicable to 21 CFR Part 114, and elsewhere. It is a threshold commonly used by experts to ensure food safety. Furthermore, it is acknowledged to be a very conservative threshold; one reference states, "Technically, an $a_W$ of 0.85 is inappropriately low as a general $a_w$ minimum because most pathogens are inhibited at values well above 0.86 and *S. aureus* toxin formation (the true hazard) is restricted at higher $a_w$ values."[44]

AHPA believes that with this definition in place, FDA should add a large number of food/activity combinations to those which the RA has already determined to be low risk. AHPA will discuss these at greater length below.

### 8.4 The low-risk activity criteria should be revised with respect to refrigeration and freezing

The draft RA states, "We considered that when a food requires refrigeration to control pathogens...temperature control is necessary at all steps, and therefore no activity involving such food would be low risk."

AHPA does not agree that on-farm activities which require refrigeration and/or freezing for safety should be automatically excluded from the "low risk" category. AHPA believes that FFMTF operators, like the rest of the general public both in the US and in other countries, are aware of the role refrigeration and freezing play in ensuring food safety. AHPA notes that FDA has acknowledged in § 117.206 that most of Subpart C is not necessary to ensure safe refrigeration by warehouses.

AHPA believes that on-farm activities requiring refrigeration and/or freezing for safety are low-risk in certain cases, such as refrigeration of eggs, butter, and milk for use in baking or other cooking (e.g. making milk chocolate), or freezing of fruit juices in order to extend shelf life. AHPA believes FFMTF operators are capable of safely keeping these items refrigerated or frozen without performing all of the requirements of Subpart C.

If necessary to ensure safety for refrigeration and freezing, AHPA believes FDA should provide modified Subpart C requirements for food/activity combinations involving refrigeration and/or freezing; FSMA expressly gives FDA this option and AHPA believes FDA should use it where appropriate. These could be modeled on the provisions outlined in § 117.206 (e.g. adequate temperature controls should be

[43] Public Health Service, Food and Drug Administration (PHS/FDA). 2009. *Food Code: 2009 Recommendations of the United States Public Health Service Food and Drug Administration*, p. 15.

[44] Institute of Food Technologists (IFT). 2003. Evaluation and definition of potentially hazardous foods – A report of the Institute of Food Technologists for the Food and Drug Administration of the United States Department of Health and Human Services, December 31, 2001. CRFSFS vol. 2 (Supplement), chapter 1.

established and implemented for refrigerators and freezers; temperature controls should be monitored with sufficient frequency; temperature monitoring and recording devices should be calibrated; etc.).

**8.5 The low-risk activity criteria should be revised with respect to time controls**

AHPA disagrees that any activity which requires the measurement of cooking time should be excluded from the "low risk" category. While time must be measured in certain circumstances with a high degree of accuracy and precision (e.g. sterilization of liquid by exposure to UHT for a defined number of seconds), this is not the case in many cooking processes, which often include a wide margin of error (e.g. baking, boiling, etc.). AHPA believes the general public, both in the US and overseas, is capable of measuring time with sufficient accuracy and precision to execute such cooking activities properly.

**8.6 The low-risk activity criteria in the RA should be expanded with respect to chemical hazards**

AHPA believes the criteria listed in the RA should be expanded to include additional criteria addressing chemical hazards in food.

Specifically, AHPA believes that food manufacturing or processing activities which involve toxic synthetic solvents or reagents should be excluded from the low-risk category, as these require special controls to ensure adequate removal of the solvent and/or complete reaction of the reagent. AHPA will discuss farther below some food/activity combinations in which this should be considered.

**8.7 The RA should be expanded to consider dietary ingredients**

The draft RA states, "Activities solely related to the production of seafood, juice, dietary supplements, and alcoholic beverages are outside the scope of this RA." Apparently as a result of this determination, the RA fails to consider many food/activity combinations which are used in making the dietary ingredients used in dietary supplements.

AHPA notes, however, that the law's exclusion for dietary supplements applies only to the facilities which manufacture dietary supplements in accordance with Part 111. It does not extend to facilities manufacturing dietary ingredients in accordance with Part 110; as such, these items are appropriate subjects for consideration in the RA.

**8.8 Packing, holding, and at least some manufacturing/processing should be uniformly considered low-risk when applied to low-moisture solid foods**

The proposed lists in § 117.5(g) and § 117.5(h), based on the conclusions of the RA, include as low-risk the following:

- § 117.5(g): Packing and/or holding of hard candy, cocoa beans, coffee beans, peanuts, tree nuts, grains and grain products.

- § 117.5(h)(1): Chopping raw peanuts and raw tree nuts; coating raw peanuts and tree nuts (e.g. adding seasonings); grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts); salting raw peanuts and raw tree nuts.
- § 117.5(h)(2): Chopping raw peanuts and raw tree nuts; coating raw peanuts and tree nuts (e.g. adding seasonings); grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts); labeling (including stickering) hard candy, cocoa beans, coffee beans, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), intact single-ingredient peanuts or tree nuts (shelled and unshelled), and sugar; mixing cocoa beans, coffee beans, grain and grain products, and peanuts and tree nuts; salting raw peanuts and raw tree nuts; shelling/hulling cocoa beans (i.e., winnowing), dried beans and peas, and peanuts and tree nuts; sifting grains and grain products; sorting, culling, and grading (other than when incidental to packing or storage) hard candy, cocoa beans, coffee beans, grain and grain products, peanuts and tree nuts, and sugar; and treating cocoa beans, coffee beans, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation).

AHPA has selected here these food/activity combinations from the longer three lists because they are all examples of low-risk activities performed on a low-moisture food in solid form.[45]

To begin with, AHPA can find no scientific basis for the inclusion of some of these items in one or more, but not all three, of these lists. AHPA believes the only reason some of these food/activity combinations are included in § 117.5(h)(2) but are excluded from § 117.5(g) and/or § 117.5(h)(1) is because FDA believes the food/activity combination is already exempt, and hence does not require an additional exemption under § 117.5(g) or (h). For example, sifting of grains and post-harvest fumigation of nuts are defined as farm activities when performed on the farm's own RACs, and are hence exempt from the entirety of Part 117, and hence do not necessarily need to be listed in § 117.5(h)(1).

However, AHPA believes there are low-risk activity/low-moisture solid food combinations which the lists fail to capture. These include:

- Packing and/or holding of popcorn; chips; crackers; dry cereal; dry pasta; dry bread and bread crumbs; dry legumes[46] (e.g. kidney beans, chickpeas); dry legume products such as besan

[45] The lists also include low-moisture liquid foods, such as honey and maple syrup; AHPA addresses these separately in later comments.

[46]AHPA disagrees that dry legumes should be considered a type of “intact fruits and vegetables,” as discussed farther below in these comments. Also, see AHPA's comments to the Produce Safety Rule regarding the definition of “produce” for a discussion of why legumes should be considered separately from grains.

(chickpea flour); jerky[47]; dry unsulfured/unsulfited fruits and vegetables in cut, chopped, sliced, shredded, or other form; dry herbs, spices, and crude dietary ingredient botanicals[48] in whole, cut, chopped, or powdered form, except where packaged as a dietary supplement; botanical extracts, gums, resins, and exudates in solid, powdered, granular, or paste form, except where packaged as a dietary supplement; vitamins, minerals, and processed dietary ingredients (e.g. bone meal) in powdered, granular, or other solid form, except where packaged as a dietary supplement; other dry food ingredients (e.g. salt, potato starch, baking powder, etc.); and dry mixtures or combinations of any of the above.

- Cutting, chopping, slicing, grinding, milling, cracking, crushing, or other size reduction, so long as the method used does not expose the food involved to water, of the following items: dry legumes and dry legume products; dry fruits and vegetables; coffee beans and cocoa beans; dry herbs, spices, and crude dietary ingredient botanicals, except where § 117.5(e) applies; botanical extracts, gums, resins, and exudates in solid, powdered, granular, or paste form except where § 117.5(e) applies; vitamins, minerals, and processed dietary ingredients in powdered, granular, or other solid form, except where § 117.5(e) applies; other dry food ingredients; popcorn; chips; crackers; dry cereal; dry pasta; dry bread and bread crumbs; jerky; and dry mixtures or combinations of any of the above.[49]
- Chopping roasted or otherwise cooked peanuts and tree nuts; coating roasted or otherwise cooked peanuts and tree nuts (e.g. adding seasonings); grinding/milling/cracking/crushing roasted or otherwise cooked peanuts or tree nuts; salting roasted or otherwise cooked peanuts and tree nuts.

(AHPA agrees that performing the above activities on raw peanuts or tree nuts is low risk, and believes that performing the same activities on cooked versions of the same items is equally or even lower risk. In fact, AHPA believes that for any low-moisture or dry material, the list of activities generally should not specify raw vs. cooked, as most activities will be equally safe when performed on raw vs. cooked forms of the food, if not even safer for the cooked version.)

- Mixing or otherwise combining dry legumes and dry legume products; dry fruits and vegetables; coffee beans and cocoa beans; dry herbs, spices, and crude dietary ingredient botanicals, except where packaged as a dietary supplement; botanical extracts, gums, resins, and exudates in solid, powdered, granular, or paste form, except where packaged as a dietary supplement; vitamins, minerals, and processed dietary ingredients in powdered, granular, or other solid form, except

[47] AHPA notes that foods such as jerky may pose microbiological hazards. However, packing and/or holding of dry jerky is not an activity which increases or decreases the risk to a greater extent than any other low-moisture food.

[48] See AHPA's comments to the Produce Safety Rule regarding the definition of “produce” for a discussion of why spices and dietary ingredients are not “fruits and vegetables.” There may be some overlap between “dry herbs” and “dry vegetables” but AHPA believes that for clarity they should be listed separately in these lists of exemptions.

[49] It is relatively uncommon for a food processor to chop or grind items such as popcorn or cereal, but it does occur; for example in making mixes intended to coat or bread meats prior to frying or baking, or toppings intended for a baked casserole. AHPA believes some small on-farm processors make such items as specialty or gourmet products.

where packaged as a dietary supplement; other dry food ingredients; popcorn; chips; crackers; dry cereal; dry pasta; dry bread and bread crumbs; jerky; and any other solid low-moisture foods in any combination.

- Cooking any low-moisture solid food, or any mixture or combination thereof, using dry heat (as by baking, toasting, roasting, or frying).[50]

AHPA wishes to emphasize that the RA must take care to consider each activity when performed on the food as it exists at the time the activity is performed. While it may be at least arguably true (according to strict application of the criteria of the RA) that roasting of raw peanuts is not a low-risk food/activity combination, this does not mean that every activity involving roasted peanuts is excluded from being low risk; only that the roasting process itself is not low risk. Similarly, while the making of jerky is probably not a low-risk food/activity combination, that does not mean that other activities (e.g. packing, holding, seasoning with dry ingredients) cannot be low-risk when performed on the jerky once it has been made. By specifying that FDA must consider food-activity combinations, Congress clearly intended for FDA to consider the specific activity at hand, rather than the production/packing/holding process of the food as a whole, in determining which items are low-risk.

Furthermore, AHPA wishes to emphasize that the RA should avoid being so constrained by its own internal logic that it yields conclusions which make little sense in the real world. For example, AHPA finds it illogical to conclude that raw peanuts which are chopped on a farm that is exempt from Subpart C are acceptably safe for distribution into commerce, but peanuts which are roasted on a farm that is exempt from Subpart C are unacceptably risky. The roasting process, even if conducted in a manner which is less than optimal from a food safety standpoint, will surely to some extent reduce the microbial load of the peanuts and hence improve the safety over that of raw peanuts. Similarly, if chopping of raw nuts is low risk, then the chopping of roasted nuts must be equally low risk or even less risky.

### 8.9 Packing, holding, and manufacturing/processing of concentrated sweeteners should be uniformly considered low-risk

The proposed lists in § 117.5(g) and § 117.5(h), based on the conclusions of the RA, include as low-risk the following:

- § 117.5(g): Packing and/or holding of honey (raw and pasteurized); maple sap for syrup and maple syrup; and sugar beets, sugar cane, and sugar.
- § 117.5(h)(1): Boiling/evaporation of maple sap to make maple syrup; making sugar from sugar beets and sugarcane.
- § 117.5(h)(2): Making honey; making maple syrup;[51] making sugar from sugar beets and sugarcane; packaging honey, maple syrup, and sugar; sorting, culling, and grading (other than

[50] Dry cooking of low-moisture foods does not increase the level of risk; if anything it decreases the level of risk, even if performed in a less than optimal manner.

when incidental to packing or storage) honey, maple sap, maple syrup, and sugar beets, sugar cane, and sugar.

AHPA has selected here these food/activity combinations from the longer three lists because they are all examples of low-risk activities involving the packing, holding, and manufacturing/processing of concentrated sweeteners and/or their raw materials.

As discussed previously, AHPA can find no scientific basis for the inclusion of some of these items in one or more, but not all three, of these lists. AHPA believes the only reason some of these food/activity combinations are included in § 117.5(h)(2) but are excluded from § 117.5(g) and/or § 117.5(h)(1) is because FDA believes the food/activity combination is already exempt, and hence does not require an additional exemption under § 117.5(g) or (h). For example, sorting, culling, and grading are defined as farm activities when performed on the farm's own RACs, and are hence exempt from the entirety of Part 117, and hence do not need to be listed in § 117.5(h)(1).

AHPA notes that, as discussed in the draft RA, maple sap and maple sugar, and sugar beets, sugar cane, and sugar, can be considered inherently safe because the processing includes boiling and because the final sweetener has a very low water activity.

Based on this logic, AHPA believes there are low-risk packing, holding, and manufacturing/processing of concentrated sweeteners and/or their raw materials which the lists fail to capture. These include:

- Packing and/or holding of cane syrup, molasses, treacle, birch sap, birch syrup, palm sap, palm sugar, coconut sap, coconut sugar, sorghum juice, sorghum syrup, dates, date sugar, barley and other grain malts, barley malt syrup, barley malt extract, and other concentrated grain malt products in liquid or powder form; and any other concentrated natural sweetener having a water activity lower than 0.85[52] and made with an adequate microbial reduction step, as well as the raw materials therefor.[53,54]
- Making cane syrup, molasses, and treacle from sugar beets and/or sugarcane; making sugar from coconut sap, palm sap, and dates; boiling/evaporation of birch sap to make birch syrup; boiling/evaporation of sorghum juice to make sorghum syrup; making grain malt for use in

[51] AHPA does not understand why § 117.5(h)(1) lists “boiling/evaporation of maple sap to make maple syrup” while § 117.5(h)(2) lists “making maple syrup,” and suggests this language should be standardized to “making maple syrup from maple sap” for consistency.

[52] AHPA suggests this number in connection with the proposed definition of low moisture food.

[53] AHPA excludes corn syrup from this list, as it requires specialized reagents and processes. To AHPA's knowledge, corn syrup is not made by small or very small businesses co-located on farms.

[54] Other natural concentrated sweeteners exist, such as one made from carob.

making grain malt syrups and extracts;[55] making grain malt syrups and extracts; and making any other concentrated liquid or powdered natural sweetener which has a water activity lower than 0.85 and is made with an adequate microbial reduction step.

The production of these sweeteners is inherently safe, as follows:

- Cane syrup, molasses, and treacle are made in the same manner as sugar, i.e. by boiling sugar beets or sugar cane. The liquid product of pressing or the first boiling of sugar cane is called cane syrup; the product of the second and third boilings of sugar cane are called molasses and blackstrap molasses respectively. The liquid product of boiling sugar beets is called beet molasses. Treacle is a by-product of sugar refinement.
- Birch sap, palm sap, coconut sap, and sorghum juice are all boiled to make, respectively, birch syrup, palm sugar, coconut sugar, and sorghum syrup.
- Dates are converted to date sugar by subjecting the dates to dry heat followed by grinding.
- Barley and other grain malts are made by grinding the grain and mixing with water to allow natural enzymatic conversion of starch to sugars, followed by boiling and evaporation to produce the malt syrup or malt extract.

### 8.10 Cut fruits and vegetables should not be inherently disqualified from the "low risk" category

The RA excludes "cut fruits and vegetables" at the outset, on the basis that they are a type of food which requires "one or more preventive controls (e.g. heat treatment, time/temperature control for safety) to significantly minimize or prevent a hazard that is reasonably likely to cause serious adverse health consequences or death." There is a concern with cut fruits and vegetables that once the outer protective covering of the plant structure is breached, bacteria on the surface of the plant gain access to the moisture and nutrients inside the plant. This has been shown to facilitate pathogen reproduction in a wide variety of fresh cut fruits and vegetables, especially in the absence of refrigeration.

However, such concerns may not apply in instances such as:

- Cut fruits and vegetables[56] which contain native antimicrobial constituents (e.g. blueberries,[57] lemons[58]). In such cases, cut fruit might actually be safer than intact fruit, since cutting will

[55] The malting of grains involves allowing them to steep in water and germinate, i.e. it is a sprouting process. However, as with the other raw materials used to make sweeteners, this is not a microbial concern so long as the sprouted grains are boiled to make the sweetener rather than consumed raw.

[56] Here and throughout, AHPA uses the phrase "fruits and vegetables" in the manner described in our comments to the Produce Safety Rule regarding the definition of "produce," i.e. to refer to fresh fruits, vegetables, and culinary herbs commonly sold at retail in the produce section of grocery stores. AHPA distinguishes between "produce" and "non-produce botanicals," which AHPA considers to include grains, algae and dry legumes as well as botanicals used as or in production of spices, dietary ingredients, flavors, colors, and excipients.

facilitate exposure of bacteria on the surface to the bacteriostatic or bactericidal constituents inside the fruit.

- Cut fruits and vegetables which are immediately moved into a drying process after cutting (or slicing, chopping, shredding, cracking, etc.).[59] Size reduction and/or cracking of items serve to speed drying and hence may improve microbiological safety.

With respect to the latter, AHPA notes that a variety of parameters must be considered in evaluating potential food safety concerns, such as the lag phase of the pathogen under applicable conditions of temperature, pH, and moisture.[60] It is well established that at room temperature and optimal pH, pathogens cannot grow or produce toxin at even moderately reduced water activities (0.92-0.98 for most pathogens; 0.83 for *Staphylococcus aureus* growth and 0.88 for *S. aureus* toxin production).[61]

It is furthermore well established that it is important to consider food microenvironments, especially those which exist at interfaces. For example, the fact that white bread can safely be stored at room temperature, despite its relatively high water activity (0.94-0.97 in the interior) and lack of acidity, is attributable to the low water activity of the crust (0.30) which forms a barrier.[62]

AHPA notes that, if cut fruits and vegetables are moved immediately into a drying process, the water activity of the outer surfaces - i.e. the microenvironment where pathogens might be located after cutting - can potentially be sufficiently reduced quickly enough to prevent pathogen growth. Drying of cut fruits and vegetables normally takes hours to days to achieve the desired residual moisture levels, which typically correlate to water activity of 0.30 for dried vegetables and 0.60-0.70 (occasionally 0.80)

[57] Biswas, D. *et al.* 2012. Pasteurized blueberry (*Vaccinium corymbosum*) juice inhibits growth of bacterial pathogens in milk but allows survival of probiotic bacteria. *J Food Safety* 32(2):204-209.

[58] Bansode, D.S. & Chavan, M.D. 2012. Studies on antimicrobial activity and phytochemical analysis of citrus fruit juices against selected enteric pathogens. *Int Res J Pharm* 3(11):122-126.

[59] AHPA is aware that many food safety experts, such as university extension programs, recommend blanching or otherwise treating (as by acid or sulfur) cut fruits and vegetables prior to drying. Such treatments serve to reduce the bioburden; they may also serve to inactivate enzymes and prevent discoloration. AHPA does not believe such procedures are always required for proper drying of botanical items; it depends on the botanical in question, as well as the ultimate use of the dried product (i.e. commercial processing vs. as-is consumption).

[60] Institute of Food Technologists (IFT). 2003. Evaluation and definition of potentially hazardous foods – A report of the Institute of Food Technologists for the Food and Drug Administration of the United States Department of Health and Human Services, December 31, 2001. CRFSFS vol. 2 (Supplement), chapter 3.

[61] Ibid chapter 3

[62] Ibid chapter 3

for dried fruits.[63] However, while it may require hours or days to achieve such uniformly low moisture levels, the outer surface of each cut piece dries faster than the interior.

Thus it may be possible that cutting and/or drying of fruits and vegetables under certain circumstances should be deemed "low risk" for the purposes of § 117.5(h). This is especially true for botanical items which are naturally low in moisture, high in sugar, low in pH, or which have native antimicrobial activity, and for those intended for further commercial processing (e.g. extraction or steam sterilization). AHPA does not propose such additions to § 117.5(h) at this time, but asks FDA to bear these issues in mind.

### 8.11 Packing, holding, and manufacturing/processing of other appropriate botanical foods should be considered low-risk

The proposed lists in § 117.5(g) and § 117.5(h) include the following:

- § 117.5(g): none
- § 117.5(h)(1): Extracting oil from grains (e.g., corn, oilseeds, soybeans).
- § 117.5(h)(2): Extracting oils from grains (e.g., corn, oilseeds, and soybeans).

AHPA believes there are many other types of extracts and other botanical preparations for which the packing, holding, and/or manufacturing/processing should be identified as low risk. Also, AHPA believes certain limits should be placed on the extraction processes used, including for the items currently in the § 117.5(h) lists.

AHPA believes the following types of botanical extracts and other botanical preparations are inherently safe for packing and holding, and hence should be included in § 117.5(g):

- Botanical extracts, exudates, gums, and resins in the form of powders, granules, or pastes, except where § 117.5(e) applies;[64]
- Liquid botanical extracts containing 20% to 95% (v/v) hydroethanolic solvent, except where § 117.5(e) applies;[65,66,67]

[63] Downes, F.P. & Ito, K. 2001. *Compendium of Methods for the Microbiological Examination of Foods, 4th Ed.*, p. 651. Washington, DC: American Public Health Association.

[64] AHPA recognizes there is some overlap between these items and the natural sweeteners discussed earlier in our comments. AHPA believes such overlap is not a problem and that, for clarity and completeness, it is desirable to list both the more-specific case (e.g. natural sweeteners) and the more-general case (e.g. botanical extracts and exudates).

[65] For further information regarding extracts generally, see Eisner, S. (Managing Ed.). 2001. Guidance for manufacture and sale of bulk botanical extracts. Silver Spring, MD: AHPA; and Anon. 2003. Standardization of botanical products: White paper. Silver Spring, MD: AHPA.

[66] AHPA excludes solvents other than water, ethanol, glycerin, fat, oil, honey, and vinegar from this and the next few listed items, both here and in § 117.5(h) discussed below, because preparations made with other alcohols and/or synthetic solvents require controls to ensure toxic residues do not remain in the final product.

- Liquid botanical extracts containing 35% (w/w) or more glycerin in water as the solvent, except where § 117.5(e) applies;[68]

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[67] Ethanol at concentrations of 60-95% (v/v) is generally biocidal, while concentrations of up to 60% are bacteriostatic/fungistatic. Generally speaking, 20% ethanol is considered inhibitory of microorganisms (Berthele, H. *et al.* 2013. Determination of the influence of factors (ethanol, pH and $a_W$) on the preservation of cosmetics using experimental design. *Int J Cosmetic Sci*: DOI: 10.1111/ics.12094); growth of bacteria and fungi is inhibited by ethanol concentrations of 8-11%, while some yeasts tolerate up to 15-18% (Kalathenos, P. & Russell, N.J. 2003. Ethanol as a food preservative. In N.J. Russell & G.W. Gould (Eds.), *Food preservatives* (pp. 196-217). New York: Springer U.S.). Some ethanol-tolerant strains of yeast are capable of growth in up to 20% ethanol (ibid). Lactic acid bacteria can tolerate up to 20% ethanol (Juvonen, R., Virkajärvi, V., Priha, O. & Laitila, A. 2011. *Microbiological spoilage and safety risks in non-beer beverages. Volume 2599 of VTT tiedotteita*. Espoo, Finland: VTT Technical Research Centre of Finland); these are among the most ethanol-resistant organisms known (Ingram, L.O. (1989). Ethanol tolerance in bacteria. *Crit Rev Biotechnol* 9(4):305-319). *Escherichia coli* grows very little in ethanol above 6% (ibid) although it may remain partially viable in 20% ethanol (Heinmets, F., Taylor, W.W. & Lehman, J.J. 1953. The use of metabolites in the restoration of the viability of heat and chemically inactivated Escherichia coli. *J Bacteriol* 67(1):5-12). The suggested level of 20% ethanol corresponds to water activity of 0.900 to 0.911, depending on the method of determination; 30% ethanol would correspond to a water activity of 0.820-0.856, depending on the method of determination, which meets FDA's food safety threshold of water activity below 0.85. However, ethanol owes its inhibitory effects not just to reduced water activity but also to disruption of cell membranes and other effects. Furthermore, AHPA notes that according to IFT's report to FDA, "an $a_W$ of 0.85 is inappropriately low as a general $a_w$ minimum because most pathogens are inhibited at values well above 0.86 and *S. aureus* toxin formation (the true hazard) is restricted at higher $a_w$ values" (Institute of Food Technologists (IFT). 2003. Evaluation and definition of potentially hazardous foods – A report of the Institute of Food Technologists for the Food and Drug Administration of the United States Department of Health and Human Services, December 31, 2001. CRFSFS vol. 2 (Supplement)). AHPA notes that FDA's definition of "potentially hazardous food" as given in its 2009 Food Code excludes foods which may contain, but do not support the growth of, infectious organisms (Public Health Service, Food and Drug Administration (PHS/FDA). 2009. *Food Code: 2009 Recommendations of the United States Public Health Service Food and Drug Administration*, p. 15); therefore ethanol at 20% is sufficient for "low risk."

[68] Preparations containing 15-20% glycerin are generally considered to be microbiologically safe (Dweck, A.C. 2003. Natural preservatives. *Cosmet Toiletries* 118(8):45-50), but data also indicate that bacteriostasis of *Staphylococcus aureus* requires concentrations of 30-32% (although toxin formation requires higher water activity than growth) (Barr, M. & Tice, L.F. 1957. A study of the inhibitory concentrations of various sugars and polyols on the growth of microorganisms. *J Am Pharm Assoc* 46(4):219-221); Litsky, W., Libbey, C.J. & Mariani, E.J. 1971. *Sterility testing and antimicrobial activity of commercial grade glycerine.* Final Report prepared for Glycerine Producers' Association); International Commission on Microbiological Specification for Foods (ICMSF). 1996. *Microorganisms in foods 5.* London: Blackie Academic and Professional). Other data show glycerin at concentrations of 50% or more prevents survival of a wide variety of microorganisms for more than a few weeks when stored at room temperature (Saegeman, V.S.M. *et al.* 2008. Short- and long-term bacterial inhibiting effect of high concentrations of glycerol used in the preservation of skin allografts. *Burns* 34:205-211). With respect to the latter, however, AHPA notes that FDA's definition of "potentially hazardous food" (as given in Public Health Service, Food and Drug Administration (PHS/FDA). 2009. *Food Code: 2009 Recommendations of the United States Public Health Service Food and Drug Administration*, p. 15) excludes foods which merely may contain, as opposed to foods that may support the growth of, infectious organisms; therefore AHPA does not believe the threshold for "low risk" needs to be set at 50%, but rather that 35% is sufficient.

- Liquid botanical extracts containing any combination of glycerin and ethanol as the solvent, except where § 117.5(e) applies;
- Liquid botanical extracts made with dry botanical material and vinegar as the solvent, except where § 117.5(e) applies;
- Liquid botanical extracts made with dry botanical material and honey as the solvent, except where § 117.5(e) applies;[69]
- Liquid botanical extracts made with dry botanical material and edible oil as the solvent, except where § 117.5(e) applies;[70]
- Fixed oils, essential (volatile) oils, and waxes, except where § 117.5(e) applies.

AHPA believes the following manufacturing/processing of botanical extracts and other botanical preparations are inherently safe, and hence should be included in § 117.5(h):

- Making powdered, granular, or paste-form botanical extracts from dry botanical material with 20% to 95% (v/v) hydroethanolic solvent, except where § 117.5(e) applies;
- Making powdered, granular, or paste-form botanical extracts from dry botanical material with water or hydroethanolic solvent containing less than 20% (v/v) ethanol by boiling for at least 15 minutes,[71] except where § 117.5(e) applies;
- Making liquid botanical extracts, except where § 117.5(e) applies, from dry botanical material (a) with 20% to 95% (v/v) hydroethanolic solvent so long as the extract is not concentrated after extraction[72] nor diluted after extraction with any solvent other than 20% to 95% (v/v) hydroethanolic solvent, or (b) in any manner whereby the resulting liquid contains 20% to 95% (v/v) hydroethanolic solvent;

[69] Honey infused with dry herbs is microbiologically safe; see for example Clemson University's http://www.foodsafetysite.com/consumers/faq/?m_knowledgebase_article=640.

[70] AHPA is aware that herb or garlic infusions in oil may present a risk of *Clostridium botulinum* growth (especially when prepared from fresh, as opposed to dry, botanical material). However, AHPA does not believe that packing and/or holding of such items are activities which affect that risk.

[71] Aqueous and hydroethanolic extracts containing only very low levels of ethanol are typically made by boiling for 15 minutes to several hours. AHPA recognizes that "at least 15 minutes" is a type of "time control," but disagrees with the RA that any activity requiring time control should be automatically excluded from the "low risk" category. AHPA believes (a) the general public is able to measure time with adequate accuracy and precision for the purposes of this activity, and (b) the specification of "at least 15 minutes" includes a sufficient margin of error to ensure safety. Most bacteria and fungi are killed or inactivated after only a few minutes' exposure to boiling; food safety experts commonly recommend 10 minutes for sterilization of canning jars, and that already includes a wide margin of error.

[72] Concentration will tend to selectively reduce the level of ethanol.

- Making liquid botanical extracts from dry botanical raw material with solvent containing 35% (w/w) or more glycerin in water so long as the extract is not diluted after extraction with any solvent other than 35% (w/w) or more glycerin in water, except where § 117.5(e) applies;
- Making liquid botanical extracts from dry botanical raw material with solvent containing any combination of glycerin and ethanol, except where § 117.5(e) applies;
- Making botanical extracts from dry botanical materials with vinegar as the solvent, except where § 117.5(e) applies;
- Making botanical extracts from dry botanical materials with honey as the solvent, except where § 117.5(e) applies;
- Isolating essential oils by means of distillation, pressing, expression, scarification, or abrasion, and/or using edible fat, oil, ethanol, and/or water as solvents, except where § 117.5(e) applies;[73,74]
- Isolating fixed oils from grains, legumes, oilseeds, olives, or other botanical matter by pressing and/or using ethanol and/or water as solvents, except where § 117.5(e) applies;[75]
- Drying botanical exudates, gums, and resins by boiling;
- Preparing in any manner botanical materials for the above-listed extractions, as by crushing; washing; cooking; inspecting; etc.;
- Mixing or otherwise combining any of the above-mentioned botanical extracts, exudates, gums, resins, or oils in any combination.

**8.12 All activities which are part of harvesting when performed on the farm's own crop should be included in § 117.5(h)(2)**

It is FDA's existing policy 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" when it is performed on the farm's own crop, at least as long as it does not transform the usual raw agricultural commodity (RAC) into a different commodity.

As discussed at length elsewhere in our comments, AHPA believes it is important that FDA specifically acknowledge in the definition of "harvesting"[76] the range of harvest activities which are traditionally used for non-produce botanicals (i.e. those used as or in production of spices, dietary ingredients, flavors, excipients, etc.). These include, among other activities, the following:

[73] See AHPA's Trade Requirement & Guidance Policy for Labeling of Undiluted Essential Oils Used Topically and Offered for Retail Sale for an explanation of terms (http://www.ahpa.org/default.aspx?tabid=223).

[74] Essential oils are inherently microbiologically safe due both to low water activity and to the chemical reactivity of the constituents.

[75] Note that this narrows the scope of permitted activities compared to FDA's original proposed language regarding extracting oils, insofar as it excludes the use of synthetic or toxic solvents.

[76] See our comments regarding the definition of "harvesting."

- Activities (e.g. peeling) which isolate the desired commodity from other parts of the plant;
- Cutting, slicing, or other size reduction to facilitate handling, drying, and/or packing;
- Temporary freezing to kill the plant tissue and/or insects;
- Use of hot or cold water or steam to soften fibrous or woody materials;
- 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 speeding drying), and/or to facilitate long-term storage (e.g. by reducing moisture content, deactivating enzymes, reducing microbial loads, and/or killing insects); and
- Aging or fermentation (sometimes known as curing or conditioning), when these are a traditional part of preparing the crop for use as food.

AHPA notes that proposed § 117.5(h)(2) includes "fermenting cocoa beans and coffee beans." AHPA believes this is included here, but not in § 117.5(h)(1), in recognition of the fact that such fermentation, when performed on the farm's own crop, is part of "harvesting" and is therefore already exempt from Part 117. However, there are many other botanicals for which fermentation is a traditional step in preparation of the crop for food use, such as tea (*Camellia sinensis*),[77] allspice, and vanilla; these should also be included in the § 117.5(h)(2) exemption.

Furthermore, each of the other "traditionally used steps" listed in our comments on "harvesting" should be included in § 117.5(h)(2). AHPA therefore suggests the following revisions and additions to § 117.5(h)(2).

- Activities (e.g. peeling) which isolate the desired commodity from other parts of the plant, when performed on botanicals other than produce as defined in 21 CFR Part 112;
- Cutting, slicing, or other size reduction to facilitate handling, drying, and/or packing, when performed on botanicals other than produce as defined in 21 CFR Part 112;
- Temporary freezing to kill the plant tissue and/or insects, when performed on botanicals other than produce as defined in 21 CFR Part 112;
- Use of hot or cold water or steam to soften fibrous or woody materials, when performed on botanicals other than produce as defined in 21 CFR Part 112;
- 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 speeding drying), and/or to facilitate long-term storage (e.g. by reducing moisture content, deactivating enzymes, reducing microbial loads, and/or killing insects), when performed on botanicals other than produce as defined in 21 CFR Part 112;

[77] AHPA recognizes that fermentation of *Camellia sinensis* arguably creates a separate commodity, i.e. black tea as opposed to green tea. However, as discussed in our comments on "harvesting" AHPA believes FDA should be guided by whichever form of the crop is normally used in the U.S. Green tea is a minor commodity in the US compared to black tea. See also our comments to the Produce Safety Rule regarding the commercial processing exemption.

- Aging or fermentation (sometimes known as curing or conditioning) of botanicals other than produce as defined in 21 CFR Part 112, when these are a traditional part of preparing the crop for use as food.
- ~~Fermenting cocoa beans and coffee beans~~

These activities are low-risk because (a) the provenance of the materials (i.e. on-farm vs. from another farm) does not affect the safety of the activities, so there is no scientifically valid reason for them to be deemed non-low-risk merely because of that provenance; and (b) the botanical materials involved will either be cooked by the end user prior to consumption, or will be commercially processed prior to retail sale.[78] Only produce (as defined in AHPA's comments to the Produce Safety Rule) is consumed without further handling and preparation.

### 8.13 Other food/activity combinations that should be included in § 117.5(g) and (h)

AHPA believes there are at least a few other food/activity combinations which should be included in § 117.5(g), such as:

- Packing and/or holding of any food which will be cooked by the end-user prior to consumption.

AHPA believes there are at least a few other food/activity combinations which should be included in § 117.5(h), such as:

- Mixing or combining any liquid low-moisture foods in any combination.
- Mixing or combining any liquid low-moisture food(s) with any solid low-moisture food(s) in any combination;

### 8.14 FDA should revisit and expand the draft RA if necessary to create comprehensive and rational lists

If necessary to create comprehensive and rational lists, FDA should revisit and expand the science-based risk analysis conducted in response to FSMA Sec. 103(c)(1)(C). However, AHPA believes it is not necessary to do so; the science behind the effect of factors such as water activity and ethanol content on microbial survival and growth is well established, and the risks (or lack thereof) are generally well understood.

If FDA does undertake revisions to the RA, AHPA urges FDA to:

- Include industry as well as academic experts having knowledge of the full range of food processing activities performed on farms and at farm mixed-type facilities worldwide, including

[78] See our comments to the Produce Safety Rule regarding the commercial processing exemption.

those with knowledge of the production of natural sweeteners, spices, botanical extracts, baked goods, etc.

- Include consideration of how previous or subsequent processing steps (such as drying of vegetables immediately after slicing) impact the risks associated with a particular food or food/activity combination.

**8.15 The qualifier of the phrase "intact fruits and vegetables" used in § 117.5(g)(6) is confusing**

AHPA finds confusing the qualifier in § 117.5(g)(6), "for purposes of paragraph (g) and paragraph (h) of this section only, 'intact fruits and vegetables' refers only to fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts." Upon initial reading it is unclear what are the purpose and implications of excluding this assortment of items from "intact fruits and vegetables." After review, AHPA finds this is language carried over from the RA, which excluded these items in order to give them separate consideration. AHPA believes that outside the context of the RA, this language should be omitted. The meaning of the list will be perfectly clear without the qualifying language, despite the fact that "intact fruits and vegetables" is redundant to certain other items in the list; and use of the qualifying language is itself unnecessarily confusing. Readers should not need to consult the RA in order to understand the language of the regulation.

**8.16 FDA's use of the word "intact" requires clarification**

AHPA believes FDA's use of the term "intact" in § 117.5(g) and § 117.5(h) is confusing and unclear. The plain English meaning of "intact" is "not altered; remaining whole or untouched; not changed or diminished,"[79] so most readers are likely to equate "intact fruits and vegetables" with "fresh, whole fruits and vegetables." However, in § 117.5(h)(2)(xx) FDA provides "dried beans and peas" as an example of "intact fruits and vegetables," which seems to indicate that FDA intends the term "intact" to include dry as well as fresh fruits and vegetables.

AHPA believes that dry items should be considered separately from fresh, as they are often much safer (i.e. much less susceptible to microbial growth) than those which contain appreciable levels of moisture. Therefore, for both scientific accuracy and to ensure clarity to the reader, dried items should be listed separately from fresh fruits and vegetables.

To avoid confusion, AHPA recommends replacing "intact" with "fresh, whole" as a descriptor for fruits and vegetables. If FDA retains the word "intact," and especially if FDA continues to intend the word to include dry items, a definition of it should be provided in the rule.

**8.17 The introductory paragraph to § 117.5(g) is confusing**

AHPA believes the paragraph in § 117.5(g) which introduces the list of exempt foods is confusing.

[79] http://dictionary.reference.com/browse/intact, accessed 11/16/13.

The paragraph says Subpart C does not apply to certain packing and holding activities when performed "on food not grown, raised, or consumed on that farm or farm mixed-type facility or another farm or farm mixed-type facility under the same ownership."

To begin with, AHPA believes many readers will erroneously take this to mean that the logical inverse is also true, i.e. if the food involved is grown, raised, or consumed on that farm or farm mixed-type facility or a co-owned farm or farm mixed-type facility, then Subpart C will apply. However, this is not necessarily true; for example Subpart C will not apply to packing and/or holding of RACs grown, raised, or consumed on the same farm or a co-owned farm because such activities remain within the farm definition.

Furthermore, from a real-world standpoint it makes little sense for this exemption to be limited to only food which is not grown, raised, or consumed on the farm or farm mixed-type facility or a co-owned farm or farm mixed-type facility ("FFMTF" for short).

- If packing and/or holding foods not grown on the FFMTF is low risk, then packing and/or holding the same foods when they are grown on the same FFMTF should be equally low risk, or possibly even lower (since the provenance is more certain, the food has not been exposed to hazards during transportation, etc.).
- If packing and/or holding foods not raised on the FFMTF is low risk, then packing and/or holding the same foods when they are raised on the same FFMTF should be equally low risk, or possibly even lower (since the provenance is more certain, the food has not been exposed to hazards during transportation, etc.).
- If packing and/or holding foods not consumed on the FFMTF is low risk, then packing and/or holding the same foods when they are consumed on the same FFMTF will certainly be even lower risk (since the distribution of the food is much more limited).

AHPA believes FSMA's requirement for FDA to analyze the risks in on-farm packing and/or holding of "food not grown, raised, or consumed" on the farm is simply a reflection of Congress' awareness that packing and holding of such foods can be low-risk, and consequent desire to ensure the RA would capture such foods. AHPA notes that FSMA Sec. 103(c)(1)(D) does not require the regulation specifically to address on-farm packing and/or holding of "food not grown, raised, or consumed" on the farm. In the draft regulation, AHPA believes this paragraph's limitation to "food not grown, raised, or consumed" on the same FFMTF is intended to reflect the fact that packing and holding of food which is grown, raised, or consumed on the same FFMTF will remain within the farm definition and hence none of Part 117 will apply, making an exemption from Subpart C unnecessary. However, in the context of this paragraph the language is confusing and unnecessary, and AHPA therefore suggests it be deleted.

### 8.18 Other areas requiring clarification

AHPA is unsure what FDA means by the term "grain products." AHPA assumes this is intended to include flour and other milled grains, as well as perhaps dry pasta, but it might also be interpreted as bakery goods or even sprouted grains. AHPA suggests this should be clarified.

AHPA believes FDA should clarify what it means by "adding seasoning" in the context of § 117.5(h)(1) and (2). In the culinary world, "seasoning" often refers to salt and/or salt and pepper; however, FDA mentions "salting" separately in § 117.5(h)(1) and (2) and dictionary definitions often include use of herbs and other flavor enhancers.[80] AHPA believes FDA intends "seasoning" to mean addition of herbs, spices, sugar, or other ingredients to enhance flavor. However, it is unclear whether FDA intends this to be limited to dry flavor ingredients, or whether it would extend to liquid flavor enhancers such as soy sauce. AHPA suggests this should be clarified.

### 8.19 A mechanism should be established to add exempted food/activity combinations to the lists

AHPA believes the food/activity combinations which can be considered "low risk" for the purposes of 21 CFR 117.5(g) and (h) are likely to change over time as new information and data emerges. Therefore, AHPA believes FDA should establish a mechanism by which new items can be added to the lists, for example based on data provided by industry. If such a mechanism is established, FDA should ensure such information is acted upon in a timely manner.

[80] E.g. "Something, such as a spice or herb, used to flavor food." http://www.thefreedictionary.com/seasoning, accessed 11/22/13.

# 9. Comments regarding Subpart B

## 9.1 Comments regarding proposed deletions of optional provisions

FDA proposes in subpart B to delete some non-binding provisions of current Part 110 (e.g., provisions using "should" or "compliance may be achieved by").

AHPA is strongly opposed to such deletions. AHPA believes the information provided in these provisions is extremely useful to clarify the intended effect of the regulations, to suggest means of compliance with the requirements, and to educate small, new, or foreign companies. AHPA believes the benefits to both the regulated industry and to the general public of retaining this information far outweighs any stylistic or other concerns.

AHPA notes that after decades of striving by local, state, and federal agencies to provide excellent food safety information and education to the food industry, by 1998 only 60% of full service restaurants had been brought into compliance with FDA food safety recommendations.[81] AHPA believes this demonstrates the difficulty of ensuring that important information fully penetrates an industry, especially one that includes many small firms and sole proprietorships. As a result, FDA should lose no opportunity to disseminate useful food safety information to the regulated industry; and this most particularly includes in the regulation itself, since this is often the first and/or a primary resource consulted by industry.

AHPA believes promulgating this information in the form of guidance will also be useful, but it should occur in addition to - not instead of - including it in the rule itself. For one thing, the process of developing and publishing guidance documents is often protracted. Secondly, even once a guidance document is published, companies are less likely to be aware of its existence than of the rule itself. Thirdly, even if both regulation and guidance exist, and even if industry is aware of both, it will still be more effective to have useful information presented in both contexts, because repetition and redundancy are important educational tools.

AHPA furthermore notes that many of the proposed requirements in Subpart B are extremely vague and confusing in the absence of the non-binding provisions. Even with a long background in food safety and food regulations, AHPA found many of the proposed requirements nearly unintelligible in their current proposed form; it was necessary to consult the corresponding provision of Part 110 in order to understand what the proposed requirement was intended to achieve.

[81] 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.

Finally, AHPA believes it important, where appropriate, for FDA to state explicitly that a range of options for achieving compliance are acceptable. In the absence of these clearly specified options, inspectors and other FDA officials commonly default to an assumption that the only effective way to ensure compliance is by conducting laboratory testing. AHPA objects strongly to the supposition that laboratory testing is the only, best, or most appropriate way to ensure specifications and controls are met. AHPA discusses this in more detail below (e.g. see comments regarding § 117.80(a)(2) and § 117.80(b)(2)), as well as in our general comments regarding testing requirements.

**9.2 Comments regarding optional vs. mandatory requirements**

AHPA supports maintaining use of the word "should" in all places where it is currently used in the proposed subpart B, and also in optional proposals AHPA proposes to reinstate from Part 110 (except as noted in AHPA's detailed markup below), rather than changing to the word "must." AHPA believes it important for the rule to allow sufficient flexibility as to be practical for a wide range of companies which differ in terms of ingredients, products, plant, equipment, and procedures.

**9.3 Comments regarding the introductory language of proposed § 117.10**

Proposed § 117.10 begins with "The plant management must take all reasonable measures and precautions to ensure" personnel disease control, cleanliness, and training."

AHPA finds use of "all" to be too extreme and prescriptive.

AHPA notes the proposed regulation defines "adequate" as "that which is needed to accomplish the intended purpose in keeping with good public health practice." AHPA sees no reason plant management should be required to implement anything beyond "adequate" practices for disease control and cleanliness of personnel. Use of any - never mind *all* - measures or precautions beyond those which are "adequate" is simply not needed or useful.

AHPA suggests use of the word "adequate" in combination with, rather than instead of, "reasonable" to properly describe the intended measures and precautions; "adequate" by itself could lead to excessive requirements. For example, the most reliable way to prevent employees with open sores or lesions from handling food might be to perform a full body visual inspection of each employee's skin each day prior to work, but it would not be reasonable to do so.

Finally, AHPA notes that the phrase "all reasonable measures and precautions" makes little sense in relation to employee education and training.

AHPA therefore suggests the introductory language of proposed § 117.10 be revised as follows:

> The plant management must take ~~all~~ reasonable and adequate measures and precautions to ensure...

### 9.4 Comments regarding proposed § 117.10(b)

AHPA suggests the following revision to § 117.10(b)(5), because the additional information is useful; and since it is presented as optional, will pose no problem for companies who have a good reason to use gloves which are not impermeable:

> Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material, especially where used for handling of ready-to-eat food.

AHPA suggests the following revision to § 117.10(b)(7) for clarity, otherwise the sentence might be interpreted to mean that no personal clothing is allowed in these areas (e.g. that employees are permitted to wear only company-issued uniforms):

> Storing extra clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

AHPA suggests the following revision to § 117.10(b)(8), because it will not be immediately obvious to many laypersons whether the chewing of gum is included in "eating food":

> Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

AHPA suggests the following revision to § 117.10(b)(9):

> Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines or other products applied to the skin) and to protect against cross-contact of food.

### 9.5 Comments regarding proposed § 117.10(c)

Proposed § 117.10(c) reads, "Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices."

It is unclear to AHPA what is meant by "personnel responsible for identifying sanitation failures or food contamination" and why "training" is not included as one of the options in "a background of education or experience." AHPA considers that all personnel working in food production are "responsible for identifying sanitation failures or food contamination," at least those which are visually observable (e.g. condensate dripping onto processing equipment; utensils dropped on floor; foreign objects observed in food), and training is an appropriate way to ensure personnel know they must be on the lookout for such problems.

AHPA speculates perhaps "personnel responsible for identifying sanitation failures or food contamination" is intended to refer to those with a higher level of authority, such as supervisors, managers, or quality control/quality assurance personnel; alternately, it might refer to personnel responsible for identifying problems which are not visually obvious, such as through laboratory testing. In either case, AHPA believes "training" is a legitimate option to ensure such personnel are able to administer their responsibilities. AHPA cannot envision any circumstance in which "training" would not be a legitimate option, unless FDA proposes to impose specific educational requirements, which does not appear to be the case in this paragraph.

AHPA urges FDA to clarify "personnel responsible for identifying sanitation failures or food contamination" and recommends the following change:

> Personnel...[clarification by FDA needed]...should have a background of education, training, or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

**9.6 Comments regarding proposed § 117.20(a)(4)**

AHPA believes the second sentence of proposed § 117.20(a)(4) should be separated into new § 117.20(a)(5), because it bears no logical relation to the first sentence.

> (4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.
>
> (5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through ~~(a)(3)~~ (a)(4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

### 9.7 Comments regarding proposed § 117.20(b)(1)

Proposed § 117.20(b)(1) requires the facility design and construction to "Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food."

AHPA finds the phrase "maintenance of sanitary operations" to be unclear and vague. Also, AHPA believes that equipment and facility maintenance is itself necessary to the production of safe food.

AHPA suggests the following revision to § 117.20(b)(1):

> Provide sufficient space for such placement of equipment and storage of materials as is necessary for ~~the~~ maintenance, ~~of~~ sanitary operations, and the production of safe food.

### 9.8 Comments regarding proposed § 117.20(b)(2)

Proposed § 117.20(b)(2) requires the facility design and construction to "Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material, and to reduce the potential for cross-contact. The potential for cross-contact and contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means."

It is not apparent how "food safety controls" and "operating practices" constitute part of plant design and construction, which causes confusion at first reading of this provision. AHPA believes FDA mentions them here to make it clear these are valid alternatives to controlling cross-contact and contamination through facility design, although they are more appropriately considered part of § 117.40 and/or § 117.80. To minimize confusion, AHPA recommends the sentence structure be changed slightly.

AHPA suggests the following revisions to § 117.20(b)(2):

> Permit ~~the taking~~ use[82] of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material, and to reduce the potential for cross-contact. The potential for cross-contact and contamination, if not adequately reduced by food safety controls and operating practices, may be reduced ~~by adequate food safety controls and operating practices or~~ through effective design, including the separation of operations in which cross-contact and contamination are likely to occur~~,~~

[82] AHPA suggests that "the taking of" should generally be replaced by "use of" throughout the rule, for brevity.

by one or more of the following means: location, time, partition, air flow systems, dust control systems,[83] enclosed systems, or other effective means.

### 9.9 Comments regarding proposed § 117.20(b)(5) through (7)

AHPA suggests the following revisions to proposed § 117.20(b)(5), for clarity:

> Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, packed, or stored and where equipment or utensils are cleaned; and provide ~~safety-type~~ shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

AHPA suggests the following revisions to proposed § 117.20(b)(6), for clarity and completeness:

> Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces and for cross-contact.

AHPA suggests the following revisions to proposed § 117.20(b)(7), for clarity and completeness:

> Provide~~, where necessary, adequate screening or other~~ protection against pests, such as by window screens, door sweeps, gap sealant, or other appropriate measures.

### 9.10 Comments regarding proposed § 117.35(a)

Proposed § 117.35(a) states, "General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact and contamination of food, food contact surfaces, or food-packaging materials."

AHPA believes it necessary to qualify the "sanitary" condition required of "buildings, fixtures, and other physical facilities of the plant," as the degree of sanitation required for, say, a warehouse or utility room is quite different from the sanitation required for a processing room. Also, AHPA believes the requirement should include "clean" as well as sanitary.

[83] Although "dust control systems" may be considered a part of "air flow systems," AHPA believes they merit separate mention, for clarity and the education of those who may not be familiar with the GMP. AHPA notes that the preamble to the proposed rule repeatedly mentions the need to control dust to minimize cross-contact.

Furthermore, AHPA does not believe cleaning and sanitizing of equipment and utensils should be included in this section, but rather should be addressed in § 117.40.

AHPA suggests the following revision to proposed § 117.35(a):

> General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in an appropriately clean and sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated. Cleaning, ~~and~~ sanitizing, and maintenance of ~~utensils and equipment~~ the plant must be conducted in a manner that protects against cross-contact and contamination of food, food contact surfaces, or food-packaging materials.

**9.11 Comments regarding § 117.35(b)**

AHPA suggests the following change to § 117.35(b), for clarity and completeness:

> Substances used in cleaning and sanitizing; ~~storage of~~ toxic materials. (1) Cleaning ~~compounds~~ and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Cleaning and sanitizing agents used on food-contact surfaces must contain only ingredients which are generally recognized as safe[84] or are approved in 21 CFR § 178.1010 for use in cleaning and sanitizing food-contact surfaces.[85] Compliance with ~~this requirement~~ the requirements of this paragraph may be verified by any effective means, ~~including~~ such as[86] purchase of these substances under a supplier's guarantee or certification, or examination or testing of ~~these~~ the substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
> (i) Those required to maintain clean and sanitary conditions;
> (ii) Those necessary for use in laboratory testing procedures;
> (iii) Those necessary for plant and equipment maintenance and operation; and
> (iv) Those necessary for use in the plant's operations.

[84] Substances which are generally recognized as safe and are commonly used for cleaning and sanitization of food-contact surfaces include, for example, food or pharmaceutical grade water, ethanol, isopropanol, and sodium hydroxide.

[85] AHPA believes this information is useful to small, foreign, and new food processors, who may otherwise be unaware that only specific kinds of substances are approved for use on food-contact surfaces.

[86] See AHPA's comments regarding use of the word “including.” AHPA suggests changing “including” to “such as” throughout the regulation wherever a partial list is intended, to make it unambiguously clear that the list is not intended to be complete.

(2) ~~Toxic cleaning compounds,~~ Cleaning and sanitizing agents~~, and pesticide chemicals~~ shall be identified, ~~held,~~ used, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials, except for permissible residual levels of cleaning and sanitizing agents which are generally recognized as safe or are approved for use on food-contact surfaces.
(3) Toxic materials shall be identified, used, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. Pesticide chemicals used inside the plant must be approved for use in food facilities, as listed in the chemical's labeling or by regulation.[87]

**9.12 Comments regarding the definition of "pest" and proposed § 117.35(c)**

The proposed rule defines "pest" as "any objectionable animals or insects including birds, rodents, flies, and larvae."

Proposed § 117.35(c) states, "Pest control. Pests must not be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials."

AHPA has a number of concerns about this definition and § 117.35(c).

- The statement "Pests must not be allowed in any area of a food plant" is oddly formulated, especially since § 117.20(b)(7) already precludes pests entering due to careless facility design or construction. The verb "allow" implies an active decision by plant employees to allow pests to enter.
- A categorical requirement to exclude pests is an impossible standard to meet. Food processors should take appropriate steps to prevent pests from entering the facility and/or control them once inside, but no building can be made absolutely pest-proof. Furthermore, most raw agricultural commodities inevitably bring with them a certain low level of pests into the facility, carried in or on the plant tissues. The rule should not include impossible provisions or those with which it is not feasible to comply except by extraordinary or absurd measures (such as excluding one's own raw materials from the facility due to their unavoidable contamination with pests).

[87] AHPA believes this information is useful to small, foreign, and new food processors, who may otherwise be unaware that only specific kinds of pesticides are approved for use in food facilities.

- The paragraph seems to equate "guard or guide dogs" with pests. However, these dogs are not "objectionable animals," therefore they are not pests.
- Since "pest" is (quite rightly) defined as "objectionable animals," and since companion animals are not generally considered objectionable, the paragraph as currently written fails to preclude companion animals from being permitted into the facility. AHPA has observed at least one food company (not among its membership!) which controls rodents by allowing cats to live in the warehouse. AHPA suggests the language should be clarified to explicitly disallow animals in the facility other than guard or guide dogs.
- AHPA notes that "plant" is defined as "the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food." Since this definition permits "plant" to mean only a portion of a building or establishment, it is not clear whether "any area of a food plant" is intended to include administrative offices, cafeterias, and other rooms which are not directly involved in the processing, packing or holding of food. AHPA suggests FDA's intent should be clarified, and recommends that animals be excluded from all areas used by production or packaging employees or which communicate with food processing, packing, or storage areas.

AHPA therefore suggests the following revisions:

> *Pest* refers to any objectionable animals or insects ~~including~~ such as[88] birds, rodents, flies, and larvae.
>
> ~~Pest control~~Animals and pests. ~~Pests~~ Animals must not be allowed in any area of a food plant, including cafeterias, restrooms, and other areas used by production or packaging employees, and including offices and other areas that communicate with areas used for food manufacturing, processing, packing, or holding. ~~Guard~~ However, guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. ~~Effective~~ Appropriate measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

**9.13 Comments regarding proposed § 117.35(d)**

AHPA suggests the following revisions to proposed § 117.35(d), for clarity and completeness:

[88] See AHPA's comments on use of the word "including." AHPA suggests changing "including" to "such as" throughout the regulation wherever a partial list is intended, to make it unambiguously clear that the list is not intended to be complete.

Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned and sanitized as frequently as necessary to protect against cross-contact and contamination of food.

(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition at the time of use. When the surfaces are wet cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against cross-contact ~~and~~ or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

**9.14 Comments regarding proposed § 117.35(e) and (f)**

AHPA suggests the following revisions to proposed § 117.35(e), for clarity and completeness:

> Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment used ~~in the operation~~ where food is exposed or in food production sections of a food plant should be cleaned, and sanitized where appropriate, in a manner and as frequently as necessary to protect against cross-contact and contamination of food, food-contact surfaces, and food-packaging materials.

AHPA suggests the following revisions to proposed § 117.35(f), for clarity and completeness:

> Storage and handling of cleaned portable equipment and utensils. Cleaned and/or sanitized portable equipment with food-contact surfaces and utensils ~~should~~ must be stored in a location and manner that protects food-contact surfaces from cross-contact and contamination.

**9.15 Comments regarding proposed § 117.37(a)**

Proposed § 117.37(a) states, "Water supply. The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities."

AHPA believes the requirement "in all areas" is too prescriptive, and is subject to misinterpretation since it is sometimes taken to mean that running water must be provided inside, or in very close proximity to, processing rooms. AHPA is aware of instances where this misinterpretation has occurred.

AHPA notes that in many facilities, especially those processing low moisture products with very low microbial counts (e.g. excipients, vitamins, minerals, powdered botanical extracts, etc.), it is actively counterproductive to locate running water (and the ancillary sinks or drains) in, or near, processing rooms, since the sink or drain itself poses a larger risk of contamination than anything else in the area.

AHPA furthermore notes that in many facilities, especially overseas, the final stages of processing and packaging (after the final microbial reduction step) are performed in cleanroom suites. In such facilities, hand washing and sanitizing facilities are located in the vestibule to the cleanroom suite, not inside the suite itself.

AHPA suggests the following revisions to proposed § 117.37(a):

> Water supply. The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality, as defined in 40 CFR § 141. Compliance with this requirement may be verified by any effective means, such as examination of the supplier's specifications or test reports; purchase of the water under a supplier's guarantee or certification; or analyzing the water. Running water at a suitable temperature, and under pressure as needed, must be provided ~~in all areas~~ at appropriate locations where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

**9.16 Comments regarding proposed § 117.37(c)**

AHPA suggests the following revisions to proposed § 117.37(c):

> Sewage disposal. Sewage ~~disposal must be made~~ must be disposed into an adequate sewerage system or disposed of through other adequate means.

**9.17 Comments regarding proposed § 117.37(d) and (e)**

Proposed § 117.37(d) states, "Toilet facilities. Each plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials."

Proposed § 117.37(e) states, "Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature."

AHPA is opposed to omitting the additional detailed information regarding toilet facilities and hand-washing facilities provided in Part 110. AHPA believes this detailed information is useful and instructive for small businesses, foreign firms, and new companies, and that it should be preserved in Part 117. As discussed elsewhere in our comments, AHPA generally opposes removal of useful information and practical guidance from the regulation, because the public health benefit of providing such information and guidance far outweighs any desire for brevity or other stylistic concerns.[89]

However, AHPA does believe some of the toilet- and handwash-related information should be made optional rather than mandatory, because the importance of compliance with the guidelines will vary depending on the facility design. For example, the design of bathroom sinks is relatively unimportant in a facility where personnel are required to re-wash and sanitize their hands in the vestibule prior to entering a cleanroom.

AHPA furthermore notes that in the U.S. most state and local jurisdictions as well as federal inspectors interpret "suitable temperature" for bathroom handwash water to mean "hot." AHPA believes that "hot" water is not appropriate for all circumstances, even in the context of toilet facilities (such as where employees will have to reclean and sanitize their hands anyway prior to entering a cleanroom suite), so the rule should make bathroom hot water explicitly optional. However, AHPA suggests that if there are circumstances under which "hot" is what will be enforced, the regulation should plainly state that hot water is required under those specifically-identified circumstances. It is counterproductive for the rule to be vague if FDA will in fact hold companies to a specific requirement.

AHPA therefore suggests the following changes to § 117.37(d) and (e):

> Toilet facilities. Each plant must provide its employees with adequate, readily accessible toilet facilities which are kept in good repair. Toilet facilities must be kept clean and appropriately sanitary, and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials. Toilet facilities should be provided with self-closing doors and refuse receptacles which do not re-contaminate employees' hands or otherwise contribute to potential contamination of food; and should not open directly into areas where food is exposed unless alternate measures are taken to avoid

[89] As discussed elsewhere in our comments, AHPA is generally opposed to omitting from the rule any information which would be helpful to educate and inform small, foreign, or new companies; to clarify what is meant by language that would otherwise be vague and confusing; and/or to suggest means of compliance with particular requirements that will be acceptable to FDA. AHPA strongly opposes FDA's idea of moving all such information to guidance documents.

exposing the food to airborne contamination (such as double doors or positive air-flow systems).

Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature. Hot water should be provided for hand washing in toilet facilities. Hand-washing facilities must provide soap and effective hand sanitizers, and single-use towels or other suitable drying devices. Hand-wash devices or fixtures, such as water control valves, should be designed and constructed to avoid recontamination of clean, sanitized hands. Hand-washing facilities located in toilet facilities should be accompanied by readily understandable signs directing employees to wash and sanitize their hands prior to leaving the toilet facility.

**9.18 Comments regarding proposed § 117.40**

In proposed § 117.40(a)(1), AHPA believes the phrase "all plant equipment" is too broad, since it could include equipment used in offices or for grounds maintenance or other purposes not related to food production. Furthermore, AHPA notes that the requirements for cleanliness differ at various stages of production; for example, equipment used for inspecting or milling raw agricultural commodities need not be nearly as clean or sanitary as equipment processing finished RTE food. AHPA therefore suggests the following revisions to proposed § 117.40(a)(1):

All ~~plant~~ equipment and utensils used for or in connection with food manufacturing, processing, packing, or holding must be ~~so~~ designed and constructed of such material and workmanship as to be adequately cleanable, as appropriate to the stage of production; and must be properly maintained.

AHPA suggests the following revision to proposed § 117.40(a)(2):

~~The design, construction, and use of equipment and utensils must preclude~~ Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

AHPA suggests the following revisions to proposed § 117.40(a)(3), for clarity and completeness:

~~All equipment should be so installed and maintained~~ Equipment should be installed so as to facilitate the cleaning and maintenance of the equipment and of all adjacent spaces.

AHPA suggests the following revisions to proposed § 117.40(a)(4), for clarity and accuracy and to eliminate redundancy:

> Food-contact surfaces must be suitably corrosion-resistant, as appropriate to the type of food and other substances with which they come in contact ~~when in contact with food~~.[90]

AHPA suggests the following revisions to proposed § 117.40(a)(5), for clarity and completeness:

> Food-contact surfaces must be made of nontoxic, food-grade materials. Except for single-use items, food-contact surfaces must be suitably durable and must be designed and constructed to withstand the environment of their intended use and the action of food, ~~and, if applicable,~~ cleaning ~~compounds~~ and sanitizing agents, and cleaning procedures.

AHPA suggests the following revisions to proposed § 117.40(a)(6) , for clarity and completeness:

> ~~Food-contact~~ Equipment, utensils, and food-contact surfaces, other than single-use items, must be appropriately[91] cleaned, sanitized, and maintained to protect food from cross-contact and from being contaminated by any source, including unlawful indirect food additives.

AHPA believes that proposed § 117.40(c) is largely redundant to § 117.40(a)(1), (2), and (6) and should be deleted. If it is retained, AHPA suggests the following revisions:

> Equipment that is in ~~the manufacturing or food-handling area~~ areas where food is manufactured, processed, or packed and that does not come into contact with food must be so constructed that it can be kept in an appropriately clean and sanitary condition.[92]

AHPA suggests the following revision to proposed § 117.40(d):

[90] AHPA notes that even food-contact surfaces which are not directly in contact with food should be corrosion-resistant (e.g. surfaces from which drainage will contact food or other food-contact surfaces).

[91] AHPA believes "appropriately" should be inserted here because the sentence applies to all equipment and utensils in the plant, not just those directly used in food processing.

[92] AHPA believes the non-food-contact equipment in food-handling areas generally needs to be reasonably sanitary as well as clean, although the necessary level of sanitation is not as high as for food-contact equipment.

> Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriately clean and sanitary condition.

AHPA suggests the following revision to proposed § 117.40(e), for clarity and completeness:

> Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature and/or with an automatic alarm system to indicate a significant temperature change in a manual operation.[93]

AHPA suggests the following revisions to proposed § 117.40(f), for clarity, accuracy, and completeness:

> Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be suitably accurate and precise, ~~and~~ adequately maintained and calibrated,[94] and adequate in number for their designated uses.

AHPA suggests the following revision to proposed § 117.40(g), for clarity:

> Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be filtered or otherwise treated in such a way that food is not contaminated with unlawful indirect food additives.

**9.19 Comments regarding proposed § 117.80(a)(2) and (4)**

AHPA suggests the following changes to § 117.80(a)(2), for clarity and completeness.

> Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe. ~~and suitable~~[95]

[93] AHPA believes that in foreign countries, refrigerators and freezers are not always so-equipped.

[94] AHPA believes proper calibration of such equipment is essential to ensure food safety, and does not entail so large a cost as to preclude even small companies from compliance.

[95] AHPA is aware that the phrase "safe and suitable" is defined at § 130.3(d). AHPA believes use of this phrase here in § 117 to describe requirements for food-packaging materials is confusing, since the definition given at § 130.3(d) defines the phrase with respect to ingredients, not food-packaging materials; and in the absence of an intelligible definition, it is not clear what "safe and suitable" is specifically intended to mean.

> Food-packaging materials must be made only of ingredients which are themselves food ingredients or approved food additives,[96] indirect additives approved for food-contact use as per 21 CFR §174-180, and/or indirect food substances generally recognized as safe as per 21 CFR §186;[97] compliance with this requirement may be verified by any effective means, such as examination of the supplier's specifications or test results, or purchase of the materials under a supplier's guarantee or certification.[98]

AHPA suggests the following changes to § 117.80(a)(4); see comments to § 117.10 regarding why AHPA believes "adequate and reasonable" is better language than "all reasonable."

> ~~All reasonable~~ Adequate and reasonable precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.

**9.20 Comments regarding proposed § 117.80(a)(5)**

Proposed § 117.80(a)(5) states, "Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible cross-contact and food contamination."

AHPA is concerned that proposed § 117.80(a)(5) is written in a manner which could be interpreted to mean the testing mentioned is always required (e.g. say, testing for cross-contact whenever food is processed in a facility with allergens), as opposed to only being required when a specific problem or failure is observed. AHPA does not believe FDA intends to require such testing routinely, and would oppose such a requirement.

Also, AHPA notes there are not always test methods or analytical standards available for the testing mentioned. AHPA is strongly opposed to any implication that food manufacturers are expected or required to develop test methods or analytical standards, or search out methods which are not readily available, for this or any other purpose; see our comments regarding a potential requirement for testing.

AHPA suggests the following changes to § 117.80(a)(5), for clarity:

> Chemical, microbial, or extraneous-material testing procedures must be used, where appropriate test methods and any appropriate analytical standards are readily available, to evaluate possible adulteration ~~where necessary to identify~~ if there is reason to

[96] AHPA notes some types of packaging are made from, for example, starch.

[97] AHPA feels it is important to include this information, otherwise small, foreign, and new companies may be unaware that specific requirements for food-packaging materials exist.

[98] AHPA also suggests it may be appropriate to separate the requirements for food-packaging materials into a new paragraph with a new number.

suspect sanitation failures, ~~or possible~~ cross-contact, ~~and~~ or food contamination has occurred.

### 9.21 Comments regarding proposed § 117.80(a)(6)

AHPA suggests the following changes to § 117.80(a)(6), for clarity:

> All food that has become contaminated to the extent that it is adulterated must be rejected, or (except as precluded by § 110.110(d))[99] ~~if permissible~~, treated, ~~or~~ processed, or otherwise reconditioned to eliminate the contamination.

### 9.22 Comments regarding proposed § 117.80(b)(1)

Proposed § 117.80(b)(1) states, "Raw materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against cross-contact and contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food or cause cross contact. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration of food."

Based on information provided in the preamble to the proposed rule, AHPA interprets "raw material" to mean an item which is so transformed during processing as to be unidentifiable in the finished product (e.g. sugarcane is a raw material for sugar manufacturing) while "ingredient" refers to an item which persists in the finished product in identifiable form (e.g. tomatoes are an ingredient in tomato juice, sauce, and salsa). As such, AHPA believes inspection, washing, cleaning, and other preparatory steps may apply to both raw materials and ingredients.

AHPA suggests the following changes to § 117.80(b)(1), for clarity and completeness:

> Raw materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food.[100] ~~and must be stored under conditions that will protect against cross-contact and contamination and minimize deterioration.~~ Raw materials and ingredients must be

[99] AHPA believes the vague and confusing phrase "if permissible" should be replaced by a statement of precisely what is impermissible.

[100] AHPA suggests deleting the remainder of this sentence to avoid redundancy with other provisions later in the rule.

washed, ~~or~~ cleaned, and/or inspected[101] as ~~necessary~~ appropriate[102] to remove soil, extraneous material, or other contamination. Water used for washing, rinsing, or conveying food must ~~be safe and of adequate sanitary quality~~ comply with 21 CFR § 117.37(a). Water may be reused for washing, rinsing, or conveying food if it does not increase ~~the level of~~ contamination of the food to an unacceptable level or cause cross contact. Containers and carriers of raw materials and ingredients should be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration of food.

**9.23 Comments regarding proposed § 117.80(b)(2), and proposed new labeling requirements to mitigate biological risks**

Proposed § 117.80(b)(2) states "Raw materials and ingredients must either not contain levels of 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."

AHPA is concerned that this requirement is overly broad. As written, it will apply to companies who merely pack or otherwise minimally process raw agricultural commodities for further processing, such as a company which packs peppercorns into bulk containers or which reduces peppercorns to powder which is packaged in bulk (not retail) containers. It will also apply to companies who pack or minimally process grain and other items which will be cooked either by a food processor or the consumer prior to consumption.

AHPA believes it will be extremely ill-advised to require such companies to pasteurize or otherwise treat their products to reduce microbial contamination. Not only will this significantly increase the economic cost of the new rule while not providing any commensurate public health benefit, it will remove an important quality marker. Knowledgeable food processors often prefer to purchase dry botanical ingredients in unsterilized form, because 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 can compromise quality and increase microbial contamination and microbial toxins to unacceptable levels; FDA's own definition of "undesirable microorganisms" acknowledges they can provide a useful indication that food has been contaminated with filth. Sterilization can be used to hide these problems from the buyer. AHPA emphasizes that this is

[101] AHPA notes that it is standard procedure in many facilities to perform 100% inspection of botanical raw materials and ingredients prior to use in processing, to remove foreign plant parts, extraneous material, decomposed or moldy pieces, etc.

[102] AHPA believes "appropriate" is preferable to "necessary" in this sentence because "necessary" may be interpreted to mean cleaning is required whenever soil, extraneous material, or other contamination is present, which AHPA believes would be an inappropriate requirement. It is not always possible or appropriate to wash or inspect raw materials and ingredients, for example if the material is in powder or liquid form or if the manufacturing process will inherently remove such contaminants through, say, filtration.

considered extremely important by many food processors. Indiscriminate sterilization of botanical materials at early stages of the supply chain will remove crucial information which these food processors rely on to judge the quality and integrity of the ingredients they buy.

AHPA acknowledges that contamination of low-moisture botanicals such as spices has in recent years been increasingly recognized as a problem, perhaps as a result of globalization, changing agricultural practices, or increased and improved surveillance. However, even where contaminated spices are known to have been distributed, this has only rarely been linked to increased incidence of salmonellosis; to the extent that such salmonellosis has occurred in recent years in the US, it appears to have been only in spices which are commonly added by consumers to RTE food at table (e.g. pepper and chili).[103]

Thus, AHPA believes FDA should not focus overmuch on the issue of microbiological contamination in foods which are early in the supply chain (other than fresh produce which will be consumed without adequate processing or cooking). The potential for microbiological contamination in materials intended for further commercial processing, if such a hazard is reasonably likely to exist in the material, should be addressed by providing clear notice in the labels, labeling or other commercial documentation accompanying the sale of the goods that they have not been treated to reduce microbial contamination and/or that they require such treatment prior to use as or in RTE food. 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, and will thereby adequately protect the public health while avoiding unnecessary burdens and regulatory prescriptions which are actively counterproductive to the quality of the food supply.

Specifically, AHPA suggests the following statement be provided in commercial documentation accompanying the sale of covered produce which was not grown in compliance with Part 112.

> 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.

For processed foods in the form of raw materials and ingredients which have not been processed in a manner which ensures adequate microbial reduction, AHPA suggests the following statement, where included in labels or labeling, serve as a preventive control under § 117.135(d):[104]

[103] A 2006 article states, "Using data from the Centers for Disease Control and Prevention National Salmonella Surveillance System, we were unable to discern any increases in the reported incidence of laboratory-confirmed salmonellosis in states that received spices contaminated with selected rare Salmonella serotypes." Vij, V. *et al.* 2006. Recalls of spices due to bacterial contamination monitored by the U.S. Food and Drug Administration: the predominance of Salmonellae. *J Food Prot* 69(1):233-7.

[104] See our comments regarding suggested new § 117.135(d)(6) below.

> NOTICE: Not processed to reduce microorganisms of public health concern. May require commercial formulation, processing, or both to adequately reduce microorganisms.

In consideration of the above, AHPA believes the requirement of § 117.80(b)(2) should apply only to companies who sell ready-to-eat food. Some companies earlier in the supply chain may also choose to implement it, for example in response to the demands of their customers, but FDA should not force a one-size-fits-all requirement on the industry.

AHPA therefore 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 § 117.126, 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."[105]

[105] AHPA believes it should be the primary responsibility of the end-user, not the farmer, to know when Part 112 compliance is required. See our comments regarding farmers vs. food processors and on the commercial processing exemption in the Produce Safety Rule.

### 9.24 Comments regarding proposed § 117.80(b)(3) through (8)

AHPA suggests the following changes to § 117.80(b)(3), for clarity and completeness:

> Raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with any current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Except as otherwise required under more-specific food regulations or unless otherwise specified in the firm's food safety plan under 21 CFR § 117.126, 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; laboratory analysis; or adequate inspection of the material to remove moldy pieces.

AHPA suggests the following changes to § 117.80(b)(4), for clarity and completeness:

> Raw materials, ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with any applicable FDA defect action level regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food, unless the manufacturing process includes steps which serve to decontaminate the food. Except as otherwise required under more-specific food regulations or unless otherwise specified in the firm's food safety plan under 21 CFR § 117.126, 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; visual examination; or laboratory analysis.

AHPA suggests the following changes to § 117.80(b)(5), for clarity and completeness, and suggests it should be moved to § 117.80(a) as it applies generally. AHPA also notes that the degree of protection against cross-contact and contamination the containers must provide, varies depending on the nature of the contents and the manufacturing process in which they are used. For example, raw agricultural commodities used as raw materials for extraction or other refinement (e.g. sugarcane for making sugar, or soybeans for the extraction of soy isoflavones) require much less protection than ingredients incorporated into the final food with minimal processing.

> Raw materials, ingredients, in-process materials, and rework must be held in ~~bulk, or in~~[106] appropriate containers designed and constructed where necessary ~~so as~~ to protect against cross-contact and contamination and must be held at such temperature and

[106] AHPA fails to see the relevance of whether the materials are held in bulk or not; the materials must be stored in some kind of container, even if the container is a silo or other large structure, and the container must provide adequate protection.

> relative humidity and in such a manner as to prevent the food from becoming adulterated and to minimize deterioration. Material scheduled for rework or reconditioning must be identified as such.[107]

AHPA suggests the following changes to § 117.80(b)(7), for clarity and completeness. This requirement includes the storage requirement clause from § 117.80(b)(1) which AHPA recommended should be deleted from that paragraph to avoid redundancy with this paragraph. AHPA notes this paragraph remains partially redundant to § 117.80(b)(5).

> ~~Liquid or dry raw~~ Raw materials and ingredients, including those in liquid or dry form and those received and stored in bulk form, must be held in a manner that protects against cross-contact, ~~and~~ contamination, and deterioration.

AHPA suggests the following changes to § 117.80(b)(8), for clarity and completeness. AHPA also suggests it should be moved to § 117.80(a) as it applies generally.

> Raw materials and ingredients that are or contain food allergens, and in-process material and rework that contains food allergens, must be so identified and held in a manner that prevents cross-contact.

**9.25 Comments regarding proposed § 117.80(c)**

AHPA suggests the following changes to § 117.80(c)(1), for completeness:

> Equipment and utensils and ~~finished~~ food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

AHPA suggests the following changes to § 117.80(c)(2), for clarity and completeness. AHPA recommends this paragraph be combined with § 117.80(c)(5) to eliminate redundancy.

> All food manufacturing, processing, packing, and holding, including of in-process materials and rework, must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, cross-contact, or ~~for~~ the contamination or deterioration of food. Such conditions and controls may include time, temperature, humidity, pressure, flow rate, pH, $a_w$, or other factors. Effective steps must be taken to ensure that mechanical breakdown, time delays, temperature fluctuations, and other factors do not contribute to the cross-contact, contamination, or spoilage of food.

[107] AHPA notes that the second sentence in this paragraph bears little logical relation to the first. AHPA recommends it be separated into a new paragraph.

AHPA suggests the following changes to § 117.80(c)(3), for clarity and completeness:

> Food that can support the rapid growth of undesirable microorganisms must be held at temperatures or in another manner[108] that will prevent the food from becoming adulterated during manufacturing, processing, packing and holding. Compliance with this requirement may be accomplished by any effective means, such as maintaining frozen foods in a frozen state; maintaining hot foods at 140 °F (60 °C) or above; or maintaining refrigerated foods at 45 °F (7.2 °C) or below.

AHPA suggests § 117.80(c)(5) should be deleted after elements of it are added to § 117.80(c)(2) as recommended above. If § 117.80(c)(5) is retained, AHPA suggests the following changes:

> ~~Work-in-process~~ In-process materials[109] and rework must be handled in a manner that protects against cross contact, contamination, and growth of undesirable microorganisms.

AHPA suggests the following changes to § 117.80(c)(6), for clarity and completeness:

> Effective measures must be taken to protect in-process and finished food from cross-contact and contamination by raw materials, ingredients, ~~or~~ refuse, cleaning and sanitizing agents, and other chemicals. When raw materials, ingredients, ~~or~~ refuse, cleaning and sanitizing agents, or other chemicals are unprotected, they must not be handled simultaneously in ~~a receiving, loading, or shipping~~ the same area if that handling could result in cross-contact or contaminated food. Food transported by conveyor must be protected against cross-contact and contamination as necessary.

AHPA suggests the following changes to § 117.80(c)(7), for clarity and completeness:

> Equipment, containers, and utensils used to convey, hold, or store raw materials, ingredients, ~~work-in-process,~~ in-process materials, rework, or food must be constructed, handled, cleaned, sanitized, and maintained during manufacturing, processing, packing and holding in a manner that protects against cross-contact and contamination.

AHPA suggests the following changes to § 117.80(c)(8), for clarity and completeness:

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[108] AHPA believes it possible that current or future technology may provide other means of preventing microbial growth besides temperature controls; for example, through use of pressure, or in another as-yet-unforeseen manner.

[109] AHPA believes "in-process materials" to be more familiar, straightforward and commonly understood terminology than "work-in-process," which is a term used by accountants. Many small companies do not have accountants on staff.

> Effective measures must be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by use of sieves, traps, magnets, electronic metal detectors, or other suitable means.

In § 117.80(c)(9), FDA proposes to omit the final clause from the equivalent section of Part 110, "or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food." AHPA disagrees with the deletion of "or it shall be reexamined and found not to be adulterated."[110] AHPA understands that such reexamination is inappropriate in certain cases, such as for contamination with pathogens or physical objects, which are often heterogeneous. However, AHPA believes that reexamination may be appropriate in cases of chemical adulteration. For example, processes exist which can remove contaminants such as pesticides and heavy metals from foods such as botanical extracts, but the efficacy of such treatments in any given extract may require confirmation after completion.[111] AHPA sees no valid reason companies should be precluded from using such techniques for reconditioning.

AHPA therefore suggests the following changes to § 117.80(c)(9), for clarity and completeness:

> Food, raw materials, and ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food, or reconditioned~~,~~ if the adulterated food is capable of being reconditioned~~,~~. If the adulteration is microbiological or physical, ~~it must be reconditioned~~ any such reconditioning must be performed using a method that has been proven to be effective. If the adulteration is chemical, reconditioning must be performed using a method that has been proven effective, or after reconditioning the food must be appropriately reexamined and found not to be adulterated.

AHPA suggests the following change to § 117.80(c)(10), for clarity and to differentiate from earlier paragraphs:

> Steps where food is exposed such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against cross-contact and contamination. Food should be protected from contaminants that may drip, drain, or be drawn into the food.

[110] However, AHPA agrees with FDA that "within the meaning of the act" is unnecessary, and believes "before being incorporated into other food" is both unnecessary and inappropriately narrow.

[111] Laboratory studies or small-scale pilot batches may give an indication that the reconditioning is likely to be effective, but cannot always guarantee the treatment will be equally effective when scaled up to commercial-scale production batches. Hence there may be need of reexamination after the reconditioning is complete.

Regarding proposed § 117.80(c)(11), AHPA definitely supports use of "should" in the first sentence because, depending on the type of food and the purpose of blanching, these detailed steps may not be important to protect the public health. For example when botanical agricultural commodities (of which there are many besides tree nuts and peanuts) are blanched, it may not be feasible to determine the interior temperature of the food, depending on the size and friability of the pieces involved. Also, for botanical agricultural commodities with low moisture content, the precise temperature achieved and the timeframe for cooling may not be critical. AHPA suggests the following change to § 117.80(c)(11), for clarity and completeness:

> Heat blanching, when required in the preparation of food capable of supporting microbial growth, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. ~~Thermophilic growth and contamination~~ Contamination by thermophilic microorganisms in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitization.

AHPA suggests the following change to § 117.80(c)(12), for clarity and to differentiate from earlier paragraphs:

> Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations which are used repeatedly over a period of time and/or in combination with various different foods must be treated or maintained in such a manner that they are protected against cross-contact and contamination, and must be maintained under appropriate conditions and disposed at appropriate intervals to protect against the growth of microorganisms.

AHPA suggests the following change to § 117.80(c)(13), for clarity and to differentiate from earlier paragraphs; otherwise it should be deleted as redundant.

> Filling, assembling, packaging, and other operations performed on finished food must be performed in such a way that the food is protected against cross-contact, contamination and growth of undesirable microorganisms.

AHPA suggests the following change to § 117.80(c)(14), for clarity:

> Food, ~~including~~ such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of $a_w$ for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, such as monitoring the $a_w$ or moisture levels of food; controlling the soluble solids-water ratio in finished food; and/or protecting finished food from moisture pickup, by use of a

moisture barrier or by other means, so that the $a_w$ of the food does not increase to an unsafe level.

AHPA suggests the following change to § 117.80(c)(15), for clarity:

Food, ~~including~~ such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, such as monitoring the pH of raw materials, in-process materials, and finished food or controlling the amount of acid or acidified food added to low-acid food.

AHPA suggests the following change to § 117.80(c)(16), for clarity:

When ice is used in contact with food, it must be made from water that ~~is safe and of adequate sanitary quality~~ complies with § 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

AHPA suggests the following be included from part § 110.80(b)(17) and added as § 117.80(c)(17), for clarity and to educate small, foreign, and new food processors:

Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

**9.26 Comments regarding proposed § 117.93**

AHPA 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.
(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:[112] "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."

[112] See AHPA's comments about rethinking the assumptions of the Produce Safety rule for an explanation of this change.

### 9.27 Comments regarding proposed § 117.110

AHPA suggests the following be included from Part § 110.110(e) and added as § 117.110(e), for clarity:

> The Defect Levels Handbook is a compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard and may be obtained at the FDA website or upon request from the Center for Food Safety and Applied Nutrition.

# 10. Comments regarding subpart C

## 10.1 Comments regarding § 117.130(b)

AHPA notes that in discussing hazard identification FDA here states that this "must consider hazards that may occur naturally or that may be unintentionally introduced," and makes no mention of identification of hazards that are intentionally introduced. FDA states in the preamble to this rule that it is not intended to address hazards that may be intentionally introduced proposed rule, and that the agency will address this is separate rulemaking. AHPA supports FDA's decision to promulgate separate rulemaking for hazards which are intentionally introduced into food.

## 10.2 Comments regarding § 117.130(b)(2)

Proposed § 117.130(b)(2) requires that the hazards considered in the hazard identification must include "Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens."

AHPA finds this requirement overly broad and vague with respect to "natural toxins."

AHPA agrees that certain natural toxins, such as aflatoxin (e.g. produced by molding of corn), patulin (e.g. produced by molding of apples), or scombrotoxin (e.g. produced by decomposition of seafood), should be included in the hazard analysis where appropriate. These are toxins which result from improper food handling and are secondary to decomposition or microbial growth; it is therefore incumbent upon food producers to ensure food is handled in a manner which prevents these hazards.

On the other hand, there are a huge variety of foods which contain naturally-occurring toxins as an inherent constituent of the food. These include, for example, lectins in beans, oxalic acid in spinach, and tomatine in tomatoes. There are also many foods which, in and of themselves, either are, or are variously reputed to be, toxic. These include substances such as sugar and high-fructose corn syrup,[113] as well as genetically modified organisms such as Roundup-Ready corn;[114] AHPA does not claim to know whether these substances are in fact toxic, but uses them merely to indicate that what constitutes a "natural toxin" can be extremely controversial and the science involved can be complicated and

[113] "Is Sugar Toxic?" http://www.nytimes.com/2011/04/17/magazine/mag-17Sugar-t.html?pagewanted=all&_r=0, accessed 10/29/13. "Sugar: The Bitter Truth" http://www.youtube.com/watch?v=dBnniua6-oM, accessed 10/29/13. *Pure, White, and Deadly* http://www.amazon.com/Pure-White-Deadly-John-Yudkin/dp/0241965284, accessed 10/29/13.

[114] Gilles-Eric Séralini, G-E. *et al.* 2012. Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. *Food Chem Tox* 50:4221-4231.

confusing. Furthermore, it is a toxicological axiom that "the dose makes the poison": even plain water can be toxic if consumed to excess.[115]

As a result, AHPA considers the requirement for food manufacturers to include "natural toxins" in their hazard analysis to be wholly impractical and unreasonable unless strictly limited to toxins which are the result of improper storage or handling. To require any more extensive consideration of natural toxins will be excessively burdensome. The issues involved, having to do with dose, consumption patterns, food matrix effects, food-drug interactions, role of gut flora, genetic factors, etc., are extremely complicated and require specialized expertise to evaluate, often on a case-by-case basis for each purported food toxin. Entire panels of scientific experts would be required to create a valid hazard analysis under these circumstances; and even then the results would often be controversial and speculative, and any purported effects likely would depend on many factors outside the food processor's control.

Furthermore, for food processors to establish specifications or controls related to most natural toxins could require very expensive testing. Many toxins could require matrix-specific test method development costing thousands of dollars; thereafter, routine testing would require anywhere from $200 per test (e.g. for HPLC tests) to $900 per test (e.g. for LC/MS tests). Isolation and appropriate characterization of the necessary analytical standards for these toxins can also be extremely difficult, time-consuming, and expensive.

AHPA notes that foods are, by definition, considered generally safe for consumption if properly handled and prepared. As a result, the regulation should not impose any requirement for individual food processors to reevaluate the inherent safety of food, including constituents that occur naturally in food.

AHPA therefore strongly suggests the following revisions to § 117.130 (b)(2), for clarity and practicality:

> Chemical hazards, including substances such as pesticide and drug residues, ~~natural toxins,~~ decomposition, unapproved food or color additives, and food allergens. This includes natural toxins only to the extent those toxins are present due to improper storage or handling.

AHPA notes that FDA might conceivably also include natural toxins that are the result of improper processing in this list (i.e. "This includes natural toxins only to the extent those toxins are present due to improper storage, handling, or processing"), but AHPA strongly advises against this. This would, for example, require a potato processor to consider residual levels of toxic glycoalkaloids present in its finished food. Depending on what is considered to be "improper processing," it might also be interpreted to require consideration of the levels of acrylamides present in its fried, baked, roasted, or grilled foods. However, such requirements would be overly burdensome, and would have limited public

[115] Farrell, D.J. 2003. Fatal water intoxication. *J Clin Pathol* 56(10):803–804.

health benefits. There is no good reason for the regulations to require a potato processor to "validate" the glycoalkaloid-reduction effects of its manufacturing process and/or the intended cooking process to be used by the consumer, which would involve expensive analytical testing, because to AHPA's knowledge undercooked potatoes have not been a significant source of public health problems in the American food supply. Similarly, a baked-pretzel maker or a fire-roasted-pepper processor should not have to "validate" the acrylamide-producing effect of its processing, nor to evaluate the potential public health effects of its finished pretzels or fire-roasted peppers; these items are generally recognized as safe for human consumption. Furthermore, the negative health effects of acrylamides in food remain unclear[116]; hence this is not an appropriate subject of regulation. For these reasons, AHPA would be opposed to FDA including an open-ended requirement for natural toxins which are present as a result of "improper" processing to be the subject of hazard analysis.

### 10.3 Comments regarding proposed § 117.130(c)

AHPA notes it is not practical for FDA or food processors to expect suppliers of raw materials and ingredients to bear the responsibility for avoiding contamination that will render finished food unsafe. Suppliers have no way to know the purpose to which their raw materials and ingredients will be put, or what effect the purchaser's manufacturing process will have on the contaminants. Some manufacturing processes serve to concentrate contaminants, while others reduce the level of contaminants and yet others have no effect. Furthermore, raw material/ingredient suppliers have no control over what the serving size, packaging, storage conditions, or target consumers of the eventual RTE food will be; which other ingredients at what levels will be combined into that RTE food; or what the contaminant levels in those other ingredients will be. As a result, the responsibility for determining what specifications for raw materials and ingredients are necessary to protect the public health must fall on the processor of each RTE food, not on the processor's suppliers.[117]

In view of these realities, AHPA believes raw material and ingredient suppliers will encounter significant difficulties in carrying out the hazard evaluation required under proposed § 117.130(c). For example:

- A raw material or ingredient supplier will often have no way to know or control, except through labeling, whether the material it sells will be used as an RTE food or will be subjected to further processing prior to retail sale.
- Lacking information about the processing to which its product will be subjected, as well as information about the formulation, serving size, target consumer, etc. of the finished RTE food in which it is used, a raw material or ingredient supplier will often have no way to know whether a contaminant in the food it sells will represent a hazard in the final RTE food, as required by proposed § 117.130(c)(1).

[116] http://www.cancer.gov/cancertopics/factsheet/Risk/acrylamide-in-food, accessed 10/29/13.

[117] See further discussion in section 2 of our comments above, regarding RTE vs. non-RTE foods.

- Lacking information about the level of its ingredient in the finished RTE food; what other ingredients it will be combined with, at what levels, and with what other contaminant loads; how it will be processed and what effect that processing will have on the levels of contaminants; and information about the serving size and target consumer of the finished RTE food, a raw material or ingredient supplier will often have no way to assess the severity of the illness or injury if the hazard were to occur, as required by proposed § 117.130(c)(1).
- Lacking information about the formulation, processing, packaging, labeling, storage, and transportation of the finished RTE food, a raw material or ingredient supplier will often have no way to assess the effect of various parameters on the safety of the consumer, as required by proposed § 117.130(c)(3).

AHPA therefore believes it essential for the regulation to reduce the hazard evaluation requirements for suppliers, and to allow suppliers to use labeling or other written disclosures as a preventive control; in fact, this currently the common commercial practice in the food industry, especially for processed raw materials and ingredients but also to some extent for raw agricultural commodities. Suppliers of raw materials and ingredients (although not farmers) are typically required by their customers to accompany each lot or batch with a certificate of analysis which accurately reports the levels of various contaminants found in the lot or batch.

AHPA therefore suggests the following changes to § 117.130(c):

> (c) Hazard evaluation. (1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to determine whether the hazards are reasonably likely to occur~~, including an assessment of the severity of the illness or injury if the hazard were to occur~~. For ready-to-eat food, this must include an assessment of the severity of the illness or injury if the hazard were to occur in the finished food. For food intended for further commercial processing, this must include an assessment of the severity of the illness or injury if the hazard were to occur, based on typical or expected usage of the food.
> (2) For ready-to-eat food, t~~T~~he hazard analysis must include an evaluation of whether environmental pathogens are reasonably likely to occur whenever ~~a~~ the ready-to-eat food is exposed to the environment prior to packaging.[118]
> (3) For ready-to-eat food, t~~T~~he hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:
> (i) The formulation of the food;
> (ii) The condition, function, and design of the facility and equipment;
> (iii) Raw materials and ingredients;
> (iv) Transportation practices;
> (v) Manufacturing/processing procedures;

[118] AHPA strongly supports limiting this to consideration of RTE food. See our extensive comments on the subject of environmental monitoring.

(vi) Packaging activities and labeling activities;
(vii) Storage, and distribution;
(viii) Intended or reasonably foreseeable use;
(ix) Sanitation, including employee hygiene; and
(x) Any other relevant factors.

**10.4 Comments regarding the need for raw material/ingredient controls in § 117.135(c), and new proposed definition for "specifications"**

FDA in drafting § 117.135(c) "Preventive controls" appears to have avoided the topic of setting specifications for raw materials and ingredients, and discusses the setting of specifications for finished product only in roundabout terms.

AHPA is confused by the omission of raw material/ingredient specifications and believes this lack to be a significant flaw in the proposed rule. In any manufacturing process, finished product quality is directly dependent on raw material/ingredient quality, and this applies to freedom from contamination (i.e. safety) as well as to flavor, nutrition, and other beneficial attributes of quality.

Some manufacturing processes may serve to remove certain kinds of contamination from the product, but this depends on the nature of the contaminants, food, ingredients, and manufacturing process. If, as is often the case, the manufacturing process cannot decontaminate the food, or may even serve to increase levels of contaminants (e.g. through removal of water), then the only way to avoid excessive contamination is through proper control of raw materials and ingredients.

As a result, it is crucially important for food processors to establish specifications for raw materials and ingredients for contaminants that are likely to occur, to the extent necessary to prevent hazards in the finished food.

AHPA therefore believes "raw material and ingredient specifications" are an extremely important preventive control that FDA must include in § 117.135.

To facilitate this, AHPA suggests the following definition be added to the rule:

> *Specification* means an attribute required of a material to significantly minimize or prevent a hazard that is reasonably likely to occur. Specifications may be in the form of a minimum or maximum value or a range or combination of values for a biological, chemical, physical or radiological parameter, or may be descriptive of the grade, ingredients, or other attributes of the material. Specifications may apply to raw materials, ingredients, food-packaging materials, food-contact surfaces, cleaning and sanitizing agents, in-process materials, and finished food as well as other items.

AHPA also suggests the following be added as § 117.135(c)(1). AHPA believes this should be placed first in the list of preventive controls both for consistency with the chronology of a production process (raw materials/ingredients - production - finished product) and because these specifications are so foundational to food safety.

> Specifications for raw materials and ingredients required to significantly minimize or prevent a hazard that is reasonably likely to occur, where such hazard will not be controlled by the manufacturing process itself. Except as otherwise required under more-specific food regulations or unless otherwise specified in the firm's food safety plan under 21 CFR § 117.126, 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.

As mentioned previously and in our comments regarding testing and supplier verification, AHPA is strongly opposed to a requirement for compliance with specifications to be confirmed through testing, especially if the rule were to require such verification on a frequent basis.

**10.5 Comments regarding § 117.135(c)(1) and (2)**

AHPA suggests the following revision to proposed § 117.135(c)(1) [which should be renumbered as (2) after addition of the new paragraph (1) proposed above], for clarity:

> ~~Parameters~~ Processing and storage parameters associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating, and refrigerating foods, and

AHPA suggests the following revision to proposed § 117.135(c)(2) [which should be renumbered as (3) after addition of the new paragraph (1) proposed above], for clarity and for consistency with (c)(1):

> ~~The maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled~~ Specifications for in-process materials and finished food required to significantly minimize or prevent a hazard that is reasonably likely to occur.

**10.6 Comments regarding current proposed § 117.135(d)(2) and (3)**

AHPA suggests the following revision to proposed § 117.135(d)(2)(ii) for clarity and completeness:

> Labeling the finished food~~, including ensuring~~ to ensure that major food allergens are properly disclosed so that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

AHPA suggests the following revision to proposed § 117.135(d)(3)(i)(A) for clarity and completeness:

> ~~Cleanliness~~ Cleaning and/or sanitization[119] of food-contact surfaces, including food-contact surfaces of utensils and equipment;

AHPA suggests the following revision to proposed § 117.135(d)(3)(i)(B) for clarity, completeness, and consistency with terminology used throughout the rule:

> Prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from ~~raw product to processed product~~ raw materials, ingredients, and in-process materials to finished food.

AHPA supports the exemption provided in proposed § 117.135(d)(3)(iii) for deviations from sanitation procedures. AHPA agrees it would be overly burdensome in these circumstances to require a formal corrective action in accordance with § 117.145.

**10.7 Comments regarding suggested new § 117.135(d)(2)**

AHPA suggests that a new paragraph (2) added to § 117.135(d), and subsequent paragraphs be renumbered, as follows. This is proposed in connection with our comments above and 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 § 117.126, 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

[119] Depending on the hazard to be mitigated, it may be cleaning or it may be sanitization which is required to control the hazard. For example, microbiological hazards may require both cleaning and sanitization, whereas chemical hazards may require only cleaning.

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."
~~(2)~~(3) Food allergen controls....

**10.8 Comments regarding suggested new § 117.135(d)(6)**

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 above 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."

**10.9 Comments regarding § 117.137**

AHPA suggests moving the requirement for a recall plan from subpart C to subpart B. AHPA believes a recall plan may be needed even for food that does not have a "hazard that is reasonably likely to occur," since there is still some possibility for the identified hazard to occur, or for unforeseen hazards to arise. Furthermore, AHPA believes all food processors should have a recall plan in place, even those which are exempt from subpart C. In case a recall is needed it is important to have the procedures and data in place to facilitate the recall, since time is often of the essence.

AHPA does not believe the requirement for a basic recall plan is an excessive burden for small companies. However, AHPA would oppose any requirement to test the recall plan (e.g. with mock recalls), as this would be an excessive and inappropriate burden.

Finally, AHPA believes the requirement for a recall plan does not fit easily within subpart C; it is of a different nature than the other provisions of subpart C. This is demonstrated by the numerous places in subpart C where FDA found it necessary to specify that the recall plan was exempted or excluded from various provisions.

If the requirement for a recall plan is moved to subpart B, then conforming amendments should be made to subpart C, such as deletion of § 117.135(d)(4), § 117.135(e)(2), and § 117.150(a)(3)(iii).

**10.10 Comments regarding § 117.145**

AHPA suggests the following revision to proposed § 117.145(b) for completeness:

> Corrective action in the event of an unanticipated problem. If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be missing or ineffective, the owner, operator, or agent in charge of a facility must:

**10.11 Comments regarding § 117.150(a)**

AHPA notes that many food processors work not on a continuous-production basis but rather on a batch-production basis, and that batches of a particular product or product type may be produced only infrequently.

AHPA agrees with FDA that validation of preventive controls will, at least in some cases, require actual production experience in order to ensure specifications and process parameters are established appropriately. In a batch-production environment, this could require manufacture of multiple full-scale production batches, as lab-scale or pilot-scale batches often do not exactly mimic full-scale batches.

AHPA is therefore concerned that the 6-week timeframe allowed by FDA for completion of these validation activities may be insufficient in a batch production context. AHPA believes FDA should provide an alternate option of completing the validation within the first 10 production batches. The amount of product manufactured in 10 production batches will often be much smaller than that produced during 6 weeks of continuous production, but AHPA feels 10 batches should be sufficient to allow proper validation of the controls.

AHPA suggests the following revision to proposed § 117.150(a)(1)(i):

> Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production or during processing of the first 10 production batches, whichever is longer; and

**10.12 Comments regarding § 117.150(d)**

Proposed § 117.150(d)(2) states facility operators must perform "Review of the following records within the following timeframes...(i) Records of monitoring and corrective action records within a week after the records are made. (ii) Records of calibration within a reasonable time after the records are made."

AHPA has no objection to (ii) above, but finds the one-week requirement in (i) to be overly prescriptive and inappropriate. It should not be assumed that establishing a specific period of time is the most appropriate way to ensure records are timely reviewed. Many food processors operate on a batch production basis rather than a continuous production basis; in such environments, management typically reviews all records related to a particular batch all at once just prior to release of the batch for distribution. This review occurs after all manufacturing, packaging, and testing is complete; and many types of testing require several weeks to complete, especially where testing is performed by an outside laboratory.[120] It would be inefficient, unnecessary, and needlessly complicated to require management to review a few production records in advance of the normal complete records review.

In addition, even in continuous processing environments, food which has been set aside for reprocessing or other corrective action will in many cases be quarantined pending management review after execution of the corrective action, rather than simply released into distribution along with the usual flow of product. In such cases, again, there is no good reason to mandate review within a specific timeframe.

AHPA therefore recommends § 117.150(d)(2) be revised as follows:

> Review of the following records within the following timeframes...(i) Records of monitoring and corrective action records within a week after the records are made or, for production systems wherein management performs a comprehensive records review for each batch or lot, or in any circumstance where a batch or lot is quarantined pending management records review, prior to release of the batch or lot for distribution. (ii) Records of calibration within a reasonable time after the records are made.

**10.13 Comments regarding § 117.150(f)**

AHPA suggests the following revision to proposed § 117.150(f)(1)(i)(D) and (E), for clarity and completeness:

> (D) Whenever a preventive control ~~is not~~ fails to be properly implemented and a specific corrective action procedure has not been established; and
> (E) Whenever a preventive control is found to be missing or ineffective.

[120] AHPA notes that many food processors are ingredient manufacturers, whose products are expected by the marketplace to be accompanied by extensive certificates of analysis documenting the physiochemical, microbiological, and other characteristics of the ingredient. These tests can require extended periods of time for completion, especially for small companies who do not have in-house laboratories. To AHPA's knowledge such testing typically requires at least 1-2 weeks and may take up to several months, depending on the product, the test, and the laboratory involved.

AHPA suggests the following revision to proposed § 117.150(f)(1)(ii), for the same reasons discussed in connection with § 117.150(a)(1)(i):

> Complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production or during processing of the first 10 production batches, whichever is longer; and

**10.14 Comments regarding § 117.155**

AHPA suggests the following revision to proposed § 117.155(c) for completeness:

> All applicable training must be documented in records, including the date of the training, the type of training, the person (which may include members of the firm's own staff) or organization which provided the training, and the person(s) trained.

# 11. Comments regarding a potential provision to require testing

FDA has not proposed to require testing in the draft regulation, but requests comment on whether such testing should be required, and if so under what circumstances.

### 11.1 Overview of AHPA's comments

AHPA is generally opposed to chemical, physical, biological, or radiation testing being required by regulation. If FDA deems testing to be necessary then it should be required only under carefully delineated circumstances where any specifically identified hazard is both acute (i.e. may cause serious adverse health consequences or death) and fairly likely (i.e. more likely than simply "reasonably likely") and can be significantly mitigated by testing, as the costs associated with such testing represent a very large burden both to industry and to the consumers who will ultimately be charged higher prices to cover the significant costs involved. Also, if testing is required, it should be left up to the manufacturer to decide whether the testing will be most appropriately conducted on finished products, raw materials and ingredients, in-process materials, or more than one of these.

Furthermore, any testing should only be required where appropriate test methods and any necessary analytical standards already exist and are publicly available; under no circumstances should food companies be required to develop or validate test methods or to isolate or characterize analytical standards.

If FDA nonetheless determines to impose any requirement(s) for testing, this should be included as part of Subpart C, rather than Subpart B, since appropriate implementation of a testing program requires appropriate hazard analysis. Small companies should be exempt from any requirement for testing.

### 11.2 Testing is not needed for most hazards

AHPA believes that for most potential hazards in most types of food, the additional assurance of safety provided by testing does not outweigh the expense which testing will entail.

FDA's own risk assessment determined that:

- Physical and radiological hazards are rarely found in the US food supply and are even less frequently the cause of significant illness or injury;
- Chemical hazards are occasionally found in the US food supply, and are generally limited to undeclared allergens, sulfites, and toxins produced by spoilage or decomposition (e.g. seafood toxins);

- Biological hazards are the most common cause of foodborne illness in the US.

Thus, only testing for biological hazards (and/or their controls, such as pH) and a few types of chemical hazards is likely to produce measurable improvements in public safety.

### 11.3 Testing is not needed for many manufacturing processes

As FDA acknowledges in the preamble to the proposed rule, it is commonly the case that a facility's processing method will serve to decontaminate various potential hazards which may be present. Such processing steps may include:

- Use of sieves, screens, or magnets to remove foreign objects or metal;
- Use of heat, cold, pressure, solvents, or other treatments to remove biological hazards;
- Use of physical or chemical processes to remove chemical hazards (e.g. cooking to destroy heat-labile toxins, or solvent partitioning to remove pesticides).

### 11.4 Test methods and analytical standards may not be available

Depending on the hazard and the food matrix in question, appropriate test methods may not exist or may not be publicly available, and appropriate analytical standards may not be commercially available.

For example, PCR tests to detect allergens cannot be used for oils or extracts, since these types of products do not contain the necessary genetic material; on the other hand, ELISA tests for allergens can give erroneous results due to matrix interference, cross reactivity, and protein denaturation.

Similarly, matrix-appropriate test methods for many food constituents which could be considered "natural toxins" (e.g. α-solanine, linamarin, bergamottin, vicine) may not be available, and commercial analytical standards for these tests may not be available or may not be suitably characterized for quality control work.[121]

AHPA is strongly opposed to any explicit or implicit requirement for food processors to develop, optimize, or validate test methods, or to isolate or characterize analytical standards. These activities are quite expensive and time-consuming, and require specialized expertise which the majority of food processors do not possess. If such work is contracted out to independent laboratories, the costs will be even more prohibitive, and furthermore the food processor will often be ill-positioned to understand or evaluate the quality or validity of the laboratory's work.

[121] As mentioned elsewhere, AHPA urges FDA to exclude consideration of such toxins from the scope of "natural toxins" required to be considered in the hazard analysis.

### 11.5 Testing may cause other problems

Depending on the circumstances, testing might cause other problems. For example, a requirement for food processors to verify the safe composition of food-contact surfaces could necessitate damage to equipment (due to removal of a sample of the equipment surface for testing), thus creating a harborage for dirt and microorganisms.

### 11.6 Facilities should have flexibility to ensure compliance with specifications and controls

AHPA believes it is generally possible to ensure compliance with specifications and controls by means other than testing, and even where testing is appropriate, the tested parameter may be different from that discussed in the regulation.

(a) For raw materials, ingredients, food-contact materials, and other items purchased by the facility, compliance with established specifications can generally be effectively ensured through reliance on a vendor's certificate of analysis, specifications, or other guarantee.[122,123]

(b) For food manufactured, processed, packed, or held by the facility, compliance can generally be effectively ensured through careful production and/or handling controls (e.g. time, temperature, ratio of solvent to solids, amount of acid, visual inspection of raw materials to remove moldy pieces, etc.). In other cases, facilities may ensure compliance by testing parameters other than the food safety control specified in the regulation (e.g. in Subpart B); for example, it is often more convenient but just as effective for any given material to test loss on drying rather than water activity *per se*.

### 11.7 If testing is required, facilities should have flexibility to decide at which stage to conduct it

Even where testing is necessary to ensure a hazard is controlled, the finished product is often not the appropriate stage to conduct that testing. Rather, many types of testing are more appropriately performed on raw materials and ingredients so as to prevent contaminated materials from entering the production process in the first place.

For example, testing for pesticides, heavy metals, drug residues, and unapproved food or color additives should logically be conducted on raw materials and ingredients. It is extremely unlikely these would be inadvertently introduced into food during processing in a Part-117-compliant facility, so there is no good reason to repeat this testing on the finished product.

[122] In the case of hazards which are intentionally introduced (e.g. melamine in whey powder), it may not be possible to rely on the integrity of the vendor. However, the current proposed rule is not intended to cover such hazards.

[123] See also AHPA's comments regarding supplier verification.

On the other hand, for hazards which have the potential to increase during processing and/or storage, it might make sense to verify proper control through finished product testing. This could include, for example, testing for parameters related to control of microbiological hazards (such as loss on drying, water activity, or pH) or certain types of decomposition products.

In addition, some hazards might be most appropriately controlled through in-process testing rather than raw material or finished product testing. These could include, for example, testing for loss on drying, Brix, or pH.

Depending on the circumstances, some manufacturers might choose to perform certain tests at multiple points in the process, e.g. both on raw materials/ingredients and on finished products.

As stated above, AHPA is generally opposed to chemical, physical, biological, or radiation testing being required by regulation. Any testing requirement that FDA nonetheless establishes in the final rule should provide manufacturers the flexibility to determine the most appropriate point(s) at which to perform the tests. If FDA prescriptively mandates finished product testing, this will have the effect of often requiring food processors to implement corresponding tests on raw materials and ingredients, because many hazards can only be controlled at the raw material/ingredient stage; and this will often result in needlessly duplicative testing expenses.

**11.8 Testing would be much more expensive than FDA estimates**

In the preamble to the proposed rule, FDA estimates that "a requirement for a finished product testing program, when implemented appropriately in particular facilities, could impose an incremental annual cost of $14,000 – $813,000 per facility based on size (number of employees) that adopts a testing and holding regime. This would result in an estimated aggregate cost of $23,500,000 for domestic facilities based on an average of a range of $12,000,000 - $35,000,000 (assuming between 25 and 75 percent of relevant facilities conducting testing) and an estimated aggregate cost of $25,600,000 for foreign facilities....These costs assume that facilities will take 5 finished product samples per product line on a monthly basis."

AHPA believes these cost estimates are far too low.

(a) To begin with, a requirement to implement finished product testing would, as a practical matter, often require the affected facilities to implement corresponding tests on raw materials and ingredients, as described above. This will significantly increase the costs.

(b) AHPA believes that if finished product testing is required by regulation, the estimate of 5 finished product samples per product line per month is far too low.

For example, one very small facility AHPA knows of produces a high-value product for which the formulation and processing have been validated to control pathogens. The microbiological safety of the

product is ensured primarily through formulation and processing; the facility also uses raw material controls, stringent cleaning and sanitation, etc. to further ensure quality. This facility tests a minimum of 1 finished product sample per day (i.e. at least 20 samples per month) simply to provide an additional level of verification and to reassure customers.[124] If the testing were required by regulation and/or if it were necessary to protect the public health, AHPA believes the facility would have to test far higher numbers of samples. In addition, AHPA believes the number of samples required per time period will obviously increase with the increasing size of the facility.

In the specific case of *Salmonella*, various scientific sampling plans - including FDA's own plan - prescribe pulling anywhere from 15 to 60 samples at a time (although some plans allow up to 15 samples to be composited together for testing, thereby reducing the expense of the actual testing) in order to obtain scientifically valid results. The time and supplies necessary to pull 15 to 60 samples, and the FedEx shipping cost of such a large quantity, will be much higher than the costs assumed in FDA's PRIA, and the testing cost will also be much higher if the full set of 15 to 60 samples is pulled 5 times per month.

AHPA further notes that in the absence of known sampling plans specific to the characteristic of interest, companies would most likely turn to generic and widely recognized sampling plans such as MIL-STD-1916.[125] Such plans indicate a truly staggering level of testing would be required to ensure the acceptability of the finished product. For example, assuming a verification level of VII (i.e. the tested characteristic is extremely important) and a batch size of 5,000 units, the attributes sampling plan[126] in MIL-STD-1916 would entail testing of 1280 units! This would clearly be extremely expensive, not only for the sampling and testing costs but also the cost of the lost product (since the sampled and tested units are normally not saleable afterward).

(c) In cases other than major pathogens and similar items for which recognized sampling plans are already available, food processors will be forced to develop their own plans. This will normally require the help of experts, especially since FDA states in the preamble, “The frequency of testing and the number of samples tested should have a scientific basis.” One authoritative reference states “Before using a sampling plan, it is usually prudent to consult a professional statistician to ascertain that the lot of food to be sampled meets the criteria required by that particular sampling plan.”[127] AHPA notes that

[124] AHPA notes the company can afford to perform so much testing due to the relatively high price of its product. AHPA believes many small food companies would not be able to afford such testing.

[125] Department of Defense Test Method Standard, DOD Preferred Methods for Acceptance of Product, April 1996.

[126] MIL-STD-1916 precludes use of variables sampling plans except where graphical or statistical analyses provide evidence that assumptions of independence and normality are met. AHPA believes most food processors will not have the working knowledge of statistics to make these determinations, and will not want to hire an expensive statistician to do this analysis for them, and therefore are likely to use the attributes sampling plans.

[127] Downes, F.P. & Ito, K. 2001. *Compendium of Methods for the Microbiological Examination of Foods, 4th Ed.*, p. 14. Washington, DC: American Public Health Association.

FDA has not included the cost of statisticians and food safety experts, which could run to thousands of dollars, in their PRIA.

(d) AHPA believes the test pricing cited in FDA's PRIA is unrealistically low (e.g. $47 for a *Salmonella* test by PCR at Silliker). For example, *Salmonella* testing by the AOAC 2009.03 method (a fully validated and internationally recognized method) at the National Food Lab costs $84/sample. Many kinds of chemical testing which could be required by the rule cost even more: prices of $200 per sample for TLC and HPLC and $400 to $900 or more for LC/MS tests are common; these tests may be required for analysis of natural toxins.[128] Similarly, ICP/MS testing for heavy metals costs $130 per sample at Eurofins Frontier, and pesticide screens can cost anywhere from $300 to over $1000 per sample.

(e) AHPA notes that the cost analysis in FDA's PRIA fails to include the value of the lost product. Most microbiological and chemical testing is destructive (i.e. the sample unit cannot be used after testing), so this cost needs to be taken into account. It is difficult to estimate the value of the lost product since it depends on the type of food being produced, but AHPA believes it could range from a few cents per unit sampled (e.g. for raw or minimally processed agricultural products) to several dollars per unit sampled (e.g. for packaged RTE foods).

In some cases it might be even higher, where specialty or gourmet foods are involved. AHPA notes that for *Salmonella*, FDA's sampling plan specifies that sample units must consist of not less than 100 g each; therefore 60 samples would represent 6 kg of product. Since some foods are valued at hundreds or thousands of dollars per kilogram, this could represent thousands or tens of thousands of dollars of lost product for one round of *Salmonella* sampling.

### 11.9 Responses to specific questions posed by FDA

In the preamble to the proposed rule, FDA poses a number of questions regarding a potential product testing requirement. AHPA responds to these questions below, but these responses should in no way be considered to counter our previous stated opposition to having testing required by regulation. AHPA believes that any such regulatory requirements are generally unnecessary.

1. Question: What is the appropriate level of specificity for a product testing program? For example, should we simply require that the owner, operator, or agent in charge conduct, as appropriate to the facility and the food, finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur?

[128] Cheaper tests may be available in certain cases, such as analysis of aflatoxins by ELISA; however, such tests are subject to interferences and are therefore unreliable. AHPA knows of cases where such tests have been shown to give erroneously high results (i.e. subsequent testing by HPLC finds no aflatoxins).

AHPA's response: To begin with, AHPA is opposed to the focus on finished product testing, both in this question and throughout this section of the preamble. To the extent testing may help ensure food safety, it cannot be assumed that the finished product is the most appropriate or effective point at which to conduct the testing, as discussed previously in our comments.

Secondly, AHPA believes that if FDA wishes to address the use of testing by food processors, this topic should be addressed in guidance rather than by regulation. Testing is often not the best way to ensure product safety. Furthermore, a guidance document provides opportunity to explain in detail why and when testing may appropriate; the limitations of testing; alternate methods to ensure safety; the considerations involved in developing sampling plans and test methods; etc.

Regarding the level of specificity which might be included in regulation, AHPA is opposed to an overly broad, vague, or unspecific requirement such as FDA outlines in the question above. It has been AHPA's observation that such regulatory provisions are difficult for companies to interpret, which leaves the company vulnerable to costly, inappropriate, excessive, and/or idiosyncratic misinterpretations by management, by outside consultants, and by individual FDA inspectors or district officials. AHPA appreciates FDA's desire to provide adequate flexibility but believes it important for FDA to provide as much specificity as possible regarding the intended scope of each regulatory provision. This is especially true for regulatory provisions which involve significant and/or ongoing expenses, as testing would.

2. Question: Is more detail appropriate, by, for example...specifying particular hazards, situations or product types for which [testing] would be required?

AHPA's response: AHPA believes FDA should provide adequate detail. If testing may be useful to help ensure food safety, FDA should describe as clearly as possible the circumstances in which this may be the case, including the particular hazards, situations, and product types.

However, FDA must take care to ensure any thus-identified circumstance does in fact present the risk FDA thinks it does. For example, in the preamble FDA identifies “the mixing of dried, treated spices and herbs” as a circumstance “where contamination with *Salmonella* spp. from the environment is a concern.” AHPA strongly disagrees with the presumption that this activity is inherently at risk of *Salmonella* contamination. There may be cases where such contamination has occurred (the preamble cites various recalls and Reportable Food Reports), but that does not mean all such processing bears the same risk. In a facility which is poorly designed, maintained, and/or managed, it may be possible for microbial contamination from untreated herbs, the outside environment, or other sources to spread to post-treatment areas; but in a well-designed and well-managed facility, such contamination is unlikely to occur. In many modern facilities dedicated to the processing of herbs and spices there is no communication of employees, equipment or utilities between the areas where raw agricultural commodities are stored, handled, and processed and the areas where post-kill-step final product is processed, packaged, and stored. In some facilities, post-kill-step processing even occurs in dedicated cleanroom suites. AHPA believes there is no more reason to expect such products will be contaminated

"with *Salmonella* from the environment" than there is for any other food; in fact the risk is probably less.[129]

Therefore, AHPA believes FDA should not contemplate requiring testing in any circumstance except where there is a clear science-based reason to believe the food involved is inherently and unusually susceptible to contamination which may cause serious adverse health consequences or death. AHPA believes the majority of these circumstances are already covered by more specific food safety programs (e.g. meat, fish, low-acid canned foods, etc.). The mere observation that a certain type of contamination sometimes occurs in a certain type of product is not sufficient evidence to prove that testing would be universally appropriate for that product. The fact that one or more unprepared or negligent processors have sometimes allowed problems to occur is not a good reason to penalize all processors with testing requirements when there are other, more effective ways to prevent problems.

In order to avoid excessive prescriptiveness and to provide flexibility, AHPA suggests that any regulatory provision regarding testing, if FDA decides to include one in these regulations, should suggest, rather than require, said testing under the circumstances described by FDA. Alternately, the provision could be written to require testing unless the food processor can justify omitting it based on the particularities of its process, plant design, raw material controls, or other factors.

To summarize our position with respect to flexibility vs. specificity, AHPA is opposed to one-size-fits-all regulations and believes it very important to provide adequate flexibility; but AHPA is similarly opposed to overly broad or vague regulations and believes it very important to provide adequate specificity. AHPA believes the optimal balance can be achieved by outlining the circumstances in which FDA envisions a particular provision may apply, while making the provision optional or giving companies an option to justify omitting it. This applies not only to the testing provision under discussion here but also to many other provisions of the regulation, and AHPA encourages FDA to consider incorporating this strategy more generally in its regulations.

3. Question: Is more detail appropriate, by, for example...specifying the frequency of testing and, if so, whether this frequency should depend on the type of product?

AHPA's response: AHPA believes it is impossible for FDA to determine appropriate test frequencies, either in general or for specific types of product. The appropriate test frequencies are strongly impacted by many factors other than product type, such as: facility design, raw material controls, cleaning and sanitation practices, product form and formula, equipment design, process design, production rates, etc. AHPA is strongly opposed to FDA specifying a frequency of testing.

4. Question: Is more detail appropriate, by, for example...identifying appropriate sampling plans for [testing]?

[129] See also AHPA's comments regarding environmental monitoring for low-moisture foods (comment # 12.3).

AHPA's response: AHPA believes it could be useful for FDA to identify what it considers to be appropriate sampling plans under various circumstances, including for raw agricultural commodities, processed raw materials and ingredients, and finished product. However, AHPA does not believe it is generally possible to specify sampling plans which will be universally appropriate, especially since, as discussed above, AHPA believes companies must be afforded the flexibility to decide what is the most appropriate point at which to conduct testing based on their own knowledge of their own circumstances. The optimal sampling plan is impacted by many factors, including the characteristic to be examined; the physical form of the material to be sampled; the manner of packaging; whether the sampling is performed on raw materials or in-process material or finished product; etc. As mentioned above, experts often recommend customization of sampling plans for each circumstance.

AHPA therefore believes any information on sampling plans provided by FDA should be in the form of guidance, and is not the appropriate subject of regulation. To the extent FDA recommends sampling plans, FDA should be sensitive to the high economic costs of extensive sampling and testing.

5. Question: Is more detail appropriate, by, for example...requiring periodic testing for trend analysis and statistical process control?

AHPA's response: AHPA strongly opposes a requirement for periodic testing for trend analysis or statistical process control (SPC). AHPA believes that while such practices may be useful for companies to optimize their processing, improve efficiency, and avoid potential problems, it should be up to the individual company to decide whether the benefits of such programs outweigh the costs. AHPA further notes that SPC is not universally applicable to all manufacturing processes. Finally, AHPA does not believe use of trend analysis or SPC is essential to protect the public health.

6. Question: Is more detail appropriate, by, for example...requiring written procedures for conducting [testing] and, if so, also require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency?

AHPA's response: AHPA believes that where testing is performed, it should be conducted in accordance with written procedures (which may include copies of published or otherwise publicly available methods), and that there should be written procedures for sampling and for sampling frequency. AHPA does not believe that test methods and sampling procedures should be required to occur in the same document, especially since the sampling and the testing are often performed by separate personnel.

AHPA believes that where testing is performed, it should be conducted using test methods that are fit for purpose. This is not necessarily the same as “scientifically valid.” For purposes of process control, it is often not particularly relevant whether test results are accurate in an absolute sense (i.e. whether the test results conform to the “true” value or are capable of being replicated by another lab); what matters is that the results be appropriately precise and that they provide signals which are meaningful within the context of the production environment.

There are exceptions, of course, such as measurement of water activity, pH, or temperature, where these are critical to ensuring proper food safety controls; or determination of nutrient content or other characteristics for which label claims are made. But AHPA believes that a blanket requirement for all test methods to be “scientifically valid” is not appropriate.

7. Question: FDA also requests comment on the impact of product testing requirements on small businesses and on whether any product testing verification requirements should differ based on the size of the operation.

AHPA's response: AHPA believes that small businesses would be particularly disadvantaged by a requirement for testing. Small businesses will not enjoy the economies of scale which are possible for large companies; they are less likely to be able to afford in-house labs or to have microbiology or chemistry experts on staff, and if forced to use outside labs they will not qualify for the same volume discounts as large companies.

Therefore AHPA believes testing will be particularly burdensome for small businesses. AHPA is already concerned that small businesses will have a difficult time coming into compliance with Part 117 without going out of business. If FDA includes mandatory testing provisions in the regulation, AHPA encourages FDA to exempt small businesses from them.

# 12. Comments regarding a potential provision to require environmental monitoring

FDA has not proposed to require environmental monitoring in the draft regulation, but requests comment on whether such monitoring should be required, and if so under what circumstances.

### 12.1 Overview of AHPA's comments

AHPA is generally opposed to environmental monitoring being required by regulation, other than temperature monitoring for foods which require refrigeration or freezing. If FDA deems additional environmental monitoring to be necessary then it should be required only under carefully delineated circumstances where any specifically identified hazard is both acute (i.e. may cause serious adverse health consequences or death) and fairly likely (i.e. more likely than simply "reasonably likely") and can be significantly mitigated by environmental monitoring, as the costs associated with such monitoring represent a very large burden both to industry and to the consumers who will ultimately be charged higher prices to cover the significant costs involved.

If FDA nonetheless determines to impose any requirement(s) for environmental monitoring, this should be included as part of Subpart C, rather than Subpart B, since appropriate implementation of such a program requires appropriate hazard analysis. Small companies should be exempt from any requirement for environmental monitoring other than of temperature where required for food safety.

### 12.2 Comments regarding microbiological environmental monitoring

Any required monitoring of the production environment for microbiological contamination should be strictly limited to foods, facilities, and locations within the facility where such microbiological contamination has the potential to actually affect consumer health. Any provision requiring environmental monitoring should make clear that microbiological environmental monitoring is not required under the following circumstances:

- At processing or holding steps, or in plant locations, which occur at or prior to a step in which the ingredient or material is subjected to an adequate microbial reduction step, at least in facilities which are designed, maintained, and operated such that post-kill-step processing and handling areas are functionally isolated from areas where untreated raw materials and ingredients are processed and handled so that introduction of microbial contaminants from raw materials and ingredients into post-kill-step food is prevented;[130]

[130] See further discussion below.

- At processing or holding steps, or in plant locations, in which the food is not exposed to environmental contaminants;
- For foods in which pathogen contamination is not likely to be a problem (e.g. botanical extracts and derivatives, such as sugar, which are subjected to extensive processing by heat, solvents, or other means) or which are inherently safe from pathogens (e.g. acid foods, salt, or essential oils).
- For foods which are intended for further commercial processing, and for which this fact is clearly stated in labels, labeling, or other commercial documentation accompanying the sale of the food. (See our comments in section 2 above regarding RTE vs. non-RTE food, our comments to § 117.80(b)(2), § 117.130(c), and § 117.93, as well as suggested new § 117.135(d)(2) and § 117.135(d)(6).)
- For foods which are rarely consumed raw but rather are thoroughly cooked by the consumer.

AHPA believes it crucial to write any such hypothetical environmental monitoring provision in a manner that clearly communicates the limited circumstances of its applicability. AHPA is aware of numerous instances where companies, through incomplete understanding of existing regulations either by management or by FDA inspectors or consultants, have wasted large amounts of money implementing various controls in circumstances beyond what is actually necessary to accomplish the intended purpose.

AHPA furthermore notes that, for facilities which use raw agricultural commodities as raw materials or ingredients, it may be impossible to maintain a pathogen-free environment in the areas where such RACs are stored, cleaned, inspected, milled, etc. prior to use. No matter how frequently the equipment and rooms are cleaned and sanitized, the environment is continually re-contaminated by microbes brought in with the RACs themselves.

### 12.3 Comments regarding *Salmonella* environmental monitoring for low-moisture foods

FDA states in the preamble, “The data from recalls and the RFR support a conclusion that *Salmonella* spp. is a hazard in low-moisture RTE food products (such as spices and seasonings, nuts and nut products, and seed products). When RTE foods such as these are exposed to the environment, FDA believes that most facilities producing such foods would identify *Salmonella* spp. as a known or reasonably foreseeable hazard under proposed § 117.130(b) and evaluate whether *Salmonella* spp. contamination from the environment is reasonably likely to occur in the facility under proposed § 117.130(c)(2).”

AHPA strongly disagrees with this conclusion. AHPA has reviewed a number of Establishment Inspection Reports and Warning Letters for companies found to be selling contaminated spices and other low-moisture foods. This review showed the contamination to be attributable to poor facility design, lack of sanitation, and negligent management, rather than to any particular risk associated with the low-moisture food. For example, the EIR for Union International Food Co., Inc. revealed open containers stored under an unscreened roof vent; use of containers which could not be properly cleaned; and a general lack of cleaning and sanitation. The Warning Letter for Badia Spices, Inc. revealed a failure to provide handwash facilities, a failure to control flying insects, and a failure to clean and sanitize food-

contact surfaces. The EIRs for Peanut Corporation of America and for Setton Pistachios of Terra Bella, Inc. revealed numerous problems, including lack of spatial separation between raw materials and finished product; poor facility maintenance; lack of sanitation; and failure to control critical process steps and/or validate their microbial reduction. Obviously most types of food will be susceptible to contamination if processed, handled, or stored under insanitary conditions, or in a facility which fails to prevent cross-contamination or to properly cook the food. This does not mean the food is inherently risky when processed, handled, and stored properly.

Many low-moisture food processing facilities are carefully designed, maintained, and operated to prevent finished product contamination. These facilities minimize communication of employees, equipment, utensils, airflow, etc. between the areas where raw agricultural commodities are stored, handled, and processed and the areas where post-kill-step final product is processed, packaged, and stored. Post-kill-step processing may even occur in cleanroom suites. Under these circumstances, AHPA does not believe *Salmonella* spp. should necessarily be identified as a known or reasonably foreseeable hazard under proposed § 117.130(b) or that the processor should necessarily evaluate whether *Salmonella* spp. contamination from the environment is reasonably likely to occur in the facility under proposed § 117.130(c)(2).

**12.4 Comments regarding other types of environmental monitoring**

FDA in the preamble and in the PRIA appears to focus primarily on microbiological environmental monitoring. AHPA notes that environmental monitoring may also include monitoring of temperature; humidity; air and compressed gas quality (e.g. particulates, oil, etc.); product residue on equipment; cleaner and sanitizer residue on equipment; etc.

AHPA opposes imposition of a requirement by regulation for any such environmental monitoring (with the exception of temperature monitoring for foods which require temperature control to ensure safety), because they do not serve to control significant hazards and therefore the public health benefits do not outweigh the costs involved.

AHPA urges FDA to make clear in any hypothetical new environmental monitoring requirement that such required monitoring is limited exclusively to temperature monitoring for foods which require such control, and microbiological monitoring as described the section above. FDA should avoid any open-ended, vague, or unclear environmental monitoring provision.

**12.5 Environmental monitoring will be much more expensive than FDA estimates**

In the preamble to the proposed rule, FDA estimates that "a requirement for an environmental monitoring program for *Salmonella* spp., when implemented appropriately in particular facilities, could impose an incremental annual cost of $3,000 – $6,000 per facility. These costs assume that facilities will take 5-15 environmental samples per month, based on facility size, and send the samples to an outside laboratory for testing. This would result in an estimated aggregate cost of $4,000,000 for domestic

facilities based on an average of a range of $3,000,000 - $5,000,000 (assuming between 50 and 75 percent of relevant facilities conducting testing) and an estimated aggregate cost of $4,400,000 for foreign facilities."

AHPA believes these cost estimates are far too low.

(a) In cases where environmental monitoring is truly needed to protect the public health, AHPA believes it unrealistic to believe facilities will be able to properly control hazards through testing of 5 - 15 environmental samples per month. Such a low number may make sense for certain production environments, but in AHPA's experience much larger numbers of samples will need to be tested. The locations to be tested may include equipment surfaces and harborage sites (of which there may be many, in a complex piece of equipment); walls, floors, ceilings, sinks, drains, and sinks; handles, knobs, buttons, and other frequently-touched surfaces; air, water, and compressed gas supplies; etc. AHPA believes that effective and useful environmental monitoring might require testing a dozen or more samples per week even in a small facility, and the number of samples required per time period will obviously increase with the increasing size of the facility.

(b) AHPA believes the test pricing cited in FDA's PRIA is unrealistically low (e.g. $28.50 for a *Salmonella* test by ELFA). For example, *Salmonella* testing by the AOAC 2009.03 method (a fully validated and internationally recognized method) at the National Food Lab costs $84/sample for swab samples. Many kinds of chemical testing which could be required by the rule cost even more: prices of $200 per sample for TLC and HPLC and $400 to $900 or more for LC/MS tests are common; these tests could be required for analysis of product or other residue on equipment surfaces.

**12.6 Responses to specific questions posed by FDA**

In the preamble to the proposed rule, FDA poses a number of questions regarding a potential environmental monitoring requirement. AHPA responds to these questions below, but these responses should in no way be considered to counter our previous stated opposition to having environmental monitoring required by regulation. AHPA believes that any such regulatory requirements are generally unnecessary.

1. Question: If [environmental monitoring requirements] are included, what is the appropriate level of specificity? For example, should we simply require the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur?

AHPA's response: AHPA believes that if FDA wishes to address the use of environmental monitoring by food processors, this topic should be addressed in guidance rather than by regulation. A guidance document provides opportunity to explain in detail why, when, and where environmental monitoring may be appropriate; the considerations involved in developing environmental sampling plans; etc.

Regarding the level of specificity which might be included in regulation, AHPA is opposed to an overly broad, vague, or unspecific requirement such as FDA outlines in the question above. It has been AHPA's observation that such regulatory provisions are difficult for companies to interpret, which leaves the company vulnerable to costly, inappropriate, excessive, and/or idiosyncratic misinterpretations by management, by outside consultants, and by individual FDA inspectors or district officials. AHPA appreciates FDA's desire to provide adequate flexibility but believes it important for FDA to provide as much specificity as possible regarding the intended scope of each regulatory provision. This is especially true for regulatory provisions which involve significant and/or ongoing expenses, as environmental monitoring would.

If environmental monitoring is included in the regulation, AHPA believes FDA should provide adequate detail to educate companies as to what type of monitoring FDA envisions and the circumstances where it may be appropriate. However, FDA must keep in mind that any thus-identified circumstance may not in fact present the risk FDA thinks it does (see our comments above regarding *Salmonella* in low-moisture food facilities). AHPA believes FDA should not contemplate requiring environmental monitoring in any circumstance except where there is a clear science-based reason to believe the food involved is inherently and unusually susceptible to contamination which may cause severe adverse health consequences or death. The mere observation that a certain type of contamination sometimes occurs in a certain type of product is not sufficient evidence to prove that environmental monitoring would be universally appropriate for that product. The fact that one or more unprepared or negligent processors have sometimes allowed problems to occur is not a good reason to penalize all processors with environmental monitoring requirements when there are other, more effective ways to prevent problems.

In order to avoid excessive prescriptiveness and to provide flexibility, AHPA suggests that any regulatory provision regarding environmental monitoring, if FDA decides to include one in these regulations, should suggest, rather than require, said environmental monitoring under the circumstances described by FDA. Alternately, the provision could be written to require environmental monitoring unless the food processor can justify omitting it based on the particularities of its process, plant design, or other factors.

To summarize our position with respect to flexibility vs. specificity, AHPA is opposed to one-size-fits-all regulations and believes it very important to provide adequate flexibility; but AHPA is similarly opposed to overly broad or vague regulations and believes it very important to provide adequate specificity. AHPA believes the optimal balance can be achieved by outlining the circumstances in which FDA envisions a particular provision may apply, while making the provision optional or giving companies an option to justify omitting it. This applies not only to the environmental monitoring provision under discussion here but also to many other provisions of the regulation, and AHPA encourages FDA to consider incorporating this strategy more generally in its regulations.

2. Question: Would more detail be appropriate, by, for example...specifying the environmental pathogen or the indicator organism for which the samples must be tested?

AHPA's response: AHPA believes it will be frequently not possible for FDA to specify the appropriate organism(s) for environmental monitoring, as these may depend on the nature of the raw materials, ingredients, and product; the product formula; details of process and equipment design; how the product is packaged; etc. For example, in a facility which relies on heat treatment to kill microorganisms it might theoretically be important to monitor for thermophilic organisms such as heat-resistant molds, which can survive heating and subsequently produce toxins. However, in reality this might not actually be a concern, depending on other aspects of the product (e.g. preservatives, water activity, or storage temperature); and such toxins are not, as far as AHPA is aware, known to be significant sources of foodborne illness in the US.

Overall AHPA considers this to be a complicated subject which is generally not amenable to one-size-fits all prescriptions, except in relatively simple cases which have already been addressed through more specific food safety programs (e.g. shell eggs or meat). AHPA is opposed to FDA specifying by regulation the environmental pathogen or the indicator organism for which the samples must be tested, but believes it may be useful to issue guidance on this subject. If such specificity is included in the regulation it should be made optional.

3. Question: Would more detail be appropriate, by, for example...specifying the corrective actions that should be taken if environmental testing identifies the presence of an environmental pathogen, such as;
• Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;
• Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;
• Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated; and
• Conducting finished product testing?

AHPA's response: If FDA includes environmental monitoring provisions in the regulation, then in the event that environmental monitoring is conducted and a microorganism of concern is identified, AHPA believes these are reasonable steps for a company to take in response.

4. Question: Would more detail be appropriate, by, for example...specifying the locations within the facility at which samples must be collected?

AHPA's response: If FDA includes environmental monitoring provisions in the regulation, AHPA believes it would be helpful for FDA to specify the types of locations which are likely to merit attention; for microbiological monitoring this could include drains, sinks, food-contact surfaces, etc. AHPA is opposed to FDA specifying that testing of such locations is required; rather such a list should be only a recommendation.

As mentioned above, AHPA does not believe any microbiological environmental monitoring is appropriate in plant locations in which the food is not exposed to environmental contaminants, or in

plant locations which occur at or prior to an adequate microbial reduction step in the manufacturing process at least as long as the plant is properly designed and operated to prevent cross-contamination to post-kill-step product. This should be made clear in any provision addressing environmental monitoring.

5. Question: Would more detail be appropriate, by, for example...specifying the frequency of collection of environmental samples (e.g., weekly or monthly depending on risk). For example, should the frequency of collection:
• Be greatest for foods that are likely to be consumed as RTE or consumed after a minimal treatment that may not adequately reduce the environmental pathogen?...

AHPA's response: AHPA is opposed to any microbiological environmental monitoring requirement for foods that are not likely to be consumed as RTE or consumed after a minimal treatment that may not adequately reduce pathogens. Microbiological environmental monitoring should only be contemplated for foods that are RTE and are consumed without adequate cooking. In any other circumstance, there is no significant public health benefit to outweigh the costs of the monitoring.

Furthermore, AHPA believes that to require environmental monitoring in facilities which handle or minimally process RACs early in the supply chain will have the effect of forcing those facilities to sterilize their goods in order to avoid continually finding pathogens in their environment, as a great many crude botanical materials are contaminated at some level with pathogens. As mentioned elsewhere in our comments, AHPA is extremely concerned that if the regulations force RACs early in the supply chain to be treated to reduce microbial contamination, this will remove an important quality marker that knowledgeable processors later in the supply chain rely upon to judge the quality and suitability of the crude botanicals they buy.[131]

Thus, AHPA believes FDA should not focus overmuch on the issue of microbiological contamination in foods which are early in the supply chain (other than fresh produce which will be consumed without adequate processing or cooking). The potential for microbiological contamination in materials intended for further commercial processing, if such a hazard is reasonably likely to exist in the material, should be addressed by providing clear notice in the labels, labeling or other commercial documentation accompanying the sale of the goods that they have not been treated to reduce microbial contamination and/or that they require such treatment prior to use as or in RTE food. 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, and will thereby adequately protect the public health while avoiding unnecessary burdens and regulatory prescriptions which are actively counterproductive to the quality of the food supply. (See our comments in section 2 above regarding RTE vs. non-RTE food, our comments to § 117.80(b)(2), § 117.130(c), and § 117.93, as well as suggested new § 117.135(d)(2) and § 117.135(d)(6).)

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

• Be greater for an environmental pathogen that is frequently introduced into a facility (e.g., L. monocytogenes which is ubiquitous in the environment and can be continually introduced into a facility from many routes, including ingredients, people and objects (Ref. 144) than for an environmental pathogen that is less frequently introduced?

AHPA's response: It cannot be assumed that simply because an environmental pathogen is ubiquitous in the environment and can be continually introduced into a facility from many routes, that it necessarily will be so introduced. As discussed previously, well-designed and well-managed facilities take appropriate precautions to minimize the transfer of contaminants into the facility, especially post-kill-step. Therefore, AHPA does not believe a greater frequency of collection is necessarily appropriate for these pathogens; it depends on the circumstances.

• Be greater for refrigerated or frozen RTE food products that support growth of L. monocytogenes than for those that do not?

AHPA's response: AHPA believes no environmental sampling for L. monocytogenes should be required for refrigerated or frozen RTE food products which do not support growth of L. monocytogenes.

• Be greater if there is greater risk of a negative impact on public health (e.g., the product is specifically intended for a sensitive population such as infants) than if there is a lesser risk of a negative impact on public health?

AHPA's response: AHPA believes increased monitoring would be justified for products that are specifically intended for a sensitive population such as infants.

• Be greater for products that undergo significant handling and exposure to the environment than for products that undergo limited or no handling or have little exposure to the environment?

AHPA's response: AHPA opposes any requirement for microbiological environmental monitoring for products that undergo limited or no handling or have little exposure to the environment, as there is little risk these will be contaminated even if the microorganism is present in the environment. Microbiological environmental monitoring should be contemplated only for products that undergo significant handling and exposure to the environment.

• Increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased risk of contamination, e.g., construction? (Ref. 52) (Ref. 185) (Ref. 184) (Ref. 187).

AHPA's response: AHPA believes that if environmental monitoring is conducted, increased monitoring would be appropriate under these conditions.

6. Question: Would more detail be appropriate, by, for example...requiring written procedures for conducting environmental testing and, if so, also requiring that procedures for environmental testing be scientifically valid and include the procedures for sampling and the sampling frequency?

AHPA's response: AHPA believes that where testing is performed, it should be conducted in accordance with written procedures (which may include copies of published or otherwise publicly available methods), and that there should be written procedures for sampling and for sampling frequency. AHPA does not believe that test methods and sampling procedures should be required to occur in the same document, especially since the sampling and the testing are often performed by separate personnel. AHPA agrees that test methods used for microbiological environmental monitoring should be scientifically valid.

7. Question: Would more detail be appropriate, by, for example...requiring data analysis to detect trends.

AHPA's response: AHPA opposes a requirement for requiring data analysis to detect trends. If environmental monitoring detects pathogens or other problems, the company will have to take appropriate action to eliminate the problem and to ensure its food is safe. AHPA does not believe trend analysis will provide significant further improvements to protection of the public health. Trend analysis may be useful to the company to optimize their procedures, improve efficiency, or avoid potential problems, but it should be up to the individual company to decide whether the benefits of such programs outweigh the costs.

8. Question: In addition, with respect to environmental testing for L. monocytogenes, FDA requests comment on whether it would be appropriate to distinguish between environmental testing for RTE foods depending on whether the food supports the growth of L. monocytogenes.

AHPA's response: AHPA opposes any requirement for environmental testing for L. monocytogenes for any food which does not support the growth of L. monocytogenes as well as for any food which is not RTE and consumed without adequate cooking.

# 13. Comments regarding a potential provision to require supplier approval and verification

FDA has not proposed to require supplier approval and verification in the draft regulation, but requests comment on whether such programs should be required, and if so under what circumstances.

## 13.1 Overview of AHPA's comments

AHPA is generally opposed to supplier approval and verification (SAV) being required by regulation, especially if it includes onsite audits by the purchaser. AHPA believes that, in general, appropriate supplier approval and verification can be accomplished through review of the supplier's specifications and/or test results; certifications by third party auditors; paper-based audits; or some combination of these. In some cases it may be beneficial to supplement these with laboratory testing to confirm the supplier's test results. AHPA believes companies should be given the flexibility to decide for themselves how best to ensure the suitability of the raw materials and ingredients they buy.

If FDA deems a specific program to be necessary then it should be required only under carefully delineated circumstances where the specifically identified hazard(s) to be controlled by the SAV program are both acute (i.e. may cause serious adverse health consequences or death) and fairly likely (i.e. more likely than simply “reasonably likely”), as the costs associated with such a program represent a very large burden both to industry and to the consumers who will ultimately be charged higher prices to cover the significant costs involved. Also, a requirement for any such program should be limited to (a) suppliers of covered produce, but only where it is necessary for the produce to be grown in compliance with Part 112 to ensure food safety (i.e. microbial hazards are not controlled by the purchaser of the produce); and (b) suppliers of processed raw materials and ingredients. Suppliers of non-produce botanicals[132] and other RACs for which no production regulation exists should be exempt from SAV.

AHPA is opposed to any requirement for a supplier’s customer to perform, or have performed by a 3rd party, onsite supplier audits. AHPA would be strongly opposed to an explicit or implicit onsite audit requirement which would require multiple buyers to audit each supplier. If onsite audits are required it will be extremely cost prohibitive if more than one audit is required per supplier. If FDA does decide to require onsite audits,

[132] 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 to the Produce Safety Rule regarding the definition of the word “produce.”

a mechanism should be established so that a single audit can be used for multiple customers.

Furthermore, if FDA determines to impose any requirement(s) for a supplier approval and verification program, this should be included as part of Subpart C, rather than Subpart B, since appropriate implementation of such a program requires appropriate hazard analysis. Small companies should be exempt from any requirement for a supplier approval and verification program.

**13.2 Any requirement for supplier approval and verification should maximize flexibility and be as narrowly tailored as possible**

AHPA is generally opposed to supplier approval and verification (SAV) being required by regulation.

AHPA believes that, in general, appropriate supplier approval and verification can be accomplished through review of the supplier's specifications and/or test results; certifications by third party auditors; paper-based audits; or some combination of these. In some cases it may be beneficial to supplement these with laboratory testing to confirm the supplier's test results. AHPA believes companies should be given the flexibility to decide for themselves how best to ensure the suitability of the raw materials and ingredients they buy.

If FDA deems a specific SAV program to be necessary then it should be required only under carefully delineated circumstances where the specifically identified hazard(s) to be controlled by the SAV program are both acute (i.e. may cause serious adverse health consequences or death) and fairly likely (i.e. more likely than simply "reasonably likely"), as the costs associated with such a program represent a very large burden both to industry and to the consumers who will ultimately be charged higher prices to cover the significant costs involved.

Furthermore, a requirement for any such program should be limited to (a) suppliers of covered produce, but only where it is necessary for the produce to be grown in compliance with Part 112 to ensure food safety (i.e. microbial hazards are not controlled by the purchaser of the produce); and (b) suppliers of processed raw materials and ingredients. Suppliers of non-produce botanicals[133] and other RACs for which no production regulation exists should be exempt from SAV.

AHPA is opposed to any requirement for a supplier's customer to perform, or have performed by a 3rd party, onsite supplier audits. AHPA would be strongly opposed to an explicit or implicit onsite audit requirement which would require multiple buyers to audit each supplier. If onsite audits are required it will be extremely cost prohibitive if more than one audit is required per supplier. If FDA does decide to

[133] 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 to the Produce Safety Rule regarding the definition of the word "produce."

require onsite audits, against AHPA's recommendation, a mechanism should be established so that a single audit can be used for multiple customers.

Furthermore, if FDA determines to impose any requirement(s) for a supplier approval and verification program, this should be included as part of Subpart C, rather than Subpart B, since appropriate implementation of such a program requires appropriate hazard analysis. Small companies should be exempt from any requirement for a supplier approval and verification program.

**13.3 Supplier approval and verification will be much more expensive than FDA estimates**

FDA states in the preamble, "The vast majority of costs related to a supplier approval and verification program are due to verification activities such as audits and testing of raw materials and ingredients, which would likely be selected based on the hazard associated with the raw material or ingredient and where the hazard is controlled. Although we are not including a provision for such a program in this proposed rule, we estimate that a requirement for a supplier approval and verification program, if implemented as part of a preventive approach, could impose an incremental annual cost of $0 – $5,000 per supplier facility based on size (number of employees) that undergoes an annual audit. This would result in an estimated aggregate cost of $11,000,000 for domestic facilities and an estimated aggregate cost of $12,000,000 for foreign facilities....We estimate that a requirement for a supplier approval and verification program could impose an incremental annual cost of $7,000 – $90,000 per facility based on size (number of employees) for testing of raw materials and ingredients. This would result in an estimated aggregate cost of $5,000,000 for domestic facilities and an estimated aggregate cost of $5,400,000 for foreign facilities."

AHPA believes these cost estimates are far too low.

(a) With respect to the costs that will be incurred by suppliers to maintain their audit certification, AHPA believes the estimate of $0 - $5000 per supplier facility to be on the low side. Suppliers that process diverse ingredients, who use complicated manufacturing procedures, or who have very large facilities will incur higher costs, which AHPA believes could go as high as $10,000 plus travel and lodging. In addition, many supplier facilities are located in foreign countries and/or remote areas; AHPA believes travel and lodging expenses, even using an auditor who is already based overseas, may go as high as several thousand dollars per audit, i.e. much higher than the $250 - $1000 cited in FDA's PRIA. AHPA furthermore notes that FDA's estimate of $0 - $5000 per audit does not appear to include any travel expenses at all, despite the fact that the PRIA notes the requirement to pay travel and lodging in addition to the base audit price.

AHPA notes that, as described in the PRIA, these cost estimates assume each supplier pays a third-party auditor to certify its operations once per year, and those results would be used to satisfy multiple

customers.[134] If each buyer is expected or required to perform its own audit on each supplier, then the costs will be exponentially higher.

(b) With respect to the costs that will be incurred by buyers who use testing as a verification activity for purchased items, AHPA believes FDA's cost estimates are far too low.

To begin with, the testing costs cited by FDA are too low; AHPA believes that testing may be $84 or more for individual microbiological tests, and $1000 or more for certain chemical tests. See our comments regarding a potential testing requirement for further information.

Also, the testing cost estimate fails to include the value of the sampled material, which AHPA believes will typically range from a few cents to several dollars. However, in the case of expensive ingredients or extensive sampling plans (such as sampling for Salmonella, which entails removal of up to 6 kg of material) and/or expensive materials, the cost may range into the hundreds or thousands of dollars. See our comments regarding a potential testing requirement for further information.

Furthermore, FDA's testing cost estimate assumes tests are conducted once per quarter for a total of 4 tests per year. AHPA believes the appropriate test frequency for one ingredient from one suppler may vary from once per year to many times per year, depending on the circumstances; in this respect, 4 times per year may be an appropriate average for one ingredient purchased from one supplier. However, AHPA believes such testing would need to be repeated on multiple ingredient-supplier combinations per year. Many food facilities handle dozens, if not hundreds, of different ingredients per year, and most companies prefer to have at least two suppliers for each ingredient. Even if only a fraction of the ingredients involve hazards for which testing is appropriate, the number of tests conducted per year will be much higher than 4.

Finally, FDA's testing cost estimate has not taken into account the cost of the statisticians and food safety experts who would be required to develop scientifically valid sampling and testing plans. See our comments regarding a potential testing requirement for further information.

### 13.4 Responses to specific questions posed by FDA

In the preamble to the proposed rule, FDA poses a number of questions regarding a potential requirement for supplier approval and verification. AHPA responds to these questions below.

1. Question: Although we have not included [supplier approval and verification] provisions in the proposed rule, we request comment on their inclusion in a final rule. If they are included, what is the appropriate level of specificity? Should the requirement be very general, for example, requiring a

[134] The PRIA states, "For purposes of this analysis we assume one audit per supplier annually based on the fact that the food industry is moving toward the practice of recognizing an audit done under certain rigors, such as a GFSI-approved audit, and that the results of such an audit can be used to satisfy multiple customers."

supplier approval and verification program as appropriate to the facility and the food, when appropriate based on risk?

AHPA's response: With one exception discussed in connection with Question 2 below, AHPA believes that if FDA wishes to address the use of supplier approval and verification programs by food processors, this topic should be addressed in guidance rather than by regulation. A guidance document provides opportunity to explain in detail why and when supplier audits or testing may appropriate; the limitations of testing; the considerations involved in developing sampling plans and test methods; etc.

Regarding the level of specificity which might be included in regulation, AHPA is opposed to an overly broad, vague, or unspecific requirement such as FDA outlines in the question above. It has been AHPA's observation that such regulatory provisions are difficult for companies to interpret, which leaves the company vulnerable to costly, inappropriate, excessive, and/or idiosyncratic misinterpretations by management, by outside consultants, and by individual FDA inspectors or district officials. AHPA appreciates FDA's desire to provide adequate flexibility but believes it important for FDA to provide as much specificity as possible regarding the intended scope of each regulatory provision. This is especially true for regulatory provisions which involve significant and/or ongoing expenses, as supplier approval and verification would.

If supplier approval and verification is included in the regulation, AHPA believes FDA should provide adequate detail to educate companies as to what FDA envisions and the circumstances where it is appropriate. However, FDA must take care to ensure any thus-identified circumstance does in fact present the risk FDA thinks it does.

In order to avoid excessive prescriptiveness and to provide flexibility, AHPA suggests that any regulatory provision regarding supplier approval and verification, if FDA decides to include one in these regulations, should suggest, rather than require, said supplier approval and verification under the circumstances described by FDA.

To summarize our position with respect to flexibility vs. specificity, AHPA is opposed to one-size-fits-all regulations and believes it very important to provide adequate flexibility; but AHPA is similarly opposed to overly broad or vague regulations and believes it very important to provide adequate specificity. AHPA believes the optimal balance can be achieved by outlining the circumstances in which FDA envisions a particular provision to apply, while making the provision optional or giving companies an option to justify omitting it. This applies not only to the supplier approval and verification provision under discussion here but also to many other provisions of the regulation, and AHPA encourages FDA to consider incorporating this strategy more generally in its regulations.

2. Question: FDA also requests comment on who a supplier approval and verification program should apply to - e.g., should it apply to all facilities that manufacture, process, pack or hold food, or be limited (such as to facilities that manufacture or process food)?

AHPA's response: AHPA believes certain companies should be required by regulation to verify the part-112-compliant status of farmers from whom they buy covered produce, either through audits, statements provided in labeling or other commercial documentation accompanying the sale, or commercial guarantees. AHPA believes this should apply to: (a) food processors who use covered produce and whose processing does not include an adequate microbial reduction step; and (b) cooperatives or other intermediaries who sell covered produce to retail establishments (e.g. groceries, restaurants) or to food processors whose processing does not include an adequate microbial reduction step. AHPA proposes this requirement in order to relieve farmers who wish or need to be part-112-exempt from the requirement to document the identity of the commercial processor who adequately reduces the presence of microorganisms of public health significance, which AHPA believes is not practical for many farmers. See our comments to the Produce Safety rule regarding the commercial processing exemption for more information.

AHPA strongly opposes any supplier approval or verification requirement for companies who merely hold food, with the possible exception of distributors of covered produce. Many such companies (e.g. public warehouses) hold food on behalf of other companies, and are not in a position to second-guess their customers' choice of suppliers (and indeed, often have no access to information regarding the suppliers). Furthermore, many such companies warehouse a huge and constantly-changing variety of products; it would be extremely impractical for them to attempt to control the suppliers involved.

With respect to whether packagers should be required to implement a supplier approval and verification program, AHPA believes such a requirement cannot be even arguably appropriate unless the packager is the one who makes the decisions as to the food which is packaged in its facility. This is often not the case; packagers are frequently hired to package food on behalf of another company. In such a case, the packager has no authority to decide the source of the food. Rather, the company which is purchasing the packager's services (i.e. the packager's customer) is responsible for manufacturing, or choosing the manufacturer or other supplier of, the food which is sent to the packager for packaging. Thus under these circumstances the packager cannot be held responsible for implementing a supplier approval and verification program.

In the case of packagers who make their own decisions regarding the suppliers of food they package, AHPA believes it is neither more appropriate, nor less appropriate, for such a packager to be subject to a supplier approval and verification program than it is for any other food processor. In general, AHPA is opposed to such a requirement.

With respect to packaging components whose purchase the packaging company decides, AHPA believes it generally appropriate for the packager to rely on specifications, certificates, guarantees, or other documentation provided by the supplier of the packaging components.

With respect to other circumstances: If FDA decides to include a supplier approval and verification provision in the final rule, AHPA believes it should be focused on the final processor or packager, whose product is RTE food ready for retail sale. AHPA is generally opposed to the imposition of duplicative requirements at multiple stages throughout the supply chain, as this increases costs without commensurate improvements in public health. Companies in the supply chain upstream or downstream from the final processor/packager must, to be sure, take care to handle, process, and store food appropriately to prevent spoilage or introduction of contaminants, and to represent their products accurately, but they should not be required to repeat all the same work the final processor/packager does. As discussed elsewhere in our comments, the final processor/packager is the most effective point of control for most hazards.

3. Question: FDA requests comment on whether more detail would be appropriate, by, for example, requiring that the supplier approval and verification program include a written list of approved suppliers.

AHPA's response: If a supplier approval and verification program is required, AHPA believes it appropriate to require the identities of approved suppliers to be maintained in writing.

However, AHPA does not believe it appropriate to specify that this occur in the form of a list; companies should have the flexibility to document the approved suppliers in the format most appropriate for their circumstances. For example, companies may find it more useful and convenient to maintain the approved suppliers for each item in specification document(s) for each item (e.g. a purchasing specification or receiving specification).

4. Question: FDA requests comment on whether more detail would be appropriate, by, for example, requiring that, in determining appropriate verification activities, the owner, operator, or agent in charge of a facility consider relevant regulatory information regarding the supplier, including whether the raw material or ingredient is the subject of an FDA warning letter or import alert relating to the safety of the food.

AHPA's response: If a supplier approval and verification program is required, AHPA believes it appropriate for plant management to consider such information in determining what verification activities to conduct. However, AHPA would oppose any regulatory provision which would, either explicitly or implicitly, automatically preclude companies from using a supplier which has been the subject of a warning letter or import alert.

5. Question: FDA requests comment on whether more detail would be appropriate, by, for example, specifying circumstances when a supplier approval and verification program would not be required - e.g., when the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur; or when the receiving facility obtains from its customer written assurance that the customer has established and is following procedures that will significantly minimize or prevent the hazard.

AHPA's response: If a supplier approval and verification program is required, AHPA believes it would be helpful for FDA to specify circumstances under which such a program is not required (although AHPA also believes FDA should specify circumstances under which it believes such a program may be required).

AHPA agrees that such a program would not be necessary to protect the public health when the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur, or when the receiving facility obtains from its customer written assurance that the customer has established and is following procedures that will significantly minimize or prevent the hazard.

AHPA is generally opposed to imposing duplicative requirements throughout the supply chain, as this often drives up costs without significantly reducing public health risks. Furthermore, excessive or premature hazard reduction early in the supply chain may cause difficulties for buyers later in the supply chain.[135] AHPA encourages FDA to permit use of written guarantees or other assurances under a wide variety of circumstances in order to reduce the burdens on and disruptions to industry as well as the increased costs passed on to consumers.

For example, AHPA believes that where a supplier's customer represents in a contract, or guarantee, or other document that it will take steps to significantly minimize or prevent a hazard in food received from the facility, this fact should be taken into account in the supplier's hazard analysis and should relieve the facility from responsibility for the hazard; i.e. depending on the hazard and other circumstances, the supplier may not need to spend any resources at all on controlling that hazard in the item sold to that customer.

Similarly, FDA should allow a supplier to mitigate hazards in the items it sells through accurate written disclosure to its customers, such as in a certificate or analysis, technical specification, or label which accurately represents the state of the material and any known hazards it may pose which require appropriate downstream processing. For example, if a crude or minimally processed agricultural commodity has not been treated to reduce microorganisms of public health concern, this fact should be disclosed to buyers, who will then be able to make an appropriate decision as to whether to go ahead and buy that material (e.g. if their process includes an adequate kill step or their formula includes sufficient preservatives) or whether to buy from a different vendor whose materials have been treated. AHPA knows for a fact that some buyers believe the option to buy unsanitized botanicals and perform the treatment themselves is extremely important, while others prefer to buy botanicals which have already been treated. FDA should not attempt to prescribe which option must be used, but rather should leave both options available since they both adequately protect the public health.[136,137]

[135] See our comments to proposed § 117.80(b)(2) for an example.

[136] AHPA notes that other options exist. For example, some botanical materials are not susceptible to contamination with microorganisms of public health concern, either due to naturally occurring acids or other constituents or due to other factors.

Similarly, if a particular ingredient is contaminated with a particular level of lead, for example, it should not be incumbent upon the ingredient supplier to determine whether that level of lead is a hazard (unless the level of lead is extreme). In general, the supplier has no way to know how the material will be combined with other ingredients, what the lead content of the other ingredients will be, what the serving size of the finished food will be, or who the target consumer will be (adults? children?). Thus it would be impractical to expect the supplier to control this hazard other than to ensure the level of lead is not unusually high. The buyer must be the one who evaluates and controls this hazard appropriately for the finished food in question.

6. Question: FDA requests comment on whether more detail would be appropriate, by, for example, specifying that the type of verification activity be linked to the seriousness of the hazard - e.g., whether to:
• Require an onsite audit when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans [SAHCOD];
• Provide more flexibility with respect to hazards for which there is not a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans - e.g., periodic onsite audits, periodic or lot-by-lot sampling and testing of the raw material or ingredient, and periodic review of the supplier's food safety records;

AHPA's response: With respect to the first point, AHPA strongly opposes an automatic requirement for an onsite audit if exposure to the hazard will result in serious adverse health consequences or death. Such a requirement is appropriate only if (a) the hazard will not be controlled through the buyer's manufacturing process and (b) the hazard cannot be controlled through raw material/ingredient testing. AHPA believes that many types of hazards, such as chemical hazards, radiological hazards, and any other hazard that is homogenously distributed in the material, can quite effectively be controlled through testing (which may be performed either by the supplier or by the buyer). Even heterogeneously distributed hazards, such as low level pathogen contamination, may be able to be effectively controlled through testing if enough samples are pulled (although the number of samples required for scientific validity may be high).

It should be up to the buyer to determine the most appropriate way to control the hazard depending on the circumstances. For example, if time is of the essence, a buyer may be motivated to pay the high cost of extensive sampling and testing rather than waiting weeks or months for an audit to be scheduled and completed.

However, for purposes of clarity and to educate industry, AHPA would support an optional recommendation to use an onsite audit to control SAHCOD hazards which are likely to be heterogenously distributed in the material.

[137] AHPA notes this is analogous to the manner in which the risk associated with the presence of allergens is mitigated under the law, i.e. through labeling to disclose presence of the hazard.

With respect to the second point, AHPA supports giving industry maximum flexibility. It is not possible for FDA accurately to envisage which control(s) will be most appropriate under which circumstances, as this will depend on many details. Furthermore AHPA strongly opposes any requirement for lot-by-lot sampling and testing; this is not even required for pharmaceuticals (except for identity testing and in some cases microbiology testing), and it would be particularly inappropriate to require such an expense for non-SAHCOD hazards.

Finally, AHPA does not understand the phrase “periodic review of the supplier’s food safety records” as distinguished from “periodic onsite audits.” The PRIA appears to equate “review [of] the supplier's food safety records” with “audits of [the] supplier for the hazard.” AHPA suggests FDA needs to clarify what is meant by “review of food safety records” and how it is distinct from “onsite audits.”

7. Question: FDA requests comment on whether more detail would be appropriate, by, for example, specifying requirements for audits - e.g., the qualifications (including training, experience, and conflict of interest) for persons who conduct audits; content of an audit (such as compliance with applicable food safety regulations and, when applicable, compliance with a facility’s food safety plan).

AHPA's response: AHPA believes these topics would be better discussed in guidance rather than regulation. Given that, according to the PRIA, onsite audits will generally be conducted by a third-party auditor hired by the supplier, it will be impractical for the buyer to be expected to investigate or control these details.

AHPA notes that it is not uncommon in the herbal industry for buyers to conduct their own audits of suppliers, in one form or another.

8. Question: FDA requests comment on whether more detail would be appropriate, by, for example, specifying the frequency of verification activities (e.g., initially, annually, or periodically).

AHPA's response: If a supplier approval and verification program is required, AHPA believes it would be appropriate for the verification to occur initially and periodically thereafter. AHPA is opposed to specifying how frequently the verification must occur; this will depend on the supplier (e.g. size, reputation, compliance history, etc.), the nature of the hazards, the nature of the items purchased, the frequency of purchase, the types of documentation or guarantees accompanying the purchase, the foods in which the supplier's products are used, etc. It might also depend on the reputability or expertise of any third-party certifier who audits the supplier.

9. Question: FDA requests comment on whether more detail would be appropriate, by, for example, specifying whether, for some hazards, it will be necessary to conduct more than one verification activity to provide adequate assurances that the hazard is significantly minimized or prevented.

AHPA's response: AHPA opposes a requirement to conduct more than one verification activity, although it may be appropriate for FDA to specify circumstances under which it is recommended to conduct more than one verification activity. The final decision as to how much verification is required should be up to the buyer, who will have a more intimate and complete knowledge of all of the facts and circumstances at hand.

10. Question: FDA requests comment on whether more detail would be appropriate, by, for example, providing for alternative requirements if a supplier is a qualified facility - e.g., documenting that the supplier is a qualified facility and obtaining written assurance that the supplier is producing the raw material or ingredient in compliance with sections 402 and 403(w) of the FD&C Act.

AHPA's response: If a supplier approval and verification program is required, AHPA would support FDA providing for alternative requirements if a supplier is a qualified facility, and believes the proposed documentation would be appropriate.

11. Question: FDA requests comment on whether more detail would be appropriate, by, for example, specifying those records that would be appropriate for a supplier approval and verification program.

AHPA's response: If a supplier approval and verification program is required, AHPA believes it would be appropriate to specify the records that would be required. As far as AHPA can tell, these would be any certificates issued by the third-party organizer or other audit-related records; any results of testing; and written records of approved suppliers. If there are other records FDA should clarify what they are.

12. Question: FDA requests comment on whether more detail would be appropriate, by, for example, providing for substitution of a regulatory inspection (e.g., by FDA or a comparable State regulatory agency or foreign food safety authority), for an onsite audit.

AHPA's response: If a supplier approval and verification program is required, AHPA would strongly support permitting an onsite audit to be substituted by a regulatory inspection.

13. Question: FDA requests comment on whether more detail would be appropriate, by, for example, specifying that a receiving facility take appropriate action (e.g., discontinuing use of a supplier) if the facility determines that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur.

AHPA's response: If a supplier approval and verification program is required, AHPA believes it would be appropriate to require the buyer to take appropriate action if it is determined that the supplier is failing to control hazards which it has represented that it controls, or which the buyer has reason to expect that it controls. However, this must apply only if such control is necessary to ensure safety and the hazard is not being effectively controlled by the buyer.

AHPA agrees that discontinuing use of the supplier could be an appropriate action, but emphasizes that other actions might also be appropriate (e.g. working in conjunction with the supplier to improve their operations), so it is important the regulation allow flexibility in this regard.

# 14. Other comments

### 14.1 Comments regarding the need for production codes

AHPA notes that although the proposed regulation defines “lot” and references “production code,” nothing in the regulation requires food processors to assign such production codes or to reference them in their recordkeeping or packaging; they are only mentioned as an option in § 117.305(f)(4).

AHPA believes that use of production codes should be mandatory in packaging, and also in recordkeeping for records that directly relate to food produced or packaged by the facility or received as shipments of raw materials and ingredients. They are necessary to facilitate effective production management, quality control, regulatory inspection, and/or recall plans. AHPA believes that most food processors already use such codes; those who do not should have no major problem in implementing them, and will find them useful once their proper use is understood.

### 14.2 Comments regarding “includes”

In the preamble 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 the rule 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.”[138]

AHPA notes that FDA's own usage of “includes” in the proposed GMP-HA/PC 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

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

> (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.

As another example, AHPA considers FDA's proposed definition of "undesirable microorganism":

> The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

AHPA believes the list of types of microorganisms in this definition is intended to be complete, i.e. there are not other types of microorganisms that FDA would consider undesirable. If there are other such microorganisms, AHPA encourages FDA to explicitly list them, so the regulated industry will better understand which types of microorganisms it should be concerned about. However, AHPA is unable to think what other problematic types of microorganisms might exist.

AHPA believes examples such as these 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 retain "includes, but is not limited to" wherever the list which follows is not intended to be exhaustive, to make it clear to the 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.

### 14.3 Comments regarding paragraph headings

AHPA supports FDA's return to use of simple, short, clear headings. The "question" format used in the previous decade (e.g. "What are the requirements for personnel?") was both wordy and patronizing.

Respectfully submitted,

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