DOCKET NO. FDA 2011-N-0143

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING for the PROPOSED RULE on

FOREIGN SUPPLIER VERIFICATION PROGRAMS FOR IMPORTERS OF FOOD FOR HUMANS AND ANIMALS

December 15, 2014

Table of contents

Prefatory Remarks

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

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

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

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

[1] 78 FR 3646-3824.

[2] 78 FR 3504-3646.

[3] 78 FR 45730-45779.

[4] 79 FR 58523 -58572.

[5] 79 FR 58433 -58473.

[6] 79 FR 58574-58599.

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

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

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

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

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

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

1. General support for many of the revisions

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

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

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

2. General concern over confusing language

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

AHPA therefore urges FDA in the strongest possible terms to ensure 21 CFR Parts 112 and 117, and Part 1 Subpart L, are written in the clearest possible language. In particular, the Rules should be written in a manner that allows firms to readily determine whether or not they are subject to each Rule (i.e., whether they handle the food or perform the activities that fall within the scope of each Rule) without having to hire consultants or lawyers, or having to wade through hundreds of pages of Preambles, policy documents, and guidance documents (which many small firms will not even realize exist). In order to accomplish this, it is particularly critical that the scope and definitions be set forth in self-explanatory language.

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

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

AHPA therefore strongly urges FDA to create definitions that (a) are written in clear, straightforward prose, (b) capture the full range of activities normally performed on farms, and (c) are self-contained

and fully understandable without reference to information contained in any other documents (including the Preambles).

3. Comments regarding testing as a preventive control

AHPA is concerned that FDA does not appear to recognize testing of raw materials and ingredients as an effective preventive control for certain types of hazards. The revised proposed GMP-HA/PC Rule lists testing of raw materials and ingredients as an element of a supplier program, but not as a preventive control in and of itself. FDA furthermore states in the Preamble of the supplemental notice to the Foreign Supplier Verification Program (FSVP) Rule, "We do not believe...that supplier verification activities actually control hazards. Rather, a key purpose of verification is to provide assurance that hazards are being effectively controlled by the foreign supplier or some other entity." This implies that raw material testing can never "actually control hazards" and can never serve as a preventive control.

AHPA understands that, in the context of traditional HACCP, a "control" is primarily considered to be not the analysis of an attribute of a food but rather an element of the facility's operations, such as heating to a specified temperature for a specified length of time to kill pathogens; use of sieves and metal detectors to remove physical contaminants; use of solvent/solvent (e.g., water/oil) partitioning to remove hydrophilic or hydrophobic chemical contaminants from a liquid food; or storing hazardous chemicals away from food processing areas. However, AHPA believes that in modern food safety systems the concept of a "control" must be expanded to include raw material and ingredient testing at least with respect to chemical testing. While it may be true that testing cannot "actually control hazards" such as pathogens or metal fragments, testing of raw materials/ingredients is both effective and also often the best means of controlling a hazard such as lead. Indeed, regulations such as those set forth in 21 CFR Part 111 and 21 CFR Part 106 explicitly acknowledge that proper evaluation of raw materials and ingredients is an important element of control. One cannot heat or sift the lead out of a raw material;[7] one can only exclude it from the food through proper control of the raw materials/ingredients used, and in many cases the most effective means to do so is to perform testing of the raw material/ingredient.

In cases where testing, alone or in combination with other controls, serves to adequately control the hazards in raw materials and ingredients, AHPA believes the receiving facility should have no obligation to implement a supplier program as outlined in the revised proposed Rule. Indeed, given the proposed definition of supplier (either as originally proposed by FDA. or as suggested by AHPA in comment 9.2 of AHPA's current comments to the GMP-HA/PC Rule, or in AHPA's previously-submitted comments to the originally-proposed FSVP Rule[8]), AHPA believes that it will in many cases be impossible to implement a

[7] For certain types of foods it is possible to remove lead during processing, but this is rare.
[8] See comment # 14.1 in AHPA's previously-submitted comments to the FSVP Rule.

supplier program since the identity of the supplier will be unknown to the receiving facility and to the intermediary that provides raw materials or ingredients to the receiving facility.

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

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

Therefore, AHPA proposes that the GMP-HA/PC Rule recognize testing as a preventive control in by renumbering § 117.135(c)(4) and inserting new (4) as follows:

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

4. Comments regarding the scope of supplier verification activities

4.1 General comments

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

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

However, in addition to requiring verification that a supplier controls identified hazards, the supplier program delineated in the newly-proposed GMP-HA/PC Rule also requires the receiving facility to evaluate whether the incoming raw material or ingredient is "adulterated under section 402" and the supplier produced it in compliance with applicable FDA food safety regulations.[9]

AHPA believes this broad scope to be inappropriate for a number of reasons. To begin with, various "technical" cGMP violations do not pose a significant public health risk and are not amenable to discovery by outside parties. For example, minor cGMP violations may occur (e.g., minor deficiencies in gowning or paperwork) without causing the food processed in a facility to actually be hazardous; furthermore, no matter how many audits or how much testing is performed, there is no way for an outside party to guarantee that such technical cGMP violations never occur.

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

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

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

it is inappropriate to make the latter responsible for every element of its supplier's regulatory compliance when the former is responsible only for controlling the pathogen hazard.

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

4.2 Comments regarding statutory language

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

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

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

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

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

4.3 Recommended changes to proposed regulatory language

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

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

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

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

> (ii) Obtains written assurance~~, at least every 2 years~~,[10] that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the receiving facility's use of the raw material or ingredient ~~is not~~ will not cause the finished food to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. ~~The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.~~[11]

[10] See comment 10.1 for an explanation of this deletion.

[11] See comment 5.4 for an explanation of this deletion.

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

> (ii) Obtains written assurance~~, at least every 2 years~~,[12] that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the receiving facility's use of the raw material or ingredient ~~is not~~ will not cause the finished food to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

> Purpose of supplier verification. Your foreign supplier verification activities must provide adequate assurances that the foreign supplier adequately controls all hazards that you have identified as requiring control by the supplier ~~produces the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419, if either~~

[12] See comment 10.1 for an explanation of this deletion.

~~is applicable, and is producing the food in compliance with sections 402 and 403(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g, 350h, 342, and 343(w))~~.

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

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

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

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

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

5. Comments regarding hazard analysis in general

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

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

> *Known or reasonably foreseeable hazard* means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

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

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

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

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

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

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

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

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

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

Or, perhaps better yet:

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

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

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

5.2 Comments regarding § 1.504(a) through (d)

AHPA notes that while § 117.130(a)(1) specifies that a hazard analysis must be conducted for each "type of food," corresponding § 1.504(a) would require the hazard analysis to be performed for each "food." AHPA believes it will be unnecessarily onerous to require a separate hazard analysis for every individual food imported; rather, importers should be permitted to group foods appropriately by type for purposes of the hazard analysis. AHPA proposes the following revisions to § 1.504(a):

> Requirement for a hazard analysis. You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food you import to determine whether there are any ~~significant~~ hazards requiring control. Your hazard analysis must be written.

With respect to the proposed inclusion of hazards "intentionally introduced for purposes of economic gain" in § 1.504(b)(2)(iii), AHPA agrees it is more practical and appropriate to address such issues as part of the hazard analysis and preventive controls program than it would be to address them along with controls designed to prevent terrorism. However, AHPA emphasizes that such hazards must be subject to the same risk-based evaluation of severity and likelihood as any other hazard. Most importantly, specific controls for such hazards must be required only when the hazard is reasonably likely to occur in the present time (as opposed to historically) and in the country or marketplace at issue (as opposed to globally). For example, while adulteration of green peas with Malachite Green has been reported as occurring in certain countries either currently or within the recent past (measured in some number of years as opposed to decades), AHPA is not aware of any information to indicate such adulteration is likely in the US[13]; therefore, no controls should be required for Malachite Green in green peas sourced from the US. Furthermore, when control of such a hazard is necessary, those controls should apply only to a receiving facility's raw materials and ingredients. In other words, the facility should not be required to implement controls to prevent its own employees from introducing such adulteration; it is very unlikely that an employee of the receiving facility would introduce an economic adulterant unless the management of the facility had made a conscious decision to flout the law, so such a requirement would needlessly burden "good actors" while doing nothing to prevent bad actions by bad actors. AHPA therefore proposes the following revisions to § 1.504(c)(1), for consistency with the language used in the revised proposed GMP-HA/PC Rule (AHPA's proposed revisions to § 117.130(c)(1)(i))[14] and to acknowledge specific factors that may influence the evaluation of the likelihood or severity of the hazard.

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

Regarding the proposed inclusion of environmental pathogens in the hazard analysis, AHPA believes that if the finished food is inherently incapable of supporting pathogen survival (e.g., acid or acidified foods)

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

[14] See comment 8.2 to AHPA's current comments to the revised proposed GMP-HA/PC Rule.

then this should preclude the need for evaluation of environmental pathogens. AHPA therefore proposes the following revisions to § 1.504(c)(2):

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

AHPA has previously commented on the difficulty of applying the list of factors given in what is currently proposed § 1.504(c)(3) to food that is not ready-to-eat (RTE) food, especially raw materials and ingredients, and the difficulty of determining "the severity of the illness or injury if the hazard were to occur" as mentioned in § 1.504(c)(1). AHPA hereby reiterates its previously-submitted comments on this topic.[15]

AHPA also proposes the following revisions to § 1.504(d):

> Review of the foreign supplier's hazard analysis. If your foreign supplier has analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any ~~significant~~ hazards requiring control, you may meet your requirement to determine whether there are any ~~significant~~ hazards requiring control in ~~a~~ the food by reviewing and assessing the hazard analysis conducted by the foreign supplier.

5.3 Comments regarding § 1.504(e) and (f)

With respect to § 1.504(e), AHPA believes it likely that many, if not most, importers will not be aware of the rather complicated and non-intuitive scheme being used to distinguish "raw agricultural commodities" from "processed foods," and may also not understand that FDA considers "fruits and vegetables" to include "nuts" and "culinary herbs." Therefore, AHPA proposes these be itemized in this paragraph for clarity. AHPA understands these additions are not strictly speaking necessary, but encourages FDA to include them in order to make the Rule more readily understood by the average reader. In addition, AHPA suggests this paragraph should specify for clarity that although microbiological hazards need not be analyzed, other types of hazards must still be analyzed; otherwise many readers may not realize that this requirement still applies. (Conversely, if FDA does not intend these firms to be required to conduct a hazard analysis with respect to non-microbiological hazards, FDA should state that clearly.)

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

> Microbiological hazards in raw agricultural commodities that are fresh, intact fruits, nuts, culinary herbs, or vegetables. If you are importing a raw agricultural commodity that is a fresh, intact fruit, nut, culinary herb, or vegetable, you are not required to determine whether there are any ~~significant~~ microbiological hazards requiring control in such food; however, you must conduct a hazard analysis with respect to other types of hazards.

For similar reasons, AHPA proposes the following revisions to § 1.504(f):

> No ~~significant~~ hazards requiring control. If you evaluate the known and reasonably foreseeable hazards in a food and determine that there are no ~~significant~~ hazards requiring control, you are not required to determine what foreign supplier verification and related activities you must conduct under § 1.505 and you are not required to conduct such activities under § 1.506. This paragraph (f) does not apply if the food is a raw agricultural commodity that is a fresh, intact fruit, nut, culinary herb, or vegetable and that is subject to part 112 of this chapter.

AHPA notes that the terms "fruit" and "vegetable," as currently defined in the proposed definition of "produce" in the Produce Safety Rule (give complete title),are so broad they include every botanical in commerce rather than being limited to those consumed as produce. AHPA therefore asks FDA to revise the definition of "produce" in the manner suggested in AHPA's previous comments.[16]

5.4 Comments regarding § 1.504(g)

With respect to proposed § 1.504(g), AHPA believes it impractical, unnecessary, and onerous to require the importer to obtain "written assurance that [the customer] has established and is following procedures...that will significantly minimize or prevent the hazard" on an annual basis.

(a) The proposed Rule requires that the written assurance must identify the procedures the customer will use to significantly minimize or prevent the hazard, which raises the question of whether the importer is required under the Rule to evaluate the adequacy of the customer's procedures. It is not at all clear that the importer will be able effectively to do so; the customer may not be willing to provide sufficiently detailed information (i.e., by omitting confidential, proprietary, and/or trade secret information) to enable a meaningful evaluation, and it may not be possible to fully evaluate adequacy without knowledge of the customer's prerequisite programs, equipment and facility design, etc.

The provision also raises concerns about the impacts of an FDA assertion or a court determination that the customer's procedures were inadequate. In such a case, the importer may be alleged to have been "on notice" of the inadequacy of the customer's procedures based on the assurance's description of

[16] See AHPA's comments regarding the definition of "produce" in AHPA's previously-submitted comments to the originally-proposed Produce Safety Rule.

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

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

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

AHPA therefore suggests that § 1.504(g) should be revised as follows:

> ~~Significant h~~ Hazards requiring control that are controlled by you and/or your customer. If the preventive controls that you ~~and/or your customer~~ implement in accordance with subpart C of part 117 of this chapter are adequate to significantly minimize or prevent all ~~significant~~ hazards requiring control in a food you import, or if any hazards requiring control are significantly minimized or prevented by your customer and you provide documentation to notify your customer of the existence of the actual or potential

> hazard in accordance with [AHPA's new proposed] § 117.135(c)(5),[17] you are not required to determine what foreign supplier verification and related activities you must conduct under § 1.505 and you are not required to conduct such activities under § 1.506. ~~If your customer controls one or more such hazards, you must annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.~~

Alternately, if FDA is insistent that written assurance must be obtained from the customer, AHPA believes such assurance should be required no more than once at the beginning of the relationship between the importer and its customer, and must not implicitly or explicitly require the importer to evaluate the adequacy of the customer's procedures. In this case AHPA suggests that § 1.504(g) should be revised as follows:

> ~~Significant h~~Hazards requiring control that are controlled by you and/or your customer. If the preventive controls that you ~~and/or your customer~~ implement in accordance with subpart C of part 117 of this chapter are adequate to significantly minimize or prevent all ~~significant~~ hazards requiring control in a food you import, or if any hazards requiring control are significantly minimized or prevented by your customer and you provide documentation to notify your customer of the existence of the actual or potential hazard in accordance with [AHPA's new proposed] § 117.135(c)(5),[18] you are not required to determine what foreign supplier verification and related activities you must conduct under § 1.505 and you are not required to conduct such activities under § 1.506. If your customer controls one or more such hazards, you must ~~annually~~ obtain from the customer written assurance that it ~~has~~ will evaluate the hazard and if necessary will establish and follow ~~established and is following~~ procedures ~~(identified in the written assurance)~~ that will significantly minimize or prevent the hazard.

5.5 Comments regarding § 1.505

AHPA suggests that § 1.505(a)(i) should be revised as follows:

> The hazard analysis that you conduct in accordance with § 1.504, including the nature of the hazards requiring control.

AHPA suggests that § 1.505(a)(ii) should be revised as follows:

[17] See comment # 8.3 in AHPA's current comments to the revised proposed GMP-HA/PC Rule.

[18] See comment # 8.3 in AHPA's current comments to the revised proposed GMP-HA/PC Rule.

> The entity that will be applying controls for the hazards requiring control ~~analyzed under § 1.504~~, such as the foreign supplier or the foreign supplier's raw material or ingredient supplier.

AHPA suggests that § 1.505(a)(v) should be revised as follows, for consistency with the wording of the proposed GMP-HA/PC Rule and to avoid an implied requirement to perform testing and auditing:

> The foreign supplier's food safety performance history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and the supplier's record of correcting problems.

AHPA suggests § 1.505(b) should be revised as follows for clarity and completeness:

> Reevaluation of risk factors. You must promptly reevaluate the risk factors specified in paragraph (a)(1) of this section associated with a food or foreign supplier when you become aware of new information about these risk factors. If you determine that it is appropriate to continue to import the food from the foreign supplier, you must document the reevaluation and your determination; if you determine you will discontinue importing the food from the foreign supplier, you must document that decision.

6. Comments regarding supplier verifications

6.1 Comments regarding § 1.506(d)

With respect to § 1.506(d)(1), AHPA is concerned that the proposed language requires the importer to "conduct" the listed verification activities; it does not allow for, say, onsite audits to be conducted by an accredited third-party auditor either on behalf of the supplier or the importer, or sampling and testing to be performed by a third-party food certifier (such as NSF International) either on behalf of the supplier or the importer. AHPA strongly opposes a requirement for all verification activities to be conducted by the importer itself. A requirement for importers to conduct on-site audits will be not only extremely expensive but also impractical for many importers due to language barriers, lack of technical expertise, etc. A requirement for importers to conduct food sampling and testing will be inappropriate because (a) many importers will not have in-house laboratories to conduct testing; (b) importers may not have access to the food to pull their own samples (this is especially true prior to import, but may also apply after import depending on the importer's business model); (c) importers may not have the necessary expertise to decide appropriate test methods; and (d) there is no food safety reason to require duplicative test results by the supplier or importer if an appropriate third party has already sampled and tested the food. Furthermore, AHPA therefore proposes the following revision to §

1.506(d)(1) and requests that similar changes be made wherever a requirement "to conduct" is mentioned in the Rule:

> (1) Except as provided in paragraphs (d)(2) and (4) of this section, you must conduct and document (or verify that a party has conducted and documented on behalf of yourself or the foreign supplier) one or more of the supplier verification activities listed in paragraphs (d)(1)(i) through (iv) of this section for each foreign supplier before using or distributing[19] the food and periodically thereafter. You must determine and document which verification activity or activities are appropriate, as well as the frequency with which the activity or activities must be conducted, based on the risk evaluation you conduct for the food and foreign supplier under § 1.505.

AHPA furthermore proposes the following revision to § 1.506(d)(1)(ii):

> (ii) Sampling and testing of the food. (A) Sampling and testing of a food may be conducted by or on behalf of either the importer or the foreign supplier.

With respect to § 1.506(d)(1)(ii), AHPA notes that when outside laboratories are used, the importer will often not have access to information about the dates on which tests were conducted, but only to the dates on which the tests were reported. AHPA proposes that § 1.506(d)(1)(ii) should be revised as follows:

> You must retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted or the results were reported, the results of the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing.

With respect to proposed § 1.506(d)(2), AHPA remains concerned that it is not sufficiently clear what constitutes a hazard "for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans." AHPA has previously provided comments on this point in connection with the originally-proposed Foreign Supplier Verification Program (FSVP) Rule.[20] AHPA looks forward to additional guidance from FDA on this topic, as mentioned in the Preamble to the revised proposed FSVP Rule.

[19] AHPA notes that this says "before using or distributing" rather than "before importing." AHPA strongly supports "before importing or distributing" since certain verification activities (e.g., sampling and testing) may be difficult to execute prior to importation.

[20] See comment # 7.3 in AHPA's previous comments to the originally-proposed FSVP Rule.

With respect to proposed § 1.506(d)(4), AHPA notes that revised proposed § 112.4(a) only applies to produce farms, and that proposed § 112.4(b) only applies to farms that are eligible for the qualified exemption in § 112.5. AHPA believes that non-produce farms (e.g., a farm that grows wheat or grows orris root for use in the manufacture of flavors) both small and large should be provided the same option as farms that are exempted under § 112.4. Based on statements in the Preamble to the FSVP Rule, AHPA believes that FDA does intend to afford the same option with respect to such farms, but fears this is not captured in the proposed language of the Rule because the proposed language is tied specifically to § 112.4. AHPA therefore proposes that § 117.136(c)(4) should be revised as follows:

> If a foreign supplier ~~of a food~~ is a farm that is not subject to the requirements established in part 112 of this chapter in accordance with § 112.4 regarding the food being imported, or is any farm that is not subject to part 112, the importer need not comply with paragraphs (d)(1) and (2) of this section if the importer:

With respect to proposed § 1.506(d)(7), AHPA notes that the Preamble to the revised proposed Rule indicates that foreign supplier verification activities are required even when the importer and the foreign supplier are under shared ownership. AHPA is therefore concerned that the first sentence of § 1.506(d)(7) appears to prohibit the importer from verifying the foreign supplier. AHPA suggests the following for clarification:

> (7) Independence of qualified individuals. A qualified individual who conducts any of the verification activities set forth in paragraph (d) of this section must not have a direct personal financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees from conducting the verification activity, even if the foreign supplier is an affiliate, subsidiary, or parent company of yours.

6.2 Comments regarding § 1.508

With respect to proposed § 1.508, AHPA believes reassessment of the FSVP may be appropriate both when there is new risk information and when there is new hazard information. For example, if new information becomes available to indicate that numerous shipments of Australian asparagus have been found to be adulterated with Malachite Green, AHPA believes the FSVP should be updated with respect to that newly-identified hazard. AHPA therefore suggests the following revision to § 1.508(a)(2):

> You must promptly reassess the effectiveness of your FSVP for a food you import when you become aware of new information about potential risks or hazards associated with the food or foreign supplier of the food.

AHPA also suggests the following revision to § 1.508(b):

Reassessment and implementation of changes. In conducting a reassessment of your FSVP as required by paragraph (a) of this section, you must update your risk evaluation and/or hazard analysis for the food and/or foreign supplier in accordance with § 1.505. If the hazards requiring control or the risks you previously identified change as a result of the reassessment, you must promptly determine whether the verification activities you conduct under § 1.506 or § 1.511(c) need to be changed to comply with that section, and you must promptly implement any such changes. You must document each reassessment you conduct and any resulting changes to your FSVP.

7. Comments regarding dietary supplement provisions

7.1 Comments regarding "dietary supplements" and "dietary supplement components"

AHPA greatly appreciates the options provided in §§ 1.511(a) and (b) for importers of dietary supplements and dietary supplement components subject to Part 111 and importers with customers subject to Part 111 (although see comment 5.4 above regarding objections to the requirement for annual written customer assurances in (b)). AHPA also greatly appreciates the added flexibility provided by the change in § 1.511(c)(4) from "in accordance with Part 111" to "in accordance with processes and procedures that provide the same level of public health protection as those required under part 111."

However, FDA's revised proposal does not provide appropriate flexibility for importers of dietary supplement components that do not qualify under subsection (a) or (b), for example, because the importer does not sell the components directly to dietary supplement manufacturers from whom the importer could obtain the written assurances FDA proposes to require. AHPA requests that FDA revise its FSVP proposal to provide additional flexibility for importers of dietary supplement components that either cannot or do not meet the requirements of § 1.511(a) or (b). Specifically, AHPA requests revisions to § 1.511(c) to permit importers of dietary supplement components to implement modified FSVP programs similar to those proposed for importers of finished dietary supplements.

As discussed in AHPA's previously-submitted comments,[21] dietary supplement components are often manufactured in compliance with cGMPs for active pharmaceutical ingredients (e.g., folic acid USP), with cGMPs for pharmaceutical excipients (e.g., microcrystalline cellulose NF), or with Part 111 (e.g., because the same ingredient is sometimes used as a component subject to further manufacturing and sometimes used directly as a dietary supplement by packaging without further processing).

[21] See comments # 9, 10, and 11 in AHPA's previously -submitted comments to the originally-proposed FSVP Rule.

These cGMP systems provide public health protection at least as high as (if not higher than) those required under Part 117, but are structured in a very different manner.

So long as the cGMPs provide an equivalent level of public health protection to that provided by Part 117 processes and procedures, any of these options should be acceptable for foreign suppliers of dietary supplement components. In such cases, importers need not evaluate dietary supplement component suppliers against Part 117 (as the current language of the regulation would require) to ensure at least the same level of public health protection.

AHPA therefore requests that § 1.511(c) be revised to apply to "Other importers of dietary supplements and dietary supplement components," and that conforming changes be made throughout the subparagraphs of § 1.511(c). In addition, AHPA requests changes to § 1.511(c)(4) as follows:

> (4) Purpose of supplier verification. Your foreign supplier verification activities must provide adequate assurances that your supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter, or, for dietary supplement components that are labeled for use exclusively in the manufacture of dietary supplements rather than conventional foods, your supplier is producing the components in accordance with processes and procedures that provide the same level of public health protection as those required under either part 111, part 117, or parts 210 and 211 of this chapter.

7.2 Additional comments regarding § 1.511

AHPA notes that the provisions of § 1.511(c) are very confusing. In § 1.511(c)(1), importers of dietary supplements are exempted from the risk evaluation specified in § 1.505(a)(1), but then are required to document the risk evaluation (as stated in § 1.505(a)(2)) and reassess the risk evaluation (as stated in § 1.505(b)). Then, § 1.511(c)(2) goes on to require firms to approve foreign suppliers on the basis of the risk evaluation conducted under § 1.505, despite the previous paragraph having exempted the firm from performing such a risk evaluation. AHPA is not sure how to reconcile these statements but urges FDA to be clear and consistent in stating the requirements that firms are expected to meet. To avoid confusion and improve readability, rather than cross-referencing from § 1.511 to sections described above FDA should instead set forth within § 1.511 the requirements that apply to importers of dietary supplements and dietary supplement components.

With respect to § 1.511(c)(5) AHPA suggests the following revisions for the same reasons as in comment 6.1 above:

> (5) Supplier verification activities. For each dietary supplement you import under paragraph (c) of this section, you must conduct (or verify that a party has conducted on behalf of yourself or the foreign supplier) one or more of the verification activities listed in paragraphs (c)(5)(i) through (c)(5)(iv) of this section before using or distributing the dietary supplement and periodically thereafter. You must determine and document which verification activity or activities are appropriate to provide adequate assurances in accordance with paragraph (c)(4) of this section. You must determine and document how frequently the verification activities must be conducted.

With respect to § 1.511(c)(5)(ii)(A), AHPA suggests the following revisions for the same reasons as in comment 6.1 above:

> (A) Sampling and testing of the dietary supplement may be conducted by or on behalf of you or the foreign supplier.

With respect to § 1.511(c)(5)(ii)(B), AHPA notes that when outside laboratories are used, the importer will often not have access to information about the dates on which tests were conducted, but only to the dates on which the tests were reported. AHPA proposes the following revision to § 1.511(c)(5)(ii)(B):

> You must retain documentation of each sampling and testing of a dietary supplement, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted or the results were reported, the results of the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing.

With respect to § 1.511(c)(8), AHPA suggests the following revisions for the same reasons as in comment 6.1 above:

> (8) Independence of qualified individuals conducting verification activities. A qualified individual who conducts any of the verification activities set forth in paragraph (c)(5) of this section must not have a significant, direct financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees from conducting the verification activity, even if the foreign supplier is an affiliate, subsidiary, or parent company of yours.

8. Definition of "very small foreign supplier" and "very small importer"

In the supplemental notice of proposed rulemaking for the proposed FSVP Rule, FDA proposes the following definitions:

> *Very small foreign supplier* means a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $1 million adjusted for inflation.
>
> *Very small importer* means an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $1 million, adjusted for inflation.

AHPA supports setting these dollar value thresholds at $1,000,000 rather than a lower number, and continuing to base them on sales of food rather than all sales.

However, AHPA remains concerned that establishment of a dollar-denominated definition of "very small foreign supplier" will place domestic firms at a disadvantage relative to foreign firms whose sales (a) are often denominated in currencies valued lower than the dollar and (b) often reflect much lower costs for land, labor, environmental compliance, etc. AHPA also has a variety of other concerns about how the definition of "very small foreign supplier" can properly be implemented in view of the complexities AHPA identified in its earlier comments on this point.[22]

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

If FDA cannot substitute an alternate measure then AHPA requests that the sales of foreign very small businesses be calculated using an appropriate measure of purchasing power parity, if there is a straightforward way to do so. AHPA furthermore requests that FDA provide an explanation of precisely how the definition is to be applied given, for example, the fact that some commodities sold by a foreign supplier will have both food and non-food use (e.g., use of raw agricultural commodities for pharmaceuticals, potpourri, perfumery, etc.) and the foreign supplier will often not be able to control whether its downstream customers switch the goods they purchase from one category to the other.

[22] See comment #2 in AHPA's previously-submitted comments to the originally-proposed FSVP Rule.

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

AHPA therefore suggests the following *minimum* changes to the current proposals (better yet would be to add adjustments for purchasing power parity in the foreign supplier definition; best would be to switch to a number-of-employees basis for the foreign supplier definition):

> *Very small foreign supplier* means a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis from year to year) is no more than $1 million adjusted for inflation.
>
> *Very small importer* means an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis from year to year) is no more than $1 million, adjusted for inflation.

9. Comments regarding conflicts of interest

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

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

AHPA requests that, with respect to supplier verification activities conducted by a receiving facility or importer, conflict of interest provisions be limited to circumstances in which the individual employee performing the verification activity has a direct personal financial interest in or financial ties to the supplier (e.g., owns a substantial amount of stock directly in the supplier, or is personally paid directly by the supplier). Circumstances in which, for example, employees of the receiving facility or importer

indirectly own stock in the supplier because they own stock in their own company, which in turn owns an interest in the supplier, or in which the employee is indirectly paid by the supplier because the supplier owns an interest in the receiving facility or importer, should not disqualify the employee from performing the verification activities.

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

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

10. Other comments

10.1 Comments regarding required schedules

AHPA notes that in various places the proposed FSVP Rule requires various activities to be conducted on a specified schedule, such as annually or every two years. AHPA believes such requirements to be overly prescriptive. For example, it is common that a facility will process a particular food only every few years, or that an importer will import a particular food only every few years. In such circumstances a requirement to perform any given activity on an arbitrarily specified schedule is inappropriate, impractical, and excessively burdensome.

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

10.2 Comments regarding "risk"

The FSVP Rule makes extensive use of the term "risk" as well as the term "hazard." AHPA believes that the average reader is unlikely to understand the distinction between these terms, as they are frequently interchanged in common usage.

AHPA therefore suggests the FSVP Rule should include a definition for the word "risk," such as:

> *Risk* is the chance or probability that harm will occur, taking into account both the likelihood that a hazard will occur in the absence of controls to prevent it and the severity of the illness or injury that the hazard might cause.

10.3 Comments regarding "foreign supplier"

AHPA remains concerned that the proposed definition of "foreign supplier" presents significant problems, and suggests it be revised as suggested in comment 9.2 of AHPA's current comments to the GMP-HA/PC Rule as well as in comment # 14.1 in AHPA's previously-submitted comments to the FSVP Rule.

Conclusions

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

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

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

Respectfully submitted,

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

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