Docket No. FDA–2014–N–0053

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE

PROPOSED RULE ON REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS FOR CERTAIN FOODS

February 22, 2021

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Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, importers, 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.

On September 23, 2020, the Food and Drug Administration (FDA or the Agency) issued a Federal Register notice (the September 23 Notice)[1] proposing to establish additional traceability recordkeeping requirements for persons that manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (the Proposed Rule). The Proposed Rule would require these entities to establish and maintain records containing information on critical tracking events in the supply chain for these designated foods, such as growing, shipping, receiving, creating, and transforming the foods, as such terms are generally used in the Proposed Rule. The Agency states in the September 23 Notice that it is issuing the Proposed Rule in accordance with the FDA Food Safety Modernization Act (FSMA)[2] and that the proposed requirements are intended to help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded.

AHPA's members are engaged in the commerce of herbs and herbal products. In the course of this commerce, AHPA members or their suppliers may engage in activities such as growing, shipping, receiving, creating, and transforming foods and food ingredients. AHPA's members therefore have an interest in this regulation, and these comments are submitted on behalf of AHPA's members.

These comments are limited and address only certain of the elements of the Proposed Rule. Absence of comments on any other element or section of the Proposed Rule

[1] 85 Fed. Reg. 59,984 (Sept. 23, 2020).

[2] Pub. Law 111-353, Jan. 4, 2011.

should not be taken to mean that AHPA agrees with such element or section, unless such agreement is specifically stated.

The scope of "herbs (fresh)" in the Food Traceability List should be limited to culinary herbs

Central to the Proposed Rule, and to the eventual final rule, is the creation by FDA of a Food Traceability List (FTL), as the rule will apply to only certain non-exempt businesses that manufacture, process, pack, or hold foods included in the FTL, and it will not apply to such operations in relation to any food that is not included in this list. Creation of this list fulfills the statutory requirement established in Section 204(d)(2)(B) of FSMA.

The September 23 Notice presents a tentative FTL. The Agency states in the September 23 Notice that it developed this tentative list through a semiquantitative risk-ranking model that utilizes multiple data sources to score commodity-hazard pairs according to a set of criteria that address the factors set out in the relevant section of FSMA. The Agency further states it used the results of this model to tentatively identify foods for which additional traceability records will be required in accordance with section 204 of FSMA.

AHPA notes that one of the listed foods in the tentative FTL is identified as "herbs (fresh)," with the following accompanying description: "Includes all types of herbs, such as parsley, cilantro, basil." AHPA further notes, however, that the risk-ranking model used by the Agency to develop the tentative FTL does not appear to support the need for additional traceability records of all plants that are described as or known as "herbs." AHPA believes that FDA did not, in fact, intend to assert that the results of the model identified "all types of herbs" as subject to the additional traceability records envisioned by and required by section 204 of FSMA. Rather, it instead appears that FDA intended to identify only fresh culinary herbs, such as those included in the above-quoted description, for inclusion in the tentative FTL and therefore as subject to the requirements of the rule.

AHPA therefore requests that FDA revise the FTL upon issuance of the final rule to specifically identify "culinary herbs (fresh)."[3]

[3] AHPA has not reviewed in detail the results FDA evaluated in making its determination to include any fresh herbs in the Food Traceability List. Thus, in making this request to appropriately narrow this list to

AHPA's request finds support in the bibliography used to develop the tentative FTL.[4] Where cited sources provide a definition for "herb," the term is consistently defined in a culinary context.[5,6] Where original research was cited on food hazards in herbs, the herbs sampled were usually culinary, including basil, chive, cilantro, coriander, dill, fenugreek, laurel, lemongrass, mint, oregano, rosemary, sage, tarragon, and thyme.[7,8,9,10,11] One cited academic source for industry similarly uses "herbs" as a

cover only culinary herbs, AHPA is offering no opinion as to whether all types of herbs that would be included in a revised "culinary herbs (fresh)" category meet the statutory criteria necessary to subject to them to the final rule.

[4] "Full List of References in the Risk-Ranking Model for Food Tracing (RRM-FT)." August, 2020; available at https://www.fda.gov/media/143495/download, accessed 2/10/21.

[5] For example, "…the dried leaves of aromatic plants used to impart flavour and odour to foods with, sometimes, the addition of colour. The leaves are commonly traded separately from the plant stems and leaf stalks." Fedoruk, A. (2011). Development of a quantitative microbial risk assessment model for foodborne pathogens in herbs and spices. The University of Guelph. (quoting Peter, K. V. (2001). Handbook of herbs and spices. Boca Raton, Fla.: Cambridge: CRC Press; Woodhead.)

[6] See, for example, citing an ISO definition, "…natural plants, vegetable products or mixtures thereof, used in whole or in ground form, mainly for imparting flavour, aroma and pungency to food, for seasoning of food and beverages, and also act as natural preservatives" Nordin, N., & Selamat, J. (2013). Heavy metals in spices and herbs from wholesale markets in Malaysia. *Food Additives & Contaminants: Part B-Surveillance*, *6*(1), 36-41.

[7] Food Standards Agency. (2004). Microbiological examination of dried spices and herbs from production and retail premises in the United Kingdom, available at http://acmsf.food.gov.uk/sites/default/files/mnt/drupal_data/sources/files/multimedia/pdfs/committee/acm913spices.pdf, accessed 2/10/21.

[8] Hsu, W. Y., Simonne, A., & Jitareerat, P. (2006). Fates of seeded *Escherichia coli* O157:H7 and *Salmonella* on selected fresh culinary herbs during refrigerated storage. *Journal of Food Protection*, *69*(8), 1997-2001.

[9] Mansfield, L., & Forsythe, S. (1996). Collaborative ring-trial of Dynabeads anti-Salmonella for immunomagnetic separation of stressed Salmonella cells from herbs and spices. *International Journal of Food Microbiology*, *29*(1), 41-47.

[10] Reinholds, I., Pugajeva, I., Bavrins, K., Kuckovska, G., & Bartkevics, V. (2017). Mycotoxins, pesticides and toxic metals in commercial spices and herbs. *Food Additives & Contaminants: Part B-Surveillance, 10*(1), 5-14.

[11] Soliman, N. F. (2015). Metals contents in spices and herbs available on the Egyptian market: Assessment of potential human health risk. *Open Conference Proceedings Journal*, *6*, 24-29.

shorthand for "Herbs (fresh culinary)."[12] These sources collectively reflect a widely shared understanding of "herbs" in terms of their culinary use, rather than a broader botanical definition.

AHPA also notes that the term "herb" appears in Federal Food, Drug, and Cosmetic, Act (FD&CA) in defining the term "dietary supplement" to mean, in relevant part, "a product (other than tobacco) … that bears or contains one or more of the following dietary ingredients … an herb or other botanical."[13] The meaning of the word "herb" in this statutory context is clearly much broader than just culinary herbs, and it can be assumed to apply to many hundreds or thousands of botanical ingredients that have uses other than as ingredients that impart flavor, aroma, or color to conventional foods.

In addition, FDA has previously communicated in preamble language its understanding that the term "herb" often has a very broad meaning in a regulatory context. In responding to a request to allow the word "herb" to be used to identify the above-ground portion of a plant used as an ingredient in a dietary supplement, for example, the Agency noted that "the primary definition of the word 'herb' in many dictionaries refers to a type of a plant, i.e., a nonwoody plant whose aerial portion is relatively short lived (only a single growing season in the temperate zone), rather than a part of a plant."[14]

Thus, if the Agency retains the listing for "herbs (fresh)" in the FTL, that term could be misunderstood to apply to many hundreds or thousands of plants. But FDA has no information to support inclusion of such a broad range of plants, and FDA has not identified any data to support identifying such a broad range as "high-risk." The Congress has authorized FDA to establish the requirements for additional traceability recordkeeping under FSMA section 204(d) only for high-risk foods.

[12] University of California, Davis. (2015). Herbs (fresh culinary): Recommendations for maintaining postharvest quality. Postharvest Technology: Maintaining Produce Quality & Safety; available at http://postharvest.ucdavis.edu/Commodity_Resources/Fact_Sheets/Datastores/Vegetables_English/?uid=17&ds=799, accessed 2/10/21.

[13] 21 U.S.C. § 321(ff)(1)(C).

[14] 62 Fed. Reg. 49,826, 49,836 (Sept. 23, 1997).

This issue can be partially resolved by revising the description of the subject foods to "culinary herbs (fresh)," and AHPA repeats here its request that FDA make this change.

Each food listed in the FTL should be described accurately and completely

AHPA recommends and requests that each of the foods identified in the FTL be described in accurate and complete terms to ensure that FDA and the regulated industries will have certainty and agreement as to exactly what foods are included on the FTL and therefore subject to the requirements for additional traceability recordkeeping set forth in the final rule.

The tentative FTL is presented in the Proposed Rule in a table of two columns, identified as "Food traceability list" in column 1 and "Description" in column 2. With regard to the foods included in this table that are plant based or plant derived,[15] AHPA notes that some of the "Descriptions" provided are reasonably clear. For example:

- Cucumbers – "Includes all varieties of cucumbers."
- Peppers – "Includes all varieties of peppers."
- Sprouts – "Includes all varieties of sprouts."
- Tomatoes – "Includes all varieties of tomatoes."
- Fruits and Vegetables (fresh-cut) – "Includes all types of fresh-cut fruits and vegetables."

On the other hand, several of the "Descriptions" in the table provide insufficient information to clearly communicate what is, or is not, within the scope of the category. These include:

- Herbs (fresh) – "Includes all types of herbs, such as parsley, cilantro, basil."
- Leafy greens – "Includes all types of leafy greens, such as lettuce, (e.g., iceberg, leaf and Romaine lettuces), kale, chicory, watercress, chard, arugula, spinach, pak choi, sorrel, collards, and endive."
- Melons – "Includes all types of melons, such as cantaloupe, honeydew, and watermelon."

[15] AHPA is not commenting here on the several listings of non-plant foods included in the tentative FTL.

- Tropical tree fruits – "Includes all types of tropical tree fruit, such as mango, papaya, mamey, guava, lychee, jackfruit, and starfruit."
- Nut butters – "Includes all types of tree nut and peanut butters; does not include soy or seed butters."

AHPA believes that implementing this approach to describing listed foods is likely to lead to confusion as to which specific fresh herbs (or fresh culinary herbs, as AHPA has requested elsewhere in these comments), leafy greens, melons, nut butters, and tropical tree fruits will be subject to the eventual traceability rule and which will not.

AHPA further believes that FDA does not intend to include "all types" of fresh herbs, leafy greens, melons, or tropical tree fruits because FDA does not have a basis for making a determination that "all types" of each of these foods are, in fact, high-risk foods.

For example, while the list of fresh culinary herbs that are high-risk may include the three examples given in the current description (i.e., parsley, cilantro, and basil), AHPA is not aware of any data that suggest that fresh bay leaf, makrut lime leaf, curry leaf, or rosemary leaf, as a limited list of examples, present any significant risks to human health that would be ameliorated through their inclusion on the FTL.

Similarly, AHPA assumes that FDA does not intend to group the fruit of what are commonly called "bitter melon" (*Momordica charantia*) and "winter melon" (*Benincasa hispida*)[16] with other melons on the FTL; neither of these are commonly eaten as a fresh fruit or, to AHPA's knowledge, are expected to present any significant risk to human health that would be ameliorated through inclusion on the FTL.

AHPA also assumes that FDA does not have information that supports identification of many tropical fruits as high-risk foods and that such classification should not be made for fresh, intact bananas or durian, for example, unless FDA has data to support such classification. On the other hand, avocado is a tropical fruit[17] that can harbor *Listeria*[18]

[16] Referred to as "Chinese waxgourd" in 85 Fed. Reg. 48,126 (Aug. 10, 2020).

[17] Although now cultivated in some temperate regions, the avocado tree is native to the tropics and is commonly classified as a tropical fruit by horticulturists. See, for example: Galán Saúco V. 2013. Potential of minor tropical fruits to become important fruit crops. *Acta Hort*. DOI: 10.17660/ActaHortic.2013.975.74.

[18] FDA sampling has found *L. monocytogenes* in avocado fruit and pulp. See https://www.fda.gov/media/119969/download, accessed 2/22/21.

and thus may be appropriate to include on the FTL, but the regulated industry may not recognize that the category “tropical fruit” includes avocado – indeed; much of the public likely considers avocado to be a vegetable rather than a fruit.

With respect to “nut butters,” AHPA notes that FDA has asserted that “coconut” qualifies as a “tree nut” for purposes of the Food Allergen Labeling and Consumer Protection Act of 2004, but in many countries it is not considered a “tree nut” (e.g., based on the fact that it does not meet common definitions of “nut” or grow on “trees”). Thus, if FDA intends “nut butter” to include coconut butter, it should say so explicitly in the list (and have data appropriate to deem it a “high-risk food”).

With respect to “leafy greens,” AHPA believes there are likely various types of food leaves that are sold to consumers in fresh form but for which no data exist to indicate they merit inclusion in the FTL. These may include, for example, Malabar spinach or toon leaf. In addition, it is unclear whether FDA intends “leafy greens” to include foods such as: banana leaf and taro leaf that are used as wrappers for food; foods such as moringa leaf or grape leaf that grow on trees and climbing vines rather than on the ground; or celery when the consumed part is primarily the stalk rather than the leaves, although some leaves are usually included with the stalk when sold at retail.

Finally, AHPA notes that many plants provide more than one culinary ingredient: parsley leaf, seed, and root all have culinary applications, as do the leaf, root, and seed of cilantro (though the seed is generally described as coriander in the United States). This is not an uncommon occurrence in the relationship between plants and the kitchen; other well known examples include: summer squash (blossoms and fruit); Florence fennel (“bulb,” seed, and root); celery (stalk, seed, and root); grape (leaf, seed, and fruit); etc. As a result, merely listing the food name (such as “parsley” or “celery”) without any indication of the plant part does not provide clarity as to the scope of the rule.

AHPA therefore repeats here its suggestion and request that each of the foods identified in the FTL be described in accurate and complete terms. AHPA believes that, ideally, FDA should individually list, with the applicable plant part(s), every fruit, vegetable, and culinary herb that is subject to the rule. This is the best way to provide full transparency to the regulated industry and FDA investigators alike. AHPA notes that FDA should include only foods for which it possesses data to indicate the specific food in question presents high risks that merit inclusion on the FTL.

If FDA declines to provide such lists, then AHPA recommends that FDA expand the language in each category to fully describe the intended subjects, including information such as: the species name(s); the plant part(s); the botanical characteristics (e.g., whether the plant grows on the ground vs. a tree or a climbing vine); and other information as appropriate to provide clear and accurate descriptions.

If FDA does not limit "herbs (fresh)" to culinary herbs it should explicitly exclude herbs used in dietary supplements from the FTL

Should FDA decide that the "herbs (fresh)" category includes herbs used outside a culinary context, FDA should include in the final rule an explicit exemption for herbs used in dietary supplements. The commodity definitions used in the FTL were initially based on the Reportable Food Registry (RFR) commodity definitions.[19] The RFR system is explicitly not intended to cover or include dietary supplements, which have a separate mandatory reporting system.[20, 21] In the development of the final commodity categories used in the risk-ranking model, the herb definition used by the RFR was not modified, and dietary supplements were identified as a separate commodity under the "Meal Replacement / Nutritional Food and Beverages" category.[22] Herbs as defined within the FTL are therefore not inclusive of their use in supplements. Where the RFR was a source of hazard data informing the inclusion of the "herbs (fresh)" commodity, any identified hazard was not related to dietary supplement use. As such, including the hundreds or thousands of herbs used in dietary supplements under "herbs (fresh)" is unsupported by either the commodity definition or the supporting public health evidence.

[19] "Reportable Food Summary Report RFR Commodities Definitions." April 19, 2012; available at https://www.fda.gov/media/78732/download, accessed 2/10/21.

[20] "Reportable Food Registry Annual Report." May, 2016; available at https://www.fda.gov/food/reportable-food-registry-industry/reportable-food-registry-annual-report, accessed 2/10/21.

[21] In addition, dietary supplements are a generally safe class of goods associated with far fewer recalls and serious adverse events than fresh produce, and dietary supplement manufacturers are required under 21 C.F.R. Part 111 to establish specifications for contaminants to prevent adulteration of the finished product and ensure these specifications are met.

[22] "Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223)." August 2020; available at https://www.fda.gov/media/142247/download, accessed 2/10/21.

AHPA supports the exemptions identified in the Proposed Rule

AHPA notes that the Proposed Rule identifies a number of conditions under which certain foods or persons are exempt from the requirements for additional traceability recordkeeping.

AHPA appreciates and supports these exemptions, and AHPA notes that one such exemption is for produce that is rarely consumed raw and that is listed as such in 21 C.F.R. § 112.2(a)(1). AHPA has significant concerns, however, that the list of foods acknowledged as rarely consumed raw in the cited regulation is incomplete and fails to list the majority of produce that is, in fact, rarely consumed raw. AHPA has related concerns regarding the underlying definition of "produce" as applied in that exemption and defined in 21 C.F.R. Part 112 (referred to herein as the "produce safety rule").

AHPA previously submitted comments to FDA in the rulemaking process that led to the final produce safety rule[23] and has recently provided extensive comments on the list of produce rarely consumed raw[24] ("the RCR List"), including comments on the definition of the term "produce" as initially proposed. Several of the points made in these earlier comments are directly germane to the present rulemaking, and the relevant portions of these earlier comments are therefore incorporated by reference in the present comments and are attached here as Addendum 1 and Addendum 2, respectively, below these comments. A short summary follows.

AHPA comments on the produce safety rule (Addendum 1)

- AHPA believes the proposed definitions of "produce," "fruit," and "vegetable" and associated inclusions and exclusions do not accurately capture the range of commodities intended either by Congress or by FDA to fall within the scope of the proposed rule.
- The "produce" definition encompasses a wide variety of non-produce botanical crops used for human consumption, e.g., as or in the production of spices, flavors, colorants, dietary ingredients, and excipients.

[23] Comments of the American Herbal Products Association on Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, November 22, 2013 (as revised and resubmitted on December 27, 2013).

[24] Comments of the American Herbal Products Association on the Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States, January 8, 2021.

AHPA comments on the list of produce rarely consumed raw (Addendum 2)

- Due to the very large number of crops used as food, it will be more practical for FDA to promulgate a positive list of crops subject to the produce safety rule than a negative list of crops exempt from the rule.
- Should FDA decide to maintain the RCR List, the Agency should abandon efforts to create an "exhaustive" list of "produce rarely consumed raw." The Agency should instead provide:
  - (a) A safe harbor list of produce that FDA acknowledges to be rarely consumed raw.
  - (b) A set of clear criteria that FDA and regulated industry can use to determine whether a particular commodity not on the RCR List is nevertheless exempt from the rule.
- If an exhaustive RCR List is maintained, FDA should evaluate a much broader range of crops than just the commodities found in the NHANES/WWEIA dataset, and those that are rarely consumed or rarely consumed raw should be added to the RCR List.

A definition of "growing" should be added to the rule

The Proposed Rule identifies five specific Critical Tracking Events (CTEs) that trigger specific requirements under the rule. AHPA notes that the Agency has defined four of the terms that describe these events (i.e., receiving, transforming, creating and shipping). AHPA further notes, however, that even though the event of growing also triggers regulatory requirements under the rule, the term "growing" is not defined in the Proposed Rule, nor is the term defined in section 201 of the FD&CA.[25]

AHPA therefore requests that the Agency provide a definition for the term "growing" in the final rule.

AHPA observes that, where FDA does not define a regulated term, there is significant potential for confusion or uncertainty. For example, 21 C.F.R. § 111.70[26] requires that

[25] The Proposed Rule at 21 C.F.R. § 1.1310 states, "The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart," and then provides additional applicable definitions.

[26] Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.

specifications be established for the identity, purity, strength, and composition of components used in dietary supplements and also for manufactured finished products. Although the Agency provided "information" to "elaborate on [FDA's] interpretation" of the meanings of these regulatory terms,[27] the rule itself does not define any of these terms. It is AHPA's experience that the absence of clear regulatory definitions continues to lead to uncertainty, nearly 14 years after the issuance of this final rule.

AHPA therefore requests that the Agency prevent similar confusion by defining "growing" in the final rule, and that the definition clarify its limitation to growing of crops for use as food (as opposed to growing the same or similar crops for medicine, agricultural seed or other propagative materials, nursery trade, fresh flower trade, bioremediation, etc.).

Additions to the FTL should have a 2-year effective date

AHPA acknowledges and appreciates that FDA has provided a 2-year effective date following publication of the FTL for all covered entities, which admittedly exceeds the FSMA Section 204(i) requirement that only small companies must receive a 2-year period. This uniform approach to the initial implementation of the rule will prevent conflicts in recordkeeping as required information moves between large and small businesses.

FDA has proposed that, when a food is added to the FTL, it will have a one-year effective date. However, when a food is added to the FTL, it will place entire industries and supply chains under the recordkeeping requirement that have not previously had any need to comply with the requirements for additional traceability recordkeeping. These entities, including small businesses, will need the same amount of time to enter compliance as industry manufacturing, processing, packing, or holding foods on the currently proposed list. AHPA therefore requests that the effective date for new FTL entries be 2 years after the list is updated for all covered entities.

FDA should apply enforcement discretion to foods pending deletion from the FTL

AHPA requests that FDA adopt a policy of enforcement discretion on recordkeeping requirements for foods subject to proposed deletion, other than under circumstances

[27] 72 Fed. Reg. 34,803-34,804 (June 25, 2007).

where necessary to address a "threat to the public health" as per § 1.1455(b)(3) of the proposed rule. Under the proposed rule, any deletion from the FTL will become effective immediately when the list is updated. However, the rule also states that FDA will "publish a notice in the Federal Register stating the proposed changes to the list and the reasons for these changes and requesting information and views on the proposed changes." AHPA believes that FDA would not consider removing a food from the FTL unless the Agency believes it is not a high-risk food. Absent a policy of enforcement discretion, FDA may be in the position of enforcing traceability rule compliance on food products that it no longer considers high-risk.

AHPA does not support a broadening of the requirements for additional traceability to all foods

AHPA notes that in the September 23 Notice the Agency implied that the additional traceability recordkeeping requirements presented in the Proposed Rule might best be extended to all foods, including foods that are not high-risk foods. AHPA disagrees and requests that the Agency refrain from making any regulatory proposal to do so without new and explicit Congressional authority.

The Agency shared its broad vision for broad application of enhanced traceability in the Proposed Rule as follows:

> Ideally, a robust traceability system would provide for traceability of all foods, not just foods on the Food Traceability List. Regardless of the type of food that is the subject of a foodborne illness outbreak investigation, sufficient traceability information is needed to identify the source of an outbreak, expedite the removal of contaminated food from the marketplace, and prevent additional consumer exposures. Although section 204 of FSMA limits recordkeeping requirements to foods on the Food Traceability List, the types of records required to be maintained under the proposed rule could be used by entities in the supply chains of all foods to improve traceability.[28]

This language seems to suggest that all foods are subject to foodborne illness outbreaks, but this is not accurate, and any such assertion or expectation is simply not borne out by facts or experience. In addition, the Agency is by this statement

[28] 85 Fed. Reg. at 59,992 (Sept. 23, 2020).

seemingly rejecting as having no value whatsoever the "one-up one-back" recordkeeping requirement established by the Bioterrorism Act[29] and codified at 21 C.F.R. §§ 1.326 to 1.368.

But the existing "one-up one-back" recordkeeping requirement has been proven effective in circumstances such as the 2007 melamine contamination of pet food, wherein FDA successfully identified the sources of the problem and appropriate recalls were completed. In addition, when passing FSMA, the Congress was quite clear that the current traceability requirements are already sufficiently protective of the public health for foods that are not high-risk foods, and so section 204(d)(7) of FSMA, titled, "No impact on non-high-risk foods," specifically limited the application of the requirements for additional traceability recordkeeping to exclude foods that are not high-risk foods:

> The recordkeeping requirements established under paragraph (1) shall have no effect on foods that are not designated by the Secretary under paragraph (2) as high-risk foods. Foods described in the preceding sentence shall be subject solely to the recordkeeping requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c) and subpart J of part 1 of title 21, Code of Federal Regulations (or any successor regulations).

The September 23 Notice also reports that "[c]omments provided during and after the October 29, 2019, public meeting on the New Era initiative indicated a strong desire for FDA to specify required CTEs (critical tracking events) and KDEs (key data elements) to enable interoperability of tracing procedures among all stakeholders."[30] Such opinions do not, of course, have the force of law, such that any future decision to extend additional traceability recordkeeping requirements to non-high-risk foods will depend on a decision by the Congress to impose additional regulatory costs throughout the food chain, including on segments that present no or quite limited actual risks.

Beyond being unnecessary and outside FDA's legal authority, AHPA notes that it would be largely impossible to implement these traceability requirements throughout the food supply. The nature of the trade of raw agricultural commodities on the world

[29] Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188).

[30] 85 Fed. Reg. at 59,993 (Sept. 23, 2020).

market, in which raw agricultural commodities are consolidated from many different farms and are traded amongst many parties (often outside the U.S.) before further processing, means that identifying the party or parties responsible for many of the designated CTEs will be impractical to accomplish or enforce.

Movement of FTL foods to other locations of the same organization should not be regarded as "shipping"

"Shipping" activities under the rule should not include the movement of listed foods between farms or other locations owned by the same entity or affiliated entities. Where the definitions of "shipping" and "receiving" are parallel, participants in the supply chain have mutually complementary recordkeeping expectations as shippers and receivers under the proposed rule. The definition of "receiving," in which the food is received by a "customer," indicates a change of ownership. The current proposed "shipping" definition states that shipping occurs where food is prepared for transport "from a defined location to another defined location at a different farm, a first receiver, or a subsequent receiver." Under circumstances where the shipped product has a receiver (including a farm owned by a different entity), these definitions have an identical scope. The proposed definition arguably covers shipping from one farm to another farm with the same ownership (e.g., where the washing operation is on a different farm), and thus the proposed definition of "shipping" would seem to include such physical transfers that do not involve a change in ownership.

Under these circumstances, if a farm moves a lot of food on the FTL from one location to another, the farm would be required to create, keep, and, per the rule, send to itself as a recipient, records about the lot. While co-owned farms may choose to treat such movements as shipping activities and maintain the associated lot numbers and records for the purpose of, for example, limiting the scope of potential future recalls, such records are not necessary to protect the public health and therefore should be left to the company's discretion.

The practical difficulties created by this requirement are worsened by the definition of "farm," taken from 21 C.F.R. § 1.328. The farm definition does not clearly indicate the circumstances in which an operation is considered one or multiple farms, defining a farm as "an operation under one management in one general (but not necessarily contiguous) physical location." While this ambiguity is a possibly understandable necessity for the purpose of applying the farm definition in other regulatory settings, it makes the distinction between intra-farm and inter-farm movement of food highly

arbitrary. The confusion and enforcement ambiguities created by these factors are resolved entirely, with no increase in tracing risk, by excluding movement of FTL foods to other locations of the same organization from the “shipping” definition.

FDA should consider issuance of a supplemental proposed rule

AHPA has identified numerous specific concerns with the Proposed Rule in these comments and has made several requests or recommendations for revisions. In addition, AHPA understands that other commenters have provided similar comments on parts of the Proposed Rule not addressed herein. Fundamental revisions to the rule may therefore be required to implement the requirements for additional traceability recordkeeping in a manner that will both be clear to the many industry segments that will need to comply with these new requirements and will meet the intended purpose to protect consumers from contaminated food.

AHPA is aware that numerous other trade associations that represent various segments of the food industry have requested that FDA issue a supplemental proposed rule as part of this rulemaking. AHPA respectfully joins that request and agrees that the resulting final rule is very likely to differ substantially from the Proposed Rule and so will necessitate a new period of notice and comment. AHPA also agrees that issuing a supplemental proposed rule will allow FDA to engage further with stakeholders to understand better ways in which the proposed rule could be simplified to achieve its public health goals.

Summary

AHPA greatly appreciates the opportunity to present comments on FDA's proposed requirements for additional traceability records for certain foods. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,

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ADDENDA

Addendum 1

Excerpt (15 pages following) from:

Comments of the American Herbal Products Association on Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, November 22, 2013 (as revised and resubmitted on December 27, 2013); Section 7 (pages 33-46): “Comments regarding the definitions of ‘produce,’ ‘fruit,’ and ‘vegetable’ and the proposed scope of the rule.”

Addendum 2

Excerpt (10 pages following) from:

Comments of the American Herbal Products Association on the Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States, January 8, 2021 (pages 6-14).

Addendum 1

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Comments of the American Herbal Products Association on Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, November 22, 2013 (as revised and resubmitted on December 27, 2013); Section 7 (pages 33-46): “Comments regarding the definitions of ‘produce,’ ‘fruit,’ and ‘vegetable’ and the proposed scope of the rule.”

DOCKET NO. FDA–2011–N–0921

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

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

November 22, 2013

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

7.1 Overview of AHPA's comments

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

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

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

AHPA makes various recommendations to improve the definitions.

7.2 Current proposed definitions and scope of the rule

FDA has proposed the following definitions:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7.4 Problems with the proposed definitions and scope

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

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

7.5 Detailed comments on the definition

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

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

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

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

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

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

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

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

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

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

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

7.6 Further comments regarding exclusions

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

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

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

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

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

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

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

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

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

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

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

[59] For brevity, AHPA uses the term "non-produce botanicals" to refer to all botanical RACs which are intended for human consumption but are not produce, i.e. grains, dry legumes, algae, and those used as or for dietary ingredients, spices, colorants, flavorings, and excipients.

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

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

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

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

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

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

7.8 Wildcrafted RACs should be excluded from the rule

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

AHPA recommends the following revisions to § 112.1:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Addendum 2

Excerpt (10 pages following) from:

Comments of the American Herbal Products Association on the
Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States, January 8, 2021 (pages 6-14).

Docket No. FDA–2020–N–1119

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE

REQUEST FOR INFORMATION AND COMMENTS ON CONSUMPTION OF CERTAIN UNCOMMON PRODUCE COMMODITIES IN THE UNITED STATES

January 8, 2021

Problems created by the use of an affirmative RCR List with an expansive definition of "produce"

FDA describes FSMA as "the largest overhaul of the nation's food safety system since the Federal Food, Drug and Cosmetics Act of 1938."[8] In the decade since its enactment the Agency has finalized seven federal regulations that establish "risk-based preventive measures"[9] that are now required throughout the food chain, and these dual emphases on risk and prevention are evident in the language of the statute itself.

Section 419 of the FD&CA, as created by Section 105(a) of FSMA, clearly articulated that the envisioned standards authorized by this section of the law should minimize harm to small businesses, including small farms, "that produce and harvest those types of fruits and vegetables that are raw agricultural commodities that [FDA, acting on behalf of] the Secretary [Health and Human Services] has determined are low risk and do not present a risk of serious adverse health consequences or death," such that the Congress provided the option to "determine not to include production and harvesting of such fruits and vegetables" in the implementing regulation, or to otherwise "modify the applicable requirements of [such] regulations."[10]

In promulgating 21 C.F.R. Part 112, FDA sought to implement these elements of the law in part through creation of an "exhaustive" list of produce "rarely consumed raw" (the RCR List) and establishing that produce included on this list is exempted from the scope of the rule. However, the RCR List contains only 34 produce commodities and is therefore hopelessly incomplete. This is especially true in view of the overly broad scope of "produce" as defined in the rule (as discussed in greater length later in these comments), but it remains true even if the definition of "produce" were narrowed as recommended in our comments below.

A truly "exhaustive" list of fruits and vegetables that are "rarely consumed raw" would include thousands of crops. For example, merely with respect to dry legumes, the U.S.

[8] "The FDA Food Safety Modernization Act at 10: Reflecting on Our Progress and the Path Forward." January 4, 2021. Accessed January 5, 2021 at https://www.fda.gov/news-events/fda-voices/fda-food-safety-modernization-act-10-reflecting-our-progress-and-path-forward.

[9] Ibid.

[10] Public Law 111-353 (Jan. 4, 2011) at 124 Stat. 3900.

Dry Bean Council lists 14 species/cultivars; Cook's Thesaurus lists 43 species/cultivars; and the Bean Institute lists 11 species/cultivars and references hundreds more.[11] In contrast, the RCR List includes only 8 types of dried legumes. The fact that these many other varieties of dried legumes apparently do not appear in the datasets FDA used to create the RCR List does not justify their exclusion from the list, and there is no other logic or justification for the exclusion of the many hundreds of other dried legumes from the list – it is no more possible to eat a raw dry rebosero bean, dry scarlet runner bean, or dry green pea (all excluded from the RCR List) than it is to eat a raw dry lentil (included on the RCR List).

Beyond the problems inherent in trying to list individual species or cultivars (as opposed to listing a category like "dry legumes"), it is simply a fact that the food world contains thousands of different food crops, and FDA does not have the resources to properly evaluate which ones are consumed raw. For example, Kew Royal Botanic Gardens lists 7,039 species of edible plants (not including fungi).[12]

These problems are exacerbated by the fact that FDA has defined "produce" to include virtually every botanical crop that enters the food supply, even if they are only ever consumed in a highly processed form far removed from what normally constitutes "produce." As a result, growers of everything from cotton to orris root are burdened by the rule, at least insofar as recordkeeping goes (e.g., records required to prove that their farm and/or crops are exempt from the most onerous elements of the rule). This is not an efficient use of industry's resources, nor would it be an efficient use of FDA's time to inspect such records.

AHPA notes that U.S. agriculture is diversifying, with new farming systems (e.g., agroforestry[13]) and new specialty crops (e.g., crosnes, oca, pea shoots) becoming more popular. These changes are critical to improving human nutrition, climate resilience, environmental balance, and farm economics.

[11] https://usdrybeans.com/industry/bean-varieties/; http://www.foodsubs.com/Beans.html; and https://beaninstitute.com/beans-around-the-world/, all accessed January 6, 2021.

[12] "State of the World's Plants and Fungi," Kew Royal Botanic Gardens, 2020.

[13] In 2017 the U.S. Census of Agriculture found 30,853 farms using agroforestry. USDA considers agroforestry an important and growing element of U.S. agriculture; see https://www.fs.usda.gov/nac/about/why-agroforestry.php, accessed on January 6, 2021.

AHPA is concerned that the overly-broad current scope of Part 112 stands to significantly impede these developments. For example, it's unclear how agroforestry operations can comply with elements of Part 112 such as the requirement to exclude animals; furthermore, such animal exclusion would obviate some of the main benefits of agroforestry, which include providing habitat and wildlife corridors.

With respect to new specialty produce crops, AHPA notes that such crops are by their nature rarely consumed in any form (whether raw or cooked) and are grown by relatively few growers in relatively small volumes.[14] AHPA further notes that FSMA in both Section 103 and Section 105 used language permitting or directing FDA to provide regulatory relief for low risk crops and activities.

Finally, AHPA notes that perceptions that regulations are impractical, illogical or unnecessary can lead to dismissive views of regulatory agencies. These are outcomes that regulators should seek to avoid. AHPA's recommendations herein are intended to help achieve that goal without compromising the safety of the U.S. food supply.

In view of the above, AHPA encourages FDA to consider alternatives to merely expanding the RCR List as proposed in its most recent request for industry input. Instead, FDA should consider additional changes aimed at tailoring the scope of the rule to areas where actual food safety hazards exist and improving transparency surrounding the scope of the rule. AHPA makes several suggestions below.

FDA should replace the RCR List with an exhaustive list of all produce subject to the Produce Safety Regulation

Due to the very large number of crops used as food, it will be far easier and more practical for FDA to promulgate a positive list of crops subject to the Produce Safety Regulation than to promulgate a negative list of crops exempt from the rule. Therefore, FDA should remove the RCR List from 21 C.F.R. Part 112 and instead expand the list of covered produce identified in § 112.1(b)(1) to be comprehensive.

[14] Although the cash value of any individual specialty produce crop may be relatively low, the aggregate revenue from all crops grown by a specialty produce farm can be well above the threshold that triggers a requirement to comply with Part 112. Therefore, it cannot be assumed that farms growing these crops will qualify for exemptions based on low annual sales volumes.

The crops to include on this positive list can be derived from data from the NHANES/WWEIA datasets, using criteria such as: (a) at least 1% of the weighted number of survey respondents reported consuming the commodity in any form; (b) the commodity is consumed uncooked by more than 0.1% of population; and (c) the commodity is consumed uncooked on more than 0.1% of eating occasions. AHPA suggests that any crop meeting all three criteria should be included on the positive list and that the positive list should be automatically updated regularly based on the most recent NHANES/WWEIA data.

If appropriate, FDA could also reference the USDA Agricultural Research Service Food and Nutrient Database for Dietary Studies (FNDDS) and EPA's Food Commodity Intake Database (FCID); any crops specifically identified as foods or ingredients in FNDDS or identified as commodities in FCID should be added to the RCR List at § 112.1(b)(1) unless there are specific factors that preclude raw consumption (e.g., inedibility due to texture, unpalatable flavor, or presence of toxins). The positive list should be automatically updated regularly based on the most recent FNDDS or FCID data.

AHPA believes that produce commodities not included in the NHANES/WWEIA, FNDDS, and FCID datasets are not likely to be commonly consumed in the U.S., and especially not in raw or unprocessed form.[15] When American dietary patterns change, these surveys are updated correspondingly.[16]

[15] AHPA recognizes that FDA has previously stated that these lists "may not necessarily reflect or fully reflect current or emerging patterns of forms in which produce is consumed or new dietary trends toward consumption of raw foods." However, FDA also stated "The identification of a commodity on this [RCR] list does not mean that the produce is never eaten raw or that it is not eaten raw, typically or occasionally, in specific regions of the United States (or among specific ethnic communities in the United States)." 80 Fed. Reg. 74,387 (Nov. 27, 2015). No matter what data source FDA uses or what regulation FDA promulgates, there is always some low risk that some small population of persons may at some point be exposed to a food safety risk. The elimination of all risk is not a feasible goal.

[16] AHPA notes that, when the regulatory status of a crop changes from being outside the scope of Part 112 to being included in Part 112, the affected farmers must be given an adequate period of time to bring their operations into compliance with the rule. This period of time should generally be commensurate with the time allowed for farmers to initially come into compliance after the original Part 112 regulation was promulgated.

If FDA maintains the RCR List as part of the rule, it should not be considered "exhaustive"

Should FDA decide to maintain the RCR List as part of the Produce Safety Regulation, FDA should abandon attempts to create an "exhaustive" list of "produce rarely consumed raw" but rather provide (a) a safe-harbor list of produce that FDA acknowledges to be rarely consumed raw, plus (b) a set of clear criteria that FDA and the regulated industry can use to determine whether a particular commodity not included on the RCR List is nevertheless exempt from the rule.

AHPA recognizes that FDA considered and rejected the idea of not providing an "exhaustive" list of RCR crops in the regulation.[17] Specifically, FDA rejected "the possibility of providing a list of rarely consumed raw commodities in guidance without establishing any specific criteria for what 'rarely consumed raw' means in the regulation." AHPA therefore proposes that the regulation – in addition to presenting a specified list of RCR crops – should also establish clear criteria for what "rarely consumed raw" means, as follows.

1) **FDA should acknowledge that if a crop is rarely consumed in the U.S. then this necessarily means the crop is rarely consumed raw.**
   As noted elsewhere in these comments, between issuance of the Proposed Rule in 2013 and the Final Rule in 2015, FDA added a third criterion in its determination of the identity of produce commodities for inclusion in the RCR List. Specifically, FDA determined for the final rulemaking that it would not include a commodity on the RCR List unless at least 1% of the weighted number of survey respondents in the referenced datasets reported consuming the commodity in any form.

   In other words, by application of this added third criterion, FDA does not consider a produce commodity that is rarely consumed in the United States, by less than 1% of the population, to be rarely consumed raw. In AHPA's view, this is illogical and has yielded a rule that burdens many farmers with no corresponding public health benefit to justify the burden.

[17] 80 Fed. Reg. 74,387 (Nov. 27, 2015).

By applying the expanded criteria, FDA identified 34 produce commodities for inclusion in the final RCR List at § 112.2(a)(1). This final list of 34 commodities includes 21 of the those in the Proposed RCR List (i.e., 15 of the commodities in the original list were removed) and also includes 13 commodities that were not in the Proposed RCR List. The Agency reported in the Final Rule that many of the 15 commodities removed from the Proposed RCR List were removed due to application of this new third criterion, and the Agency reported that it removed others because there is no consumption reported in the NHANES/WWEIA database.

Specifically, the following produce commodities were found by FDA to not meet the third criterion since the data referenced indicated each of these are eaten by less than one percent of Americans, irrespective of whether these are eaten raw or cooked: artichokes (globe); black-eyed peas; bok choy; parsnips; plantains; rhubarb; rutabaga; taro (or dasheen) corm and leaves; turnip roots and tops; and yam. In addition, arrowhead, arrowroot, and crabapple were not found in the NHANES/WWEIA database and were therefore removed from the Proposed RCR List. Each of these commodities are therefore excluded from the final RCR List at § 112.2(a)(1), and each is therefore now considered to be a covered commodity under the Produce Safety Regulation.[18]

AHPA strongly encourages FDA to reconsider the illogical assumption that a produce commodity must be consumed by more than 1% of the U.S. population in order to be considered rarely consumed raw. AHPA believes FDA should instead take the opposite position such that any produce commodity that is rarely consumed in the U.S. should automatically be considered to be rarely consumed raw, unless that commodity is both (a) known to be not-infrequently

[18] As one example, artichokes (globe) were included in the proposed RCR List but are excluded from the final RCR List. The decision to remove this produce commodity was based only on the fact that in the NHANES/WWEIA datasets reports it is consumed by less than 1% of Americans. With this decision, the 215 farms that produce globe artichokes in California (unless they qualify for an exemption based on small sales volume) are now covered by the Produce Safety Regulation, even though this is clearly a low risk produce commodity that is rarely consumed raw. (Farm numbers as reported for “Artichokes (excluding Jerusalem)” in USDA National Agricultural Statistic Service, Census of Agriculture: 2017 Census Volume 1, Chapter 1: State Level Data: California. Table 36. Vegetables, Potatoes, and Melons Harvested for Sale: 2017 and 2012. Accessed January 8, 2021 at https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_State_Level/California/st06_1_0036_0036.pdf.)

consumed raw and (b) known to present a risk of serious adverse health consequences from raw consumption and the risk is of a type that would be controlled through application of Part 112.

As one way to address this, AHPA recommends that FDA establish a clear criterion based on publicly available data to allow members of the public readily to determine which crops are rarely consumed raw even if they are not explicitly included in the RCR List.

In developing the RCR List, FDA decided not to use the USDA Agricultural Research Service Food and Nutrient Database for Dietary Studies (FNDDS). AHPA recognizes FDA's justification for choosing not to use this database to perform a quantitative analysis of raw food consumption. However, one advantage of the FNDDS is that its list of foods and ingredients is updated regularly to reflect current consumption patterns. The FNDDS and FCID food and commodity listings are also both publicly accessible. AHPA therefore recommends that FDA determine that crops not specifically identified as foods or ingredients in the most recent release of the FNDDS, nor identified as commodities in the FCID, should be considered rarely consumed and therefore, rarely consumed raw, even if those crops are not explicitly included in the current RCR List.[19]

2) **FDA should establish criteria by which crops that are not rarely consumed will nevertheless be considered rarely consumed raw**
With respect to crops that are not, according to the criterion suggested above, rarely consumed in the U.S. (i.e., commodities specifically identified as foods or ingredients in the most recent release of the FNDDS or identified as

[19] An alternate approach could be to establish a threshold in the NHANES/WWEIA data below which a commodity is considered to be rarely consumed and therefore, also, rarely consumed raw. For example, the rule could state that, if less than X% of the weighted number of survey respondents reported consuming the commodity in any form, then this commodity is exempt from the rule by virtue of being rarely consumed and therefore, also, rarely consumed raw and outside the scope of the rule. “X%” for this purpose might appropriately be set in the range of 0.1% to 1%. However, AHPA understands from comments made by FDA that determining the weighted number of survey respondents requires complex statistical analyses and specialized software. These complexities would prevent such an approach from being useful to the average member of the regulated industry. AHPA has therefore made recommendations based on the FNDDS and FCID listings.

commodities in the FCID), FDA should establish additional threshold(s) below which the crop is automatically considered "rarely consumed raw."

For example, the rule could state that if, in the most recent NHANES/WWEIA dataset, a commodity will be considered "rarely consumed raw" and therefore outside the scope of the rule if any of the below apply.[20]

i. The commodity is reported as both (a) consumed uncooked by less than 0.1% of population and (b) consumed uncooked on less than 0.1% of eating occasions; or
ii. There is no category for the "uncooked" cooked form of the commodity in the dataset; or
iii. The consumption of the commodity is reported in the NHANES/WWEIA dataset not as raw agricultural commodity, but only in the form of processed foods.

AHPA believes the establishment of the above criteria for evaluating whether a particular commodity qualifies as "rarely consumed raw," even when it is not explicitly included in the RCR List, would be extremely valuable for both FDA and the regulated industry, with no diminution in protection of public health. Providing a clear mechanism to evaluate the regulatory status of particular crops through examination of publicly available data will enable regulators and farmers alike to focus their resources where they are most needed to protect public health, and it will eliminate a significant part of the excessive burdens imposed by the current Produce Safety Regulation. FDA should strive to eliminate any and all burdens that are not justified by actual public health risks.

FDA should evaluate a broader range of crops for inclusion on the RCR List

If the RCR List is maintained as part of the rule, AHPA recommends that, in order to ease unnecessary burdens on industry, FDA should evaluate a much broader range of crops than just the commodities found in the NHANES/WWEIA dataset, and that those which are rarely consumed or rarely consumed raw should be added to the RCR List.

[20] These proposed criteria mirror much of FDA's own analysis by which the original RCR list was created. See 80 Fed. Reg. 74,387 (Nov. 27, 2015).

AHPA notes that other Federal agencies have compiled lists of botanical crops and food ingredients that are relevant to other agencies' regulations. These other lists include: the Food and Nutrient Database for Dietary Studies (FNDDS) maintained by USDA's Agricultural Research Service; the many minor and specialty crops included in Crop Group 25 (Herb Group) and Crop Group 26 (Spice Group) codified by EPA at 40 C.F.R. §§ 180.41(c)(34) and 180.41(c)(35), respectively; and the list of Common Cultivars and Common Food Crops maintained by USDA's Animal and Plant Health Inspection Service.[21]

AHPA believes that these lists of food crops should be evaluated by FDA according to standards equivalent to the NHANES/WWEIA dataset threshold criteria suggested in the section above, and any crop meeting the criteria should be explicitly added to the RCR List.

In AHPA's view, such amendments – especially in combination with adjustments to the definition of "produce" – would appropriately focus the regulation on the Congressional intent of Section 105(a) of FSMA in creating Section 419 of the FD&CA.

The approach that FDA has taken with the currently very limited RCR List has resulted in the Produce Safety Regulation being applicable to all operations that produce or harvest any "produce," as currently defined to include every botanical crop that may ever enter the food supply, except for the very few (34) commodities identified in the list. Unless the Agency refines "produce" as requested elsewhere in these comments, and also significantly expands the RCR List, either based on data and information received in response to the August 10 Notice or through other processes, the Produce Safety Regulation will continue to be applicable to far more farm operations than is needed to protect public health. AHPA encourages FDA to rethink its current approach so that this rule applies as exclusively as possible to just those operations that produce or harvest produce commodities that are not, in fact, low risk commodities.

[21] Accessible as of January 6, 2021 at https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/lacey-act/declaration/common-cultivars-food-crops.