NATIONAL SUSTAINABLE AGRICULTURE COALITION

May 13, 2020

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852.

Re: Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds Guidance for Industry, Docket No. FDA-2019-D-1266-0003

The National Sustainable Agriculture Coalition (NSAC) is an alliance of grassroots organizations[1] from across the country that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities. NSAC member groups work directly with small and mid-sized family farmers, sustainable and organic farmers, and on-farm food processors who conduct activities within the scope of the Food Safety Modernization Act (FSMA) rules, including the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule) and the Preventive Controls for Human Food. NSAC members across the country also provide food safety training and technical assistance for farmers and food businesses.

[1] Agriculture and Land-Based Training Association Salinas, CA; Alternative Energy Resources Organization Helena, MT; CCOF Santa Cruz, CA; California FarmLink Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture) Hereford, TX; Catholic Rural Life St Paul, MN; Center for Rural Affairs Lyons, NE; Clagett Farm/Chesapeake Bay Foundation Upper Marlboro, MD; Community Alliance with Family Farmers Davis, CA; Community Involved in Sustaining Agriculture South Deerfield, MA; Dakota Rural Action Brookings, SD; Delta Land and Community, Inc. Almyra, AR; Ecological Farming Association Soquel, CA; Farmer-Veteran Coalition Davis, CA; Florida Organic Growers Gainesville, FL; FoodCorps, OR; GrassWorks New Holstein, WI; Hmong National Development, Inc. St Paul, MN and Washington, DC; Illinois Stewardship Alliance Springfield, IL; Institute for Agriculture and Trade Policy Minneapolis, MN; Interfaith Sustainable Food Collaborative Sebastopol, CA; Iowa Natural Heritage Foundation Des Moines, IA; Izaak Walton League of America St. Paul, MN/Gaithersburg, MD; Kansas Rural Center Topeka, KS; The Kerr Center for Sustainable Agriculture Poteau, OK; Land Stewardship Project Minneapolis, MN; LiveWell Colorado Denver, CO; MAFO St Cloud, MN; Michael Fields Agricultural Institute East Troy, WI; Michigan Food & Farming Systems – MIFFS East Lansing, MI; Michigan Organic Food and Farm Alliance Lansing, MI; Midwest Organic and Sustainable Education Service Spring Valley, WI; Missouri Coalition for the Environment St. Louis, MO; Montana Organic Association Eureka, MT; The National Center for Appropriate Technology Butte, MT; National Center for Frontier Communities Silver City, NM; National Hmong American Farmers Fresno, CA; Nebraska Sustainable Agriculture Society Ceresco, NE; Northeast Organic Dairy Producers Alliance Deerfield, MA; Northern Plains Sustainable Agriculture Society LaMoure, ND; Northwest Center for Alternatives to Pesticides Eugene, OR; Ohio Ecological Food & Farm Association Columbus, OH; Oregon Tilth Corvallis, OR; Organic Farming Research Foundation Santa Cruz, CA; Organic Seed Alliance Port Townsend, WA; Rural Advancement Foundation International – USA Pittsboro, NC; Union of Concerned Scientists Food and Environment Program Cambridge, MA; Virginia Association for Biological Farming Lexington, VA; Wild Farm Alliance Watsonville, CA; Women, Food, and Agriculture Network Ames, IA.

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NSAC members have engaged in the Food Safety Modernization Act (FSMA) process at the legislative, rulemaking, and implementation stages, and we are thankful for our continued partnership with the FDA throughout this process to ensure the implementation of FSMA is successful and supportive of sustainable, organic, historically underserved, small-scale, and diversified farm operations. We appreciate the opportunity to discuss continued changes to the Produce Safety Rule over the last several months, including a meeting on the rarely consumed raw list.

NSAC thanks FDA for the time and effort put into the Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds; Guidance for Industry ("Enforcement Policy"). We welcome the opportunity to submit comments on this, and look forward to continuing to work with FDA around the implementation of a new process for determining whether or not an item should be on the Produce Safety Rule rarely consumed raw list.

We understand FDA is determining whether or not certain covered commodities—hops, wine grapes, pulse crops, and almonds—should be exempt from the requirements of the Produce Safety Rule. In addition to commodities addressed in the Enforcement Policy, FDA must (a) establish a clear, transparent, and practical path for moving or adding produce items to the rarely consumed raw list; (b) provide clarity for products not explicitly listed on the covered produce list, such as bitter melon and opo (squash); (c) review items currently on the covered produce list to determine if any items need to be moved to the rarely consumed raw list (e.g., taro root), and; (d) conduct further research on certain products, like mustard greens, bok choy, and fava (faba) beans, to determine if they should be moved to the rarely consumed raw list. We encourage FDA to reconsider the classification of certain products, including, but not limited to, taro root, opo (squash), bitter melon, fava (faba) beans, mustard greens, and bok choy, based on the following justifications.

To accomplish this, we put forward the following recommendations and information to assist FDA with their Enforcement Policy and a future process for determining what is on the rarely consumed raw list. Thank you for considering these recommendations.

Sincerely,

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1. FDA must establish a clear, transparent, and practical path for moving, removing or adding produce to the rarely consumed raw list

FDA should develop formal policy and public resources for determining whether or not a produce item should be on the rarely consumed raw list. In the preamble to the final Produce Safety Rule, FDA admitted there are flaws with the rarely consumed raw list and the National Health and Nutrition Examination Survey/What We Eat in America survey data used to create the list.[2] Therefore, FDA should use additional information instead of using only one national survey to create the rarely consumed raw list. FDA should develop, through draft and final Guidance, a policy on how FDA will consider and address the rarely consumed raw list gaps. The Guidance should first be released in draft form, and it should be submitted for public comment before a final guidance document is released.

FDA should establish a clear process for requests regarding the evaluation of items on the covered produce list and the rarely consumed raw list. FDA should include in the Guidance document a description of the process for any produce items submitted for addition to the rarely consumed raw list by FDA or other stakeholders. This process must include how FDA will communicate their final decision for each produce item to the public. FDA should also provide opportunities to gather input and feedback from historically underserved communities and farmers of color to ensure the rarely consumed raw and covered produce lists accurately represent all communities.

The draft Guidance should also describe and give examples of what types of information farmers and organizations can submit to FDA for them to consider adding a produce item to the rarely consumed raw list. In addition to the survey data, further research should be conducted on each item using realistic methods to determine each product's classification. Methods to determine product classification can include links to foodborne illness outbreaks, actual food safety risks, and recipes that showcase whether a product is commonly cooked or consumed raw.

FDA should also create a public-facing approach that will provide farmers with adequate notice on when the produce they grow is officially listed under the covered produce list. For example, in the Draft Guidance on the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption document on pages 9-10 FDA added produce to the covered produce list.[3] FDA failed to provide an explanation about how they concluded these additional crops should be officially added to the covered produce list. Through a clear, transparent process, farmers can prepare more adequately for compliance with the Produce Safety Rule.

Until FDA has developed this Guidance, we recommend FDA add taro root, bitter melon, and opo (squash) to the Enforcement Policy until each item has been researched and a final designation has

[2] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. at 74387, 74390.
[3] https://www.fda.gov/media/117414/download

been determined based on a true science-based approach. FDA should take immediate action to research and determine whether fava (faba) beans, bok choy, and mustard greens should be added to the Enforcement Policy as well. FDA should also conduct robust research into the classification of several other produce items, including, but not limited to: Luffa gourd, squash; Hairy melon, squash; bottle gourd, squash; snake gourd, squash; yu choy; Choy sum; Gai choy; Nai yow choy; Gai lan; tat soi; Lablab (hyacinth) bean; guar, bean; mountain potato (yama imo); okra leaf; cassava leaf; yam leaf; pumpkin tips; pumpkin flowers; chrysanthemum leaves (tong ho); amaranth; black nightshade; Zĭsū (perilla); Shanghai Bok Choy (green stem); chayote; chayote tips; pigeon pea; taro root; burdock; Japanese yam; Malabar (Ceylon) spinach; Chinese celery; water spinach (ong choy); and garlic chives (yellow and green).[4]

FDA should also take into consideration how frequently certain items are actually consumed in the U.S. In the sections below, we highlight six products (bok choy, mustard greens, taro root, fava (faba) beans, bitter melon, and opo (squash)) that are not commonly consumed or distributed in the United States, so the risk of consumption is generally low. These six products are typically distributed and consumed by particular cultures and communities that have extensive knowledge on preparation and cooking methods for each item. Because the risk of accidental and/or inappropriate consumption of these items is low, we believe moving these items to the Enforcement Policy until FDA conducts more research and assigns a final designation is an appropriate course of action.

Recommendation: FDA should develop draft Guidance for public comment that describes a realistic process for producers and organizations to submit information and documentation as to why an item should be moved, removed, or added to the rarely consumed raw list. FDA should also add crops to the Enforcement Policy where extensive evidence already exists that these products are rarely consumed raw.

2. FDA must add crops to the rarely consumed raw list that are rarely consumed raw and are not explicitly listed in the Produce Safety Rule.

FDA should add crops to the rarely consumed raw list that are not frequently consumed raw, and are not listed in the Produce Safety Rule. We acknowledge that all produce is covered by the rule, unless it is excluded under section 112.2 (the rarely consumed raw list) of the Produce Safety Rule. However, there are several crops that are not on either list that should be added to the rarely consumed raw list, including, but not limited to, bitter melon and opo (squash).

In the preamble to the final rule, FDA admitted there are flaws with the rarely consumed raw list and the survey data that FDA used to create this list.[5] FDA acknowledged the list fails to include

[4] Thank you to Community Alliance with Family Farmers (CAFF) and the University of California Extension Small Farms team for gathering a comprehensive list from growers on the items where additional clarity to the rarely consumed raw list would be welcomed.

[5] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. at 74387, 74390.

certain cultures and communities, as well as several different types of produce, but did not address how FDA will ensure these populations' crops are added to the rarely consumed raw list. We request FDA revise the rarely consumed raw list and conduct the necessary research to ensure all cultural or traditional crops are included in their decision.

As FDA revisits section 112.2 of the Produce Safety Rule and issues Enforcement Policy for operations growing, harvesting, packing, or holding hops, wine grapes, pulse crops, and almonds, we request FDA adds bitter melon and opo (squash) to the Enforcement Policy list.

Bitter melon and opo (squash) should be added to the Enforcement Policy and the rarely consumed raw list because there is a low or very low food safety risk associated with the human consumption of these items. CDC's List of Multistate foodborne illness outbreak investigations does not implicate any of the above food items in a multistate outbreak from 2006 to 2020.[6] FDA's Enforcement Reports from June 8, 2012 through March 1, 2020 contain no finding of foodborne pathogen concerns for bitter melon and opo (squash).[7] FDA's recent list of recall notifications also do not indicate that these produce items have been recalled in recent years.[8] Therefore, because there are no known risks or "history and severity of foodborne illness outbreaks" FDA must add bitter melon and opo (squash) to the rarely consumed raw list.[9]

Bitter melon is thoroughly cooked before consumption. Bitter melons are typically cultivated in China, India, Japan, Vietnam, Thailand, and Malaysia, and also less frequently in East Africa, the Caribbean, and South America.[10] Bitter melons are also grown in the United States primarily on small farms in California and Florida.[11] They are prepared for human consumption in numerous ways, depending on the region, including steaming, boiling, and stir-frying, and are also pickled or canned.[12] The bitterness of this fruit has led to the use of different processing and cooking techniques, such as soaking before cooking, to remove the bitter compounds.[13]

Bitter melon must be cooked for several reasons, including human health and taste preferences.[14] Bitter melon used for culinary purposes is blanched, parboiled or soaked in salt water before

6 As of March 2020. https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html
7 https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
8 see https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
9 21 U.S.C. 350h(a)(4).
10 Gupta, M. , Sharma, S. , Gautam, A. K. , & Bhadauria, R. (2011). Momordica charantia Linn. (Karela): Nature's silent healer. *International Journal of Pharmaceutical Sciences Review and Research*, 11(1), 32–37.
11 Raina, K., Kumar, D., & Agarwal, R. (2016). Promise of bitter melon (Momordica charantia) bioactives in cancer prevention and therapy. *Seminars in cancer biology*, 40-41, 116–129. https://doi.org/10.1016/j.semcancer.2016.07.002
12 Tan, S. P. , Kha, T. C. , Parks, S. E. , & Roach, P. D. (2016). Bitter melon (Momordica charantia L.) bioactive composition and health benefits: A review. *Food Reviews International*, 32, 181–202. 10.1080/87559129.2015.1057843
13 Bong, W. C., & Savage, G. (2018). Oxalate content of raw, wok-fried, and juice made from bitter gourd fruits. *Food science & nutrition*, 6(8), 2015–2019. https://doi.org/10.1002/fsn3.706
14 Bong, W. C., & Savage, G. (2018). Oxalate content of raw, wok-fried, and juice made from bitter gourd fruits. *Food science & nutrition*, 6(8), 2015–2019.

cooking to reduce the bitter taste.[15] Bitter melon is also thoroughly cooked because it contains oxalate, which is an unwanted nutrient in human diets due to its adverse effects on health.[16] Bitter melon is rarely consumed raw to prevent adverse health consequences and to avoid its extremely bitter taste.[17]

Opo (squash) is also typically cooked before consumption.[18] In China, cubed opo (squash) is frequently added to soups, stews and stir-fries or grated and used in batter for quick breads and fritters.[19] More mature opo (squash) can be slow roasted or pureed and added to sauces and soups.[20] In China, opo (squash) is also popularly hollowed out slightly, stuffed then steamed or baked.[21]

FDA could also promote additional information on cooking and preparing opo (squash) to ensure it is rarely consumed raw.[22] For example, there is a public health concern if the public consumes opo (squash) with a bitter taste.[23] FDA messaging should warn consumers about the public health concerns of eating a bitter tasting or raw opo (squash), and inform consumers around the importance of cooking opo (squash).

Overall, FDA should provide adequate notice to farmers for crops that are not explicitly listed on either the rarely consumed raw list or the covered produce list. For produce items that are not on either list, FDA should ensure that a true science-based approach, as required by FSMA, is taken to ensure only crops that are commonly consumed raw are covered by the rule. It is not fair to farmers who grow crops that are rarely consumed raw, but are not on either list.

Recommendation: FDA must add bitter melon and opo (squash) to the Enforcement Policy and the rarely consumed raw list.

3. FDA must review crops that are rarely consumed raw but are currently included in the covered produce list. FDA should move these items to the rarely consumed raw list.

Certain items currently on the covered produce list should be reviewed and moved to the rarely consumed raw list. An example of such an item is taro root. Taro produces both edible corms and

[15] Raina, K., Kumar, D., & Agarwal, R. (2016). Promise of bitter melon (Momordica charantia) bioactives in cancer prevention and therapy. *Seminars in cancer biology*, 40-41, 116–129. https://doi.org/10.1016/j.semcancer.2016.07.002
[16] Bong, W. C., & Savage, G. (2018). Oxalate content of raw, wok-fried, and juice made from bitter gourd fruits. *Food science & nutrition*, 6(8), 2015–2019.
[17] Bong, W. C., & Savage, G. (2018). Oxalate content of raw, wok-fried, and juice made from bitter gourd fruits. *Food science & nutrition*, 6(8), 2015–2019. Raina, K., Kumar, D., & Agarwal, R. (2016). Promise of bitter melon (Momordica charantia) bioactives in cancer prevention and therapy. *Seminars in cancer biology*, 40-41, 116–129. https://doi.org/10.1016/j.semcancer.2016.07.002
[18] https://specialtyproduce.com/produce/Opo_Squash_396.php
[19] https://specialtyproduce.com/produce/Opo_Squash_396.php
[20] https://specialtyproduce.com/produce/Opo_Squash_396.php
[21] https://specialtyproduce.com/produce/Opo_Squash_396.php
[22] See generally https://www.producemarketguide.com/produce/opo-squash
[23] https://specialtyproduce.com/produce/Opo_Squash_396.php

leaves that are used as vegetables.[24] Taro is a common staple grown and consumed throughout Asia, Africa, the Pacific Islands, and the Caribbean.[25] In North America, taro consumption and distribution are rare, except through ethnic supermarkets and a few other supply chains.[26]

There are low food safety risks associated with taro, and therefore, it should also be included in FDA's Enforcement Policy and eventually moved to the rarely consumed raw list. Taro is not listed on CDC's List of Multistate foodborne illness outbreak investigations from 2006 to 2020.[27] FDA's Enforcement Reports from June 8, 2012 through March 1, 2020 contain no finding of foodborne pathogen concerns for taro.[28] FDA's recent list of recall notifications also do not indicate that taro has been recalled in recent years.[29] Therefore, FDA should add taro to the rarely consumed raw list because there are no known risks or "history and severity of foodborne illness outbreaks."[30]

Taro is commonly eaten cooked, since raw consumption can result in an acrid taste followed by swelling and irritation of the mouth and throat.[31] The irritation is caused by calcium oxalate crystals, but the soluble oxalate content of taro can be reduced by cooking.[32] Populations that consume taro as part of their diet, boil and eat taro leaves and use the leaves to wrap food that is then baked, which neutralizes its negative health consequences.[33] In fact, the most often recommended method for detoxifying taro is to cook it in boiling water for at least 30 minutes.[34] Properly cooking taro eliminates the irritation effects in the throat and mouth associated with consumption of raw taro.[35]

[24] Oscarsson, K.V., & Savage, G.P., 2007. Composition and availability of soluble and insoluble oxalates in raw and cooked taro (Colocasia esculenta var. Schott) leaves. *Food Chemistry*. 101, 559−562.
[25] Matthews, P.J. 2004. Genetic Diversity in Taro, and the Preservation of Culinary Knowledge. Ethnobotany Research & Applications, **2**: 5571. Rao, V., Matthews, P., Eyzaguirre, P., and Hunter, D. 2010. The Global Diversity of Taro: Ethnobotany and Conservation
[26] Omura, J. D., Blake, C., Mcintyre, L., Li, D., & Kosatsky, T. (2014). Two cases of poisoning by raw taro leaf and how a poison control centre, food safety inspectors, and a specialty supermarket chain found a solution. Environmental Health Review, 57(03), 59–64. doi: 10.5864/d2014-027
[27] As of March 2020. https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html
[28] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
[29] see https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
[30] 21 U.S.C. 350h(a)(4).
[31] Omura, J. D., Blake, C., Mcintyre, L., Li, D., & Kosatsky, T. (2014). Two cases of poisoning by raw taro leaf and how a poison control centre, food safety inspectors, and a specialty supermarket chain found a solution. Environmental Health Review, 57(03), 59–64. doi: 10.5864/d2014-027. Savage, G.P., Ma¨rtensson, L., and Sedcole, J.R. 2009. Composition of oxalates in baked taro (Colocasia esculenta var. Schott) leaves cooked alone or with additions of cows' milk or coconut milk. J.
[32] Oscarsson, K.V., & Savage, G.P., 2007. Composition and availability of soluble and insoluble oxalates in raw and cooked taro (Colocasia esculenta var. Schott) leaves. Food Chemistry. 101, 559−562.
[33] Savage, G.P., and Dubois, M. 2006. The effect of soaking and cooking on the oxalate content of taro leaves. Int. J. Food Sci. Nutr, 57(56): 376381. doi: 10.1080/09637480600855239. Omura, J. D., Blake, C., Mcintyre, L., Li, D., & Kosatsky, T. (2014). Two cases of poisoning by raw taro leaf and how a poison control centre, food safety inspectors, and a specialty supermarket chain found a solution. Environmental Health Review, 57(03), 59–64. doi: 10.5864/d2014-027
[34] Savage, G.P., and Dubois, M. 2006. The effect of soaking and cooking on the oxalate content of taro leaves. Int. J. Food Sci. Nutr, 57(56): 376381. doi: 10.1080/09637480600855239.
[35] Amon, S.A., René, Y.S., Emma, F.A., Edmond, A.D., & Lucien, P.K., 2011. Effect of boiling time on chemical composition and physico-functional properties of flours from taro (Colocasia esculenta cvfouê) corm grown in Côte d'Ivoire. Journal ofFood Science and Technology DOI 10.1007/s13197-011-0578-7.

In the United States, consumption of raw taro would be due to a lack of public awareness regarding proper preparation and cooking techniques, rather than the product being typically consumed raw.[36] To prevent accidental raw consumption of taro, FDA could promote additional information on cooking and preparing taro root to ensure it is rarely consumed raw. Furthermore, FDA could work with sellers of taro and ask them to post signage instructing customers to cook taro prior to consumption.[37]

Overall, because taro root is rarely consumed raw, farmers should not be required to ensure that taro complies with the Produce Safety Rule. Taro root should be added to the Enforcement Policy and the rarely consumed raw list because there is a low food safety risk associated with the human consumption of this item.

Recommendation: FDA must remove taro root from the covered produce list and add it to the Enforcement Policy and the rarely consumed raw list.

4. FDA must conduct further research on certain crops on the covered produce list or absent from the rarely consumed raw list. FDA should consider adding these items to the Enforcement Policy.

Certain items currently on the covered produce list require further research before a final classification is made for each item.

Fava (faba) beans should be further researched by FDA to determine a final classification. We recommend FDA consider adding this item to the Enforcement Policy and the rarely consumed raw list. CDC's List of Multistate foodborne illness outbreak investigations did not include fava (faba) beans in any multistate outbreak from 2020 to 2006.[38] FDA's Enforcement Reports from June 8, 2012 through March 1, 2020 also do not list fava (faba) beans.[39] FDA's recent list of recall notifications also do not include fava (faba) beans in recent years.[40]

Fava (faba beans) are commonly cooked to ensure that particular molecules that can be harmful to human health are reduced.[41] Fava (faba) beans are also cooked to reduce the tough nature of their

[36] Omura, J. D., Blake, C., Mcintyre, L., Li, D., & Kosatsky, T. (2014). Two cases of poisoning by raw taro leaf and how a poison control centre, food safety inspectors, and a specialty supermarket chain found a solution. Environmental Health Review, 57(03), 59–64. doi: 10.5864/d2014-027
[37] Omura, J. D., Blake, C., Mcintyre, L., Li, D., & Kosatsky, T. (2014). Two cases of poisoning by raw taro leaf and how a poison control centre, food safety inspectors, and a specialty supermarket chain found a solution. Environmental Health Review, 57(03), 59–64. doi: 10.5864/d2014-027
[38] As of March 2020. https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html
[39] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
[40] see https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
[41] Multari, S., Stewart, D., & Russell, W. R. (2015). Potential of Fava Bean as Future Protein Supply to Partially Replace Meat Intake in the Human Diet. *Comprehensive Reviews in Food Science & Food Safety*, 14(5), 511.

seed coats.[42] Raw fava (faba) beans contain antinutritional molecules that reduce their digestibility, but many food processing methods, like cooking at high temperatures and soaking, significantly reduce or completely eliminate these molecules from fava (faba) beans.[43] Because fava (faba) beans tend to be cooked due to palatability issues and the need for them to be cooked to eliminate antinutritional molecules, we recommend FDA consider adding fava (faba) beans to the rarely consumed raw list. Furthermore, we recommend FDA encourage public messaging around the importance of cooking fava (faba) beans to avoid negative health consequences from consuming raw fava (faba) beans.

There is also a low food safety risk for bok choy and mustard greens, and FDA should conduct additional research to determine if these two items should be moved to the rarely consumed raw list. CDC's List of Multistate foodborne illness outbreak investigations also does not include bok choy or mustard greens in a multistate outbreak from 2006 to 2020.[44] FDA's Enforcement Reports from June 8, 2012 through March 1, 2020 only include one recall due to potential foodborne pathogen contamination of bok choy; three additional food products that contained multiple ingredients, including bok choy were also recalled, but the exact ingredient or cause that raised the foodborne pathogen concern were not identified.[45] There were only two potential foodborne pathogen contamination concerns related to mustard greens during that same time period.[46]

While foodborne illness outbreaks and recalls based on foodborne illness risks are not the only measurement for food safety risks, they do provide FDA with one source of information on the actual risk to humans. In fact, there are currently some products on the rarely consumed raw list, that also have a low risk, but have also seen similar recall numbers. For example, asparagus, which is typically cooked, or products with asparagus as one of many ingredients, were associated with approximately nine recalls from June 8, 2012 through March 1, 2020 because of potential foodborne pathogens.[47] All of these instances are relatively low compared to the thousands of food products recalled for foodborne pathogens during this same time period.[48] Based on this, FDA should consider the actual food safety risk when deciding whether or not bok choy and mustard greens should be on the rarely consumed raw list.

Both bok choy and mustard greens are commonly cooked as well.[49] The cooking process makes these vegetables more palatable.

[42] Sharma, A., & Sehgal, S. (1992). Effect of processing and cooking on the antinutritional factors of faba bean (Vicia faba). *Food Chemistry*, 43(5), 383–385. https://doi-org.proxy.library.nyu.edu/10.1016/0308-8146(92)90311-O
[43] Multari, S., Stewart, D., & Russell, W. R. (2015). Potential of Fava Bean as Future Protein Supply to Partially Replace Meat Intake in the Human Diet. Comprehensive Reviews in Food Science & Food Safety, 14(5), 511.
[44] As of March 2020. https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html
[45] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
[46] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
[47] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
[48] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
[49] Dekker M, Verkerk R, Jongen WM. 2000. Predictive modelling of health aspects in the food production chain: a case study on glucosinolates in cabbage. Trends Food Science & Technology;11:174-181; https://theforkedspoon.com/bok-choy-recipe/; https://www.spendwithpennies.com/sesame-ginger-bok-choy/; https://www.thespruceeats.com/roasted-

FDA could also increase public messaging about the food safety and health reasons for cooking bok choy and mustard greens, which could ensure they are rarely consumed raw. Bok choy and mustard greens are part of the Brassica vegetable family. When brassica vegetables are eaten raw, the enzyme myrosinase is released.[50] This enzyme accelerates a process that leads to inhibitory effects on the thyroid, and when consumed in large quantities over extended periods of time can lead to hypothyroidism.[51] Cooking brassica vegetables, however, deactivates the myrosinase enzyme, eliminating potential negative health outcomes.[52] If the general public learns to cook these items, they will no longer be accidentally consumed raw.

We recommend FDA consider moving bok choy and mustard greens to the rarely consumed raw list because of the low food safety risks and the health benefits associated with cooking these two items.

Recommendation: FDA must add mustard greens, bok choy, and fava (faba) beans to the Enforcement Policy, while the agency conducts further research to determine a classification for each item.

5. Conclusion

We thank FDA for their work on the Enforcement Policy and for the opportunity to share our comments. To summarize our above comments, first, NSAC encourages FDA to establish a clear, transparent, and practical path for moving or adding produce to the rarely consumed raw list. In an effort to address some of the issues regarding the rarely consumed raw list, we recommend FDA establish a process to ensure historically underserved communities' crops that are rarely consumed raw are included on the rarely consumed raw list. FDA should also conduct additional research on each item using realistic methods to determine each product's classification, including links to foodborne illness outbreaks, actual food safety risks, and recipes that showcase whether a product is commonly cooked or consumed raw.

As an immediate action, we recommend FDA move taro root, bitter melon, and opo (squash), and consider moving fava (faba) beans, bok choy, and mustard greens to the Enforcement Policy until each item has been researched and a final designation has been determined.

We also recommend FDA add crops that are rarely consumed raw and that are not explicitly listed in the Produce Safety Rule to the rarely consumed raw list including, but not limited to, bitter melon

bok-choy-4690759; https://www.thespruceeats.com/chicken-stir-fry-with-bok-choy-694880; https://www.jessicagavin.com/how-to-cook-bok-choy/

[50] Chu, M., & Seltzer, T. F. (2010). Myxedema coma induced by ingestion of raw bok choy. New England Journal of Medicine, 362(20), 1945–1946. https://doi-org.proxy.library.nyu.edu/10.1056/NEJMc0911005

[51] Chu, M., & Seltzer, T. F. (2010). Myxedema coma induced by ingestion of raw bok choy. New England Journal of Medicine, 362(20), 1945–1946. https://doi-org.proxy.library.nyu.edu/10.1056/NEJMc0911005

[52] Chu, M., & Seltzer, T. F. (2010). Myxedema coma induced by ingestion of raw bok choy. New England Journal of Medicine, 362(20), 1945–1946. https://doi-org.proxy.library.nyu.edu/10.1056/NEJMc0911005.

and opo (squash). The research presented in our comments supports our recommendations that bitter melon and opo (squash) be added to the Enforcement Policy and the rarely consumed raw list because there is low or no food safety risk associated with the human consumption of these items.

In addition to those items not on either list, we recommend FDA review certain crops currently included in the covered produce list, like taro root, that are rarely consumed raw. Based on the above information, we recommend FDA move taro root to the Enforcement Policy and to the rarely consumed raw list.

Some items included in the covered produce list need to be further researched before a final classification is made. We recommend FDA move mustard greens, bok choy, and fava (faba) beans to the Enforcement Policy, while the agency conducts further review to determine a classification for these items. Based on the research presented in our comments, mustard greens, bok choy, and fava (faba) beans are rarely consumed raw due to palatability issues and antinutritional molecules present in these vegetables when raw. Additionally, mustard greens, bok choy, and fava (faba) beans all have a low food safety risk. For these reasons, we recommend FDA add these items to the Enforcement Policy and the rarely consumed raw list.

We look forward to working with FDA around the implementation of a new process for determining whether or not an item should be on the Produce Safety Rule rarely consumed raw list, and hope the process is both cognizant and supportive of sustainable agriculture and food systems. Thank you for considering our comments and we look forward to providing additional input, future education resources, and further opportunities for dialogue between FDA and farmers and food businesses within our network.