



January 8, 2021

Dr. Samir Assar
Center for Food Safety and Applied Nutrition (HFS-317)
Food and Drug Administration
5001 Campus Dr.
College Park, MD 20740

Re: FDA Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States (Docket No. FDA-2020-N-1119)

The Center for Foodborne Illness Research and Prevention at The Ohio State University (CFI) appreciates the opportunity to provide comments on the consumption of certain uncommon produce commodities to be considered for addition to the Rarely Consumed Raw (RCR) exemption from produce safety regulation.

The Center for Foodborne Illness Research and Prevention (CFI) was founded as a national, 501 (c)(3) non-profit organization to drive the development and implementation of innovative, science-based solutions for the food safety challenges of the 21st Century. We view ourselves as knowledge brokers, working to translate science into practical, evidence-informed policies that protect public health and prevent foodborne disease. Our objective is to provide an independent voice, committed to using the best available science to develop evidence-informed policies and practices that create a positive food safety culture from farm to table and beyond. In all that we do, we are rooted in science and best practices for science-based advocacy are our guiding principles. In August 2019, CFI was established as a center within the College of Food, Agricultural, and Environmental Sciences (CFAES) to further establish Ohio State and CFI's global leadership in food safety; encourage and facilitate transdisciplinary collaborations around food safety; build a network of food safety experts to address existing and emerging food safety problems; and create lasting strategic partnerships with food safety stakeholders.

On August 10, 2020, the Food and Drug Administration (FDA) issued a Request for Information on 60 produce commodities that are potentially being considered for the RCR list, which was established with the 2015 final rule "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (80 FR 74354). Produce commodities on the RCR list are exempt from the Produce Safety Rule, which outlines minimum science-based standards for safe growing, harvesting, packing, and holding, of fruits and vegetables grown for human consumption.¹ Produce commodities are eligible to be added to the RCR list if they are typically consumed only after being cooked by consumers. The original list of commodities included in the RCR list was based on data collected through The National Health and Nutrition Examination Survey (NHANES)² and from the EPA's Food Commodity Intake Database (FCID)³. NHANES provides national consumption data based on 1-day and 2-day dietary recall. The FCID

¹ Center for Food Safety and Applied Nutrition, "FSMA Final Rule on Produce Safety," *FDA*, September 9, 2020, <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>.

² "NHANES - National Health and Nutrition Examination Survey Homepage," October 13, 2020, <https://www.cdc.gov/nchs/nhanes/index.htm>.

³ "What We Eat In America - Food Commodity Intake Database," accessed October 22, 2020, <https://fcid.foodrisk.org/>.

disaggregates food commodities that appear in NHANES data into raw agricultural commodities and identifies the cooking status of the commodities. FDA used three criteria to determine if a produce commodity should be placed on the RCR list:

Criteria 1: Consumption of uncooked commodity by < 0.1% of NHANES respondents on Day 1 **or** over 2 days,

Criteria 2: Consumption of uncooked commodity at < 0.1% of eating occasions on Day 1 **or** over 2 days, and

Criteria 3: Consumption of commodity in all forms by > 1% of NHANES respondents.

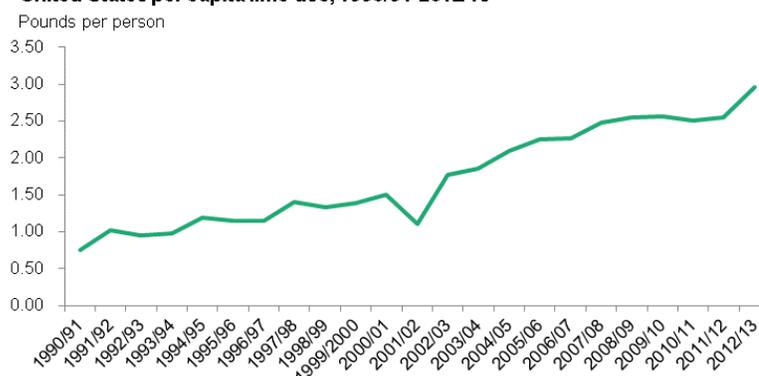
To be included on the RCR list, a commodity must satisfy all three criteria. Commodities that satisfy criteria 1 and 2 but fail to meet criteria 3 are considered “produce commodities with low reported consumption,” and are the main subject of this RFI. These criteria were listed in the RFI, but the FDA further clarified that either 1-day or 2-day NHANES consumption were considered in evaluating criteria 1 and 2 at a meeting with consumer groups on October 2, 2020.

Since foods that are deemed to be RCR are exempt from important food safety regulations, the development of the RCR list needs to be informed by the best available data and appropriate statistical analyses. Upon reviewing the data and methods used to propose expanding the RCR list, CFI has three major concerns that are further described below:

- 1) The data used to estimate consumption of products is over 10 years old, despite the availability of more recent data, and may not capture recent changes in consumption trends.
- 2) The validity of assumptions made during the analysis of NHANES data should be evaluated and made available for review by consumers and stakeholders.
- 3) Data on handling and preparation practices should also be considered when determining if a produce commodity should be included on the RCR list.

First, CFI is concerned about the use of *outdated* consumption data in developing the RCR list. Data quality includes *relevance*. Consumption data that is 10 years old is of questionable relevance for identifying produce commodities that will be exempted from the Produce Safety Rule. Using incorrect or outdated data could lead to increased risk of illness. The current RCR list is based on the data from the 2003-2010 cycles of NHANES, even though more recent data (i.e., NHANES 2017-2018 data) is available. For example, FDA has identified limes as a RCR commodity even though the 2014 USDA ERS Fruit and Nut Outlook identified a steady increase in per capita lime use over the years 1990-2013 (see Figure)⁴. Based on this information, the classification of limes as a commodity with low reported consumption in the RFI may no longer be accurate.

United States per capita lime use, 1990/91-2012/13



Source: USDA, Economic Research Service, *Fruit and Tree Nuts Yearbook*, various years.

⁴ Kristy Plattner, “Fresh-Market Limes,” 2014, 9, https://www.ers.usda.gov/webdocs/outlooks/37059/49132_fresh-market-limes-special-article.pdf?v=6937.9.

For the RCR list to be informed by the best available data, FDA should use the most recent cycles of the NHANES data to obtain current information about consumption patterns in the United States. Given the continual collection and release of NHANES data in two-year cycles, it is hard to understand why FDA's analysis did not use more recent data. When the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" were released in 2015, FDA stated they would consider updating the RCR list based on availability of new data. NHANES data has been published roughly every two years, but the RCR list has not been updated. FDA should repeat the analysis with the most recent NHANES data available to ensure that the RCR list is populated with appropriate commodities, to prevent introducing consumers to unnecessary risk.

Second, CFI urges the FDA to follow the NHANES Analytic Guidelines, including verifying the validity of combining multiple data cycles, and making these analyses transparent and readily accessible to consumers and stakeholders. *The National Health and Nutrition Examination Survey: Analytic Guidelines, 1999-2010* specifies that certain considerations must be taken into account when analyzing NHANES data, including the selection of proper weights for combined data sets; verification of consistent survey wording, methods, and inclusion/ exclusion criteria; and confirming the inherent assumption that there is no trend in consumption rates over the cycles being combined.⁵ Importantly, the Analytic Guidelines state that two assumptions are made by the user when two or more consecutive cycles of NHANES data are combined: (a) there are no differences in the estimates over the time periods being combined; and (b) in regard to the interpretation, the estimate is the average over the time period. In their analysis, FDA combined several cycles of NHANES data, but it is not clear whether the FDA verified these assumptions.

First, it is not clear if FDA determined if there was no trend in consumption estimates for the produce commodities being considered over the cycles being combined. In fact, there is evidence to suggest that consumption trends did change over the time period analyzed. For example, as mentioned previously, ERS has shown steady increases in per capita use of limes between 2003 and 2010, and the NHANES data would be expected to reflect that trend. Similarly, in 2014, the CDC's Morbidity and Mortality Weekly Report reported on a study that analyzed NHANES data and found that consumption of fruits among children increased significantly from 2003 to 2010.⁶ Since FDA combined multiple NHANES cycles, we expect that the assumption that there are no differences in the estimate over the time periods being combined was validated. However, these sources call into question the validity of the assumption.

Second, FDA's estimates reflect the average consumption over 2003 – 2010. It is unclear why the FDA chose to produce average estimates over the years 2003 to 2010 instead of using only the data in the 2009-2010 NHANES cycle, which would be the more accurate in predicting current and future trends in consumption. Because details of the analysis performed by FDA has not been made available, it is not possible to verify if their analysis of the NHANES data followed the NHANES guidelines.

Finally, FDA evaluated Criteria 1 and Criteria 2 using both one-day and the combined two-day dietary recall data, and classified produce commodities as RCR if they met the criteria for either analysis. For example, using the 1-day dietary recall data, apricots were estimated to be consumed raw on 0.03% of eating occasions but, based on the 2-day combined dietary recall data, apricots were consumed raw on 0.31% of eating occasions. Since apricots met Criteria 2 for Day 1, FDA has proposed designating this as a RCR commodity even though it did not meet the criteria for Day 2. It is well established that people's diets

⁵ National Center for Health Statistics (U.S.), ed., *National Health and Nutrition Examination Survey: Analytic Guidelines, 1999-2010*, Vital and Health Statistics. Series 2, number 161 (Hyattsville, Maryland: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, 2013).

⁶ Sonia A. Kim et al., "Vital Signs: Fruit and Vegetable Intake among Children - United States, 2003-2010," *MMWR. Morbidity and Mortality Weekly Report* 63, no. 31 (August 8, 2014): 671-76.

can vary widely, and 1-day dietary recalls fail to capture foods that are sporadically consumed⁷. The use of two-day estimates provides a more representative picture of a person's diet and, therefore, a more inclusive list of commodities consumed by respondents. Using the one-day dietary recall data could lead to gaps in data for foods that are not consumed on daily basis by consumers. Since the RCR list is used to recommend commodities for exemption from regulation, a conservative approach should be taken. To ensure that commodities are appropriately recommended for inclusion on the RCR list, the two-day dietary recall estimates should be used in considering both Criteria 1, the percentage of respondents consuming the commodity raw and Criteria 2, the percentage of eating occasions where the commodity is consumed raw. The appropriate use of NHANES data is essential to ensuring the appropriate selection of commodities to be included on the RCR list.

Finally, in addition to the already identified data sources, CFI urges FDA to consider the knowledge, attitudes and practices of restaurant and retail food workers and consumers around the handling of fresh produce in determining the RCR list. Before recommending a commodity to be included in the RCR list, FDA could evaluate literature on restaurant, retail, and consumer knowledge, attitudes and practices around the handling of fresh produce and, where there are gaps, conduct studies to understand practices in preparing the commodity under consideration for the RCR list. For example, data collected from resources such as CFSAN's Consumer Behavior Research Surveys⁸ and The USDA's Consumer Research Surveys⁹ can be used to assess whether food preparers and consumers are aware that a cook/kill step is needed before certain produce commodities can be reasonably assumed safe for consumption. Without such information, the potential health impact of adding products to the RCR list is underestimated.

In practice, many of the commodities currently on or being considered for addition to the RCR list are indistinguishable from other FDA-regulated, fresh produce commodities for most consumers and food handlers. FDA recommendations for proper handling and storing of produce do not communicate the available exemptions for fresh produce, which means some products are regulated differently by FDA, although they are next to each other in the grocery store and not identified as higher risk by suppliers. For example, figs and cranberries are often displayed on grocery store shelves next to fresh berries, but most consumers will not know that the berries are covered by the Produce Safety Rule and are considered safe to eat raw while the figs and cranberries are not regulated to ensure safe raw consumption. To best protect public health, FDA should evaluate consumer awareness of produce regulations and identify where further communication about exempted produce commodities is needed.

CFI holds that the use of only consumption data in informing the RCR list is inconsistent with the goals of FSMA and the Produce Safety Rule to use a risk-based approach to protecting public health and reducing the burden of foodborne illness. Consumption data alone does not provide sufficient information to ensure there is negligible risk associated with the consumption of raw produce that is exempt from regulation. Since foods that are deemed to be RCR are exempt from important food safety regulations, the development of the RCR list needs to be informed by current, high quality data and a clear understanding of the produce handling knowledge, attitudes, and practices of preparers and consumers.

⁷ Institute of Medicine (US) Subcommittee on Interpretation and Uses of Dietary Reference Intakes and Institute of Medicine (US) Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, *Using Dietary Reference Intakes for Nutrient Assessment of Individuals, DRI Dietary Reference Intakes: Applications in Dietary Assessment* (National Academies Press (US), 2000), <https://www.ncbi.nlm.nih.gov/books/NBK222891/>.

⁸ Center for Food Safety and Applied Nutrition, "CFSAN Consumer Behavior Research," FDA (FDA, March 16, 2020), <https://www.fda.gov/food/science-research-food/cfsan-consumer-behavior-research>.

⁹ "Consumer Research," accessed October 22, 2020, <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/teach-others/download-materials/consumer-research-and-focus-group-testing>.

In conclusion, CFI recommends that the 2017-2018 NHANES data used to be evaluate produce commodities for inclusion on the RCR list and these analyses be made available for review by stakeholders and consumers. Further, FDA should use the updated analytic guidelines, published in 2018, that account for changes in NHANES data collection that were implemented starting in 2011. If NHANES data are going to be used to inform the RCR list, only the most current data should be analyzed, adhering to the analytic guidelines provided, and made available for stakeholders to review. Lastly, in addition to consumption data, consumer and food handler knowledge, attitudes, and practices around produce handling should be considered in the development of the RCR list to ensure commodities are added to the list appropriately.

CFI appreciates the opportunity to provide comments on the development of the RCR exemption list, and we look forward to working further with the FDA to ensure the safety of food and protect public health.

Respectfully submitted,

A handwritten signature in cursive script that reads "Barbara B. Kowalcyk".

Barbara Kowalcyk
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The Ohio State University
Columbus, Ohio