



Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Joseph A. Levitt
Maile Gradison Hermida
Elizabeth Barr Fawell
Leigh G. Barcham

Date: April 3, 2019

Re: FDA Announces Produce Safety Rule Enforcement Discretion Policy for Almonds, Pulse Crops, Wine Grapes, and Hops under FSMA

The U.S. Food and Drug Administration (FDA) has issued Guidance detailing its intent to exercise enforcement discretion for the requirements of the Produce Safety rule as they apply to entities growing, harvesting, packing, and holding almonds, pulse crops, wine grapes, and hops. ^{1/} FDA received feedback from these entities that they should be exempt after it issued the final Produce Safety rule, and FDA is exercising enforcement discretion while it considers pursuing rulemaking to address the challenges each of the commodities presents. Comments on the Guidance may be submitted at any time. This action is part of FDA's continued implementation of the FDA Food Safety Modernization Act (FSMA).

Background

The Produce Safety rule is one of the foundational regulations that FDA has developed under FSMA. Produce is not subject to the Produce Safety rule, however, if it is identified by FDA under the regulation as "rarely consumed raw" (i.e., foods that are almost always eaten only after being cooked). Foods that FDA has determined are "rarely consumed raw" are included in an exhaustive list at 21 C.F.R. § 112.2(a)(1) (the "RCR list"). FDA established the RCR list when it issued the final Produce Safety rule, and it based the list on consumption patterns reported in the National Health and Nutritional Examination Survey (NHANES). In the preamble to the final rule, FDA said it planned to consider updating the RCR list as appropriate and encouraged stakeholders to submit data to allow FDA to reach a conclusion that additional foods should be added to the RCR list. Since the time the RCR list was established when the final rule was promulgated, several industries have asked FDA to consider expanding the list to include additional commodities.

^{1/} "Guidance for Industry: Enforcement Policy for Entities Growing, Harvesting, Packing or Holding Hops, Wine Grapes, Pulse Crops, and Almonds," (Mar. 2019), available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM634252.pdf>.

Enforcement Discretion

The new Guidance announces FDA's intent to exercise enforcement discretion for the following four commodities, none of which currently is included in the RCR list: almonds, all pulse crops, wine grapes, and hops. The common theme appears to be that each of these commodities is subject to commercial processing to control pathogens prior to consumption, so not applying the provisions of the Produce Safety rule would be appropriate from a public health standpoint.

- **Almonds:** FDA previously concluded that almonds do not meet the criteria to be considered “rarely consumed raw” because the NHANES analysis did not conclude that less than 0.1% of the population consumed them uncooked. Since publishing the final rule, however, FDA received input from almond growers and conducted its own analysis. FDA notes that virtually all almonds commercially produced in the United States are grown in California, and that pursuant to the California Almond Federal Marketing Order issued by the U.S. Department of Agriculture, all almonds shipped from handlers to locations within the United States must undergo treatment for the control of *Salmonella*, which may include blanching, roasting, steam treatment, and treatment with propylene dioxide. Accordingly, FDA will exercise enforcement discretion while it “explore[s] this topic further” and considers rulemaking to address almonds.
- **Pulse Crops:** Pulses are the dry, edible seeds of plants in the legume family. There are 11 varieties: dry beans, broad beans, dry peas, chick peas, cow peas, pigeon peas, lentils, bambara beans, vetches, lupins, and pulses NES (not elsewhere specified). ^{2/} Some pulse crops currently are on the RCR list (e.g., black beans, kidney beans, pinto beans), while others are not. FDA has received feedback that all pulse crops should be included in the RCR list, because they are all dried, processed, and cooked prior to consumption. Accordingly, FDA is exercising enforcement discretion for pulse crops that are not currently on the RCR list while FDA explores the topic further and considers rulemaking to address pulse crops.
- **Wine Grapes:** In the preamble to the final Produce Safety rule, FDA noted that it did not have sufficient information on specific grape cultivars or varieties that are exclusively grown for use in winemaking to establish a separate category in the RCR list covering only “wine grapes.” FDA also noted that some grape varieties are multi-purpose and used as both wine grapes and table grapes. FDA has since received feedback from wine grape growers that only certain grape varieties are used for winemaking, and that these varieties and the growing and harvesting practices used on them differ from those marketed as table grapes or for other uses. Additionally, FDA noted in the Guidance that the Consolidated Appropriations Act of 2019 restricts the agency’s funding from being used to enforce the Produce Safety rule against grape varieties used solely for wine and receiving commercial processing. Accordingly, FDA is exercising enforcement discretion for grape varieties that are grown, harvested, and used solely for wine while the agency explores options for potentially exempting the commodity from the rule.

FDA acknowledged that some farms may not have sufficient information to determine whether a grape variety is grown, harvested, and used solely for making wine on an industry-wide basis. In other words, even if a farm uses a variety only for making wine, the farm may not know whether other farms use the variety for other purposes. In those

^{2/} The term “pulses” includes only crops harvested solely in dried form; it does not include crops harvested green for food, such as green peas or green beans, or crops used primarily for oil extraction.

situations, where the individual farm grows, harvests, and uses the varietal solely for making wine, FDA will exercise enforcement discretion with respect to the growing and harvesting of the varietal on that farm.

- **Hops:** FDA did not include hops on the original RCR list because it was not able to conclude that hops are not consumed uncooked in any measurable quantity by most consumers across the United States, though it recognized that hops used in the making of beer are eligible for the separate commercial processing exemption. FDA's analysis has led the agency to believe that, given hops' unique circumstances, the agency should explore options for potentially exempting hops from the Produce Safety rule. In the meantime, FDA will exercise enforcement discretion while it considers the topic further and possibly pursues rulemaking.

FDA will not expect farms growing, harvesting, packing, or holding these commodities to meet any requirements of the Produce Safety rule with respect to these commodities. However, the Federal Food, Drug, and Cosmetic Act's (FFDCA's) prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food continues to apply to these commodities.

Note that, at some point in time, rulemaking would be warranted to codify these examples of enforcement discussion because the RCR list is contained in regulation and can only be changed by going back through the rulemaking process.

* * *

We will continue to monitor developments related to implementation of the Produce Safety rule. Please contact us if you have any questions or would like to discuss strategies your business can take to comply with the rule.