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MEMORANDUM

From: Joseph A. Levitt
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Re: FDA Issues Draft Guidance on FSMA Food Safety Requirements for Produce Growers and Processors

The Food and Drug Administration (FDA) has issued two draft guidance documents intended to assist industry in complying with certain FDA Food Safety Modernization Act (FSMA) regulations regarding fresh produce. The first document is for farms covered by the Produce Safety Rule (PSR). The second document is for facilities subject to FDA's Preventive Controls for Human Food (PCHF) rule and that manufacture, process, pack, or hold fresh-cut produce. The deadline for comments on both guidance documents is April 22, 2019.

Draft Guidance on Produce Safety Rule

FDA has issued Draft Guidance to assist covered farms in understanding and complying with the requirements of the PSR. ^{1/} The Draft Guidance outlines how farms can determine if they are eligible for exemptions from some or all of the PSR's requirements and also provides FDA's recommendations for satisfying the requirements of most subparts of the rule. The Draft Guidance includes separate chapters on the following subparts of the rule:

- General Provisions (Subpart A);
- Personnel Qualifications and Training (Subpart C);
- Health and Hygiene (Subpart D);
- Biological Soil Amendments of Animal Origin and Human Waste (Subpart F);
- Domesticated Animals (Subpart I);
- Growing, Harvesting, Packing, and Holding Activities (Subpart K);
- Equipment, Tools, Buildings, and Sanitation (Subpart L);
- Records (Subpart O); and
- Variances (Subpart P).

^{1/} *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry* (Oct. 2018), available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623178.pdf>.

The entire Draft Guidance is open for comment. FDA also specifically requested comments on a few issues regarding equipment and tools intended to or likely to contact covered produce and potential contamination of product that could be caused by domesticated or wild animals.

FDA also plans to hold four public meetings throughout the country to discuss the Draft Guidance, and further information on the date and location of those meetings will be provided in forthcoming *Federal Register* notices.

Draft Guidance on Reducing Food Safety Hazards Associated with Fresh-Cut Produce

FDA also issued a draft guidance document targeted toward facilities that are subject to the PCHF regulation and that manufacture, process, pack, or hold fresh-cut produce. ^{2/} The Draft Guidance defines “fresh-cut produce” as “any fresh fruit or vegetable or combination thereof that has been physically altered from its whole state after being harvested from the field (e.g., by chopping, dicing, peeling, ricing, shredding, slicing, spiralizing, or tearing) without additional processing (such as blanching or cooking).” ^{3/}

When finalized, the Draft Guidance will supersede FDA’s previous guidance entitled “Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,” which FDA issued in 2008. The 2008 Guidance explained FDA’s thinking on how to comply with the Current Good Manufacturing Practice (CGMP) regulations in 21 C.F.R. Part 110, which have been superseded by the updated CGMPs in FDA’s PCHF rule (21 C.F.R. Part 117, Subpart B). The recently issued Draft Guidance explains FDA’s current thinking on how to comply with the updated CGMPs and the new requirements for hazard analysis and risk-based preventive controls under the PCHF rule. The Draft Guidance uses the production of fresh-cut leafy greens as an example to demonstrate the PCHF requirements for a supply-chain program as well as to demonstrate process preventive controls.

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We will continue to monitor FDA’s implementation of FSMA. Please contact us if you have any questions.

^{2/} Guide To Minimize Food Safety Hazards of Fresh-Cut Produce: Draft Guidance for Industry (Oct. 2018), available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623718.pdf>.

^{3/} The Draft Guidance also elaborates that fresh-cut produce may or may not undergo a wash or other treatment before being packaged for use by the consumer or a retail food establishment. Fresh-cut produce can be a single commodity or two or more mixed in the same package, such as coleslaw or fruit salads, and sometimes called “ready to use,” “pre-cut,” or “value added” produce. Fresh-cut produce also does not include produce that has been processed by freezing, cooking, canning, or packing in a juice, syrup, or dressing.