

FDA Releases Report on Inspection and Environmental Sampling of Ice Cream Production Facilities for Harmful Bacteria

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- A large number of pathogen-related recalls of ice cream (16 over the three-year period of 2013, 2014, and 2015) and a deadly outbreak of listeriosis in 2015 that was linked to ice cream from Blue Bell Creameries (reported [here](#)), spurred a special assignment by the Food and Drug Administration (FDA). Specifically, FDA conducted inspections and environmental sampling of 89 of the nation's largest ice cream production facilities in 32 states from September 12, 2016, to August 30, 2017.
- On April 24, 2019, FDA [announced](#) the release of its [report](#) on the inspection and environmental sampling of about 16% of the domestic ice cream manufacturers in fiscal year 2017/2017 for *Salmonella* and *Listeria monocytogenes*. FDA's activity began about a month before larger food facilities were required to comply with the Preventive Controls for Human Food Rule that was established by the Food Safety Modernization Act (FSMA). No objectionable conditions or practices were found at 44 of the 89 inspected plants. *Listeria monocytogenes* was detected on non-food contact surfaces in 19 plants and from a food contact surface at 1 plant. *Salmonella* was less prevalent, reportedly detected only from a non-food contact surface and only in one facility.
- FDA suspended Food Facility Registration for one of the inspected plants, Working Cow Homemade, Inc., after it was linked to a clinical listeriosis case. After ceasing operations, the firm later resumed business as a warehouse distributor of ice cream products with no production operations. FDA worked with two other firms to conduct voluntary recalls, held seven regulatory meetings, and notified management at 39 facilities of the need to take voluntary corrective actions. FDA is also conducting follow-up inspections at all six of the facilities where objectionable conditions or practices warranting official action were observed in the first inspection.
- FDA's findings underscore the need for ice cream production plants and other food production facilities to develop and implement a food safety plan. Please email us at fooddrug@khlaw.com with any questions regarding the Preventive Controls for Human Food Rule or other FSMA requirements.

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