



## Assignment Findings: FY 16/17 Inspection and Environmental Sampling of Ice Cream Production Facilities for *Listeria monocytogenes* and *Salmonella*

(Grouped by Inspection Outcome)

Estab. ID	Estab. State	Inspection Outcome <sup>1</sup>	Pathogen Detected	Detection Zone <sup>2</sup>	Percent of Subsamples Positive	Initial Regulatory Response
1	CA	OAI	<i>Listeria monocytogenes</i>	2	2%	Regulatory Meeting
2	FL	OAI	<i>Listeria monocytogenes</i>	1, 2	16%	Voluntary Recalls, Suspension of Food Facility Registration <sup>3</sup>
3	IN	OAI	<i>Listeria monocytogenes</i>	2, 3, 4	30%	Regulatory Meeting
4	MA	OAI	<i>Listeria monocytogenes</i>	2, 3	6%	Regulatory Meeting
5	MI	OAI	<i>Listeria monocytogenes</i>	2, 3	2%	Regulatory Meeting
6	NY	OAI	<i>Listeria monocytogenes</i>	3	6%	Regulatory Meeting
7	AL	VAI	None	NA	NA	Corrective Actions Indicated
8	CA	VAI	<i>Listeria monocytogenes</i>	3	3%	Corrective Actions Indicated
9	CA	VAI	<i>Listeria monocytogenes</i>	2	2%	Corrective Actions Indicated
10	CA	VAI	None	NA	NA	Corrective Actions Indicated
11	CO	VAI	None	NA	NA	Corrective Actions Indicated
12	CT	VAI	<i>Listeria monocytogenes</i>	2, 3	5%	Corrective Actions Indicated
13	FL	VAI	<i>Salmonella</i>	3	1%	Corrective Actions Indicated

<sup>1</sup> The FDA uses three terms to classify the outcome(s) of inspections: Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI). An "OAI" classification indicates significant violations and is accompanied by regulatory follow-up. A "VAI" classification indicates lesser violations.

<sup>2</sup> The FDA classifies environmental sampling zones based on proximity to food. Zone 1 refers to all direct food contact surfaces (e.g., utensils, mixers, conveyors or dispensers); Zone 2 refers to areas directly adjacent to food contact surfaces (e.g., carts, equipment housing, or ventilation units); and Zone 3 refers to surfaces immediately surrounding Zone 2 (e.g., walls, forklifts, or doorways leading to food production areas).

<sup>3</sup> Following the suspension, the firm submitted a proposed shift in business to become a warehouse distributor of ice cream products. The company will not resume ice cream manufacturing operations, but instead will store and distribute products sourced from third party manufacturers. Given the proposed changes and commitments by the firm, along with FDA site inspection and verification, the FDA lifted the suspension, reinstating the firm's facility registration.

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14	FL	VAI	<i>Listeria monocytogenes</i>	2	2%	Corrective Actions Indicated
15	GA	VAI	<i>Listeria monocytogenes</i>	3	2%	Corrective Actions Indicated
16	GA	VAI	None	NA	NA	Corrective Actions Indicated
17	HI	VAI	None	NA	NA	Corrective Actions Indicated
18	IL	VAI	None	NA	NA	Corrective Actions Indicated
19	IL	VAI	None	NA	NA	Corrective Actions Indicated
20	MA	VAI	None	NA	NA	Corrective Actions Indicated
21	MD	VAI	None	NA	NA	Corrective Actions Indicated
22	MD	VAI	None	NA	NA	Corrective Actions Indicated
23	MD	VAI	<i>Listeria monocytogenes</i>	3	4%	Corrective Actions Indicated
24	MD	VAI	<i>Listeria monocytogenes</i>	3	2%	Corrective Actions Indicated
25	ME	VAI	<i>Listeria monocytogenes</i>	3	2%	Corrective Actions Indicated
26	MI	VAI	None	NA	NA	Corrective Actions Indicated
27	MN	VAI	None	NA	NA	Corrective Actions Indicated
28	MO	VAI	None	NA	NA	Corrective Actions Indicated
29	MO	VAI	None	NA	NA	Corrective Actions Indicated
30	ND	VAI	None	NA	NA	Corrective Actions Indicated
31	NJ	VAI	<i>Listeria monocytogenes</i>	2	10%	Corrective Actions Indicated
32	NY	VAI	None	NA	NA	Corrective Actions Indicated
33	NY	VAI	None	NA	NA	Corrective Actions Indicated
34	OH	VAI	None	NA	NA	Corrective Actions Indicated
35	OH	VAI	<i>Listeria monocytogenes</i>	2, 3	6%	Regulatory Meeting
36	OH	VAI	None	NA	NA	Corrective Actions Indicated
37	PA	VAI	<i>Listeria monocytogenes</i>	2	2%	Voluntary Recall, <sup>4</sup> Corrective Actions Indicated

<sup>4</sup> Due to the presence of allergens not declared on the product labeling.

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38	PA	VAI	None	NA	NA	Corrective Actions Indicated
39	TN	VAI	None	NA	NA	Corrective Actions Indicated
40	TX	VAI	None	NA	NA	Corrective Actions Indicated
41	UT	VAI	<i>Listeria monocytogenes</i>	2, 3	8%	Corrective Actions Indicated
42	UT	VAI	None	NA	NA	Corrective Actions Indicated
43	VT	VAI	None	NA	NA	Corrective Actions Indicated
44	WA	VAI	<i>Listeria monocytogenes</i>	3	2%	Corrective Actions Indicated
45	WA	VAI	None	NA	NA	Corrective Actions Indicated
46	WI	VAI	None	NA	NA	Corrective Actions Indicated
47	AR	NAI	None	NA	NA	NA
48	CA	NAI	None	NA	NA	NA
49	CA	NAI	None	NA	NA	NA
50	FL	NAI	None	NA	NA	NA
51	FL	NAI	None	NA	NA	NA
52	FL	NAI	None	NA	NA	NA
53	GA	NAI	None	NA	NA	NA
54	HI	NAI	None	NA	NA	NA
55	HI	NAI	None	NA	NA	NA
56	IA	NAI	None	NA	NA	NA
57	IL	NAI	None	NA	NA	NA
58	IL	NAI	None	NA	NA	NA
59	IL	NAI	None	NA	NA	NA
60	IN	NAI	None	NA	NA	NA
61	MI	NAI	None	NA	NA	NA
62	MN	NAI	None	NA	NA	NA
63	MO	NAI	None	NA	NA	NA
64	MO	NAI	None	NA	NA	NA
65	MT	NAI	None	NA	NA	NA

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66	NJ	NAI	None	NA	NA	NA
67	NJ	NAI	None	NA	NA	NA
68	NJ	NAI	None	NA	NA	NA
69	NY	NAI	None	NA	NA	NA
70	NY	NAI	None	NA	NA	NA
71	OH	NAI	None	NA	NA	NA
72	OH	NAI	None	NA	NA	NA
73	OH	NAI	None	NA	NA	NA
74	OK	NAI	None	NA	NA	NA
75	OR	NAI	None	NA	NA	NA
76	PA	NAI	None	NA	NA	NA
77	PA	NAI	None	NA	NA	NA
78	TN	NAI	None	NA	NA	NA
79	TN	NAI	None	NA	NA	NA
80	TN	NAI	None	NA	NA	NA
81	TX	NAI	None	NA	NA	NA
82	TX	NAI	None	NA	NA	NA
83	UT	NAI	None	NA	NA	NA
84	UT	NAI	None	NA	NA	NA
85	VA	NAI	None	NA	NA	NA
86	WA	NAI	None	NA	NA	NA
87	WI	NAI	None	NA	NA	NA
88	WI	NAI	None	NA	NA	NA
89	WI	NAI	None	NA	NA	NA