



**FY18/19 Sample Collection and Analysis of
Domestically Manufactured,¹ Dairy-Free Dark Chocolate Products for Milk Allergen**

(Table of Analytical Results and Follow-Up Actions)

Sample No.	Product Category	Firm ID ²	Analytical Result ³	Follow-Up Action ⁴
1	Chocolate Bar(s)	A	*	-
2	Chocolate Bar(s)	B	*	-
3	Chocolate Bar(s)	B	*	-
4	Chocolate Bar(s)	B	*	-
5	Chocolate Bar(s)	B	*	-
6	Chocolate Bar(s)	B	*	-
7	Chocolate Bar(s)	B	*	-
8	Chocolate Bar(s)	C	Milk Detected (600 ppm ⁵)	Recall (Event #1)
9	Chocolate Bar(s)	C	Milk Detected (1,600 ppm)	Recall (Event #1)
10	Chocolate Bar(s)	D	Milk Detected (1,700 ppm)	Recall (Event #2)
11	Chocolate Bar(s)	D	Milk Detected (2,100 ppm)	Recall (Event #2)
12	Chocolate Bar(s)	D	Milk Detected (2,300 ppm)	Recall (Event #2)

¹ The FDA collected samples from different regions of the country. Some samples were purchased online.

² Samples of product from the same firm are grouped based on de-identified firm ID. For example, samples 2 through 7 were all manufactured by the same firm (firm “B”).

³ The quantities of milk allergen detected and reported in this column represent the results of Neogen Veratox for Total Milk Allergen ELISA kit testing. The asterisk (*) indicates that the agency did not detect milk allergen using the Veratox kit or that the detection was below 5 parts per million. The FDA confirmed all positive Veratox kit findings (i.e., those above 5 ppm) by conducting Morinaga Institute of Biological Science Casein ELISA kit testing. The level of detection (LoD) and the level of quantitation (LoQ) of the Veratox kit are 0.1 ppm and 2.5 ppm milk, respectively. The LoD and LoQ of the Morinaga kit are 0.9 ppm milk each.

⁴ This assignment resulted in the recall of four products made by three firms (two of the recalled products were made by the same firm), for a total of three recall events, as indicated.

⁵ Parts per million.

Sample No.	Product Category	Firm ID ²	Analytical Result ³	Follow-Up Action ⁴
13	Chocolate Bar(s)	D	Milk Detected (700 ppm)	Recall (Event #2)
14	Chocolate Bar(s)	D	Milk Detected (800 ppm)	Recall (Event #2)
15	Chocolate Bar(s)	D	Milk Detected (3,100 ppm)	Recall (Event #2)
16	Chocolate Bar(s)	D	Milk Detected (1,600 ppm)	Recall (Event #2)
17	Chocolate Bar(s)	D	Milk Detected (1,600 ppm)	Recall (Event #2)
18	Chocolate Bar(s)	E	*	-
19	Chocolate Bar(s)	E	*	-
20	Chocolate Bar(s)	E	*	-
21	Chocolate Bar(s)	E	*	-
22	Chocolate Bar(s)	E	*	-
23	Chocolate Bar(s)	E	*	-
24	Chocolate Bar(s)	F1 ⁶	*	-
25	Chocolate Bar(s)	F1	*	-
26	Chocolate Bar(s)	F2	*	-
27	Chocolate Bar(s)	F2	*	-
28	Chocolate Bar(s)	F2	*	-
29	Chocolate Bar(s)	G1	*	-
30	Chocolate Bar(s)	G1	*	-
31	Chocolate Bar(s)	G1	*	-
32	Chocolate Bar(s)	G2	*	-
33	Chocolate Bar(s)	G2	*	-
34	Chocolate Bar(s)	G2	*	-
35	Chocolate Bar(s)	G2	*	-
36	Chocolate Bar(s)	H	*	-

⁶ Firm IDs that feature a letter and number signify that the samples tested were collected from products manufactured in different facilities owned by the same firm. For example, samples 24 and 26 were both made by firm "F"; however, sample 24 was made in firm "F" facility 1, and sample 26 was made in firm "F" facility 2."

Sample No.	Product Category	Firm ID ²	Analytical Result ³	Follow-Up Action ⁴
37	Chocolate Bar(s)	H	*	-
38	Chocolate Bar(s)	H	*	-
39	Chocolate Bar(s)	H	*	-
40	Chocolate Bar(s)	H	*	-
41	Chocolate Bar(s)	H	*	-
42	Chocolate Bar(s)	H	Milk Detected (90 ppm) ⁷	-
43	Chocolate Bar(s)	H	*	-
44	Chocolate Bar(s)	H	*	-
45	Chocolate Bar(s)	H	*	-
46	Chocolate Bar(s)	I	*	-
47	Chocolate Bar(s)	I	*	-
48	Chocolate Bar(s)	I	*	-
49	Chocolate Bar(s)	J	*	-
50	Chocolate Bar(s)	J	*	-
51	Chocolate Bar(s)	J	*	-
52	Chocolate Bar(s)	J	*	-
53	Chocolate Bar(s)	J	*	-
54	Chocolate Bar(s)	J	*	-
55	Chocolate Bar(s)	K	*	-
56	Chocolate Bar(s)	K	*	-
57	Chocolate Bar(s)	L	Milk Detected (1,500 ppm)	Recall (Event #3)
58	Chocolate Bar(s)	L	Milk Detected (1,700 ppm)	Recall (Event #3)
59	Chocolate Bar(s)	M	*	-
60	Chocolate Bar(s)	M	*	-

⁷ The FDA did not seek a recall in response to this positive sample; three other samples of the same product (Nos. 37, 43 and 44) tested negative for milk allergen. The agency notified the manufacturer of the test result, so that it could take appropriate action.

Sample No.	Product Category	Firm ID ²	Analytical Result ³	Follow-Up Action ⁴
61	Chocolate Bar(s)	M	*	-
62	Chocolate Bar(s)	M	*	-
63	Chocolate Bar(s)	M	*	-
64	Chocolate Bar(s)	M	*	-
65	Chocolate Bar(s)	M	*	-
66	Chocolate Bar(s)	M	*	-
67	Chocolate Bar(s)	M	*	-
68	Chocolate Bar(s)	M	*	-
69	Chocolate Bar(s)	M	*	-
70	Chocolate Bar(s)	M	*	-
71	Chocolate Bar(s)	M	*	-
72	Chocolate Bar(s)	M	*	-
73	Chocolate Bar(s)	M	*	-
74	Chocolate Bar(s)	M	*	-
75	Chocolate Bar(s)	M	*	-
76	Chocolate Bar(s)	M	*	-
77	Chocolate Bar(s)	M	*	-
78	Chocolate Bar(s)	M	*	-
79	Chocolate Bar(s)	M	*	-
80	Chocolate Bar(s)	M	*	-
81	Chocolate Bar(s)	M	*	-
82	Chocolate Bar(s)	M	*	-
83	Chocolate Bar(s)	N	*	-
84	Chocolate Bar(s)	N	*	-
85	Chocolate Bar(s)	N	*	-
86	Chocolate Bar(s)	N	*	-
87	Chocolate Bar(s)	N	*	-
88	Chocolate Bar(s)	N	*	-

Sample No.	Product Category	Firm ID ²	Analytical Result ³	Follow-Up Action ⁴
89	Chocolate Chips	O	*	-
90	Chocolate Chips	O	*	-
91	Chocolate Chips	O	*	-
92	Chocolate Chips	O	*	-
93	Chocolate Chips	P	*	-
94	Chocolate Chips	P	*	-
95	Chocolate Chips	P	*	-
96	Chocolate Chips	P	*	-
97	Chocolate Chips	P	*	-
98	Chocolate Chips	P	*	-
99	Chocolate Chips	Q	*	-
100	Chocolate Chips	G1 ⁸	*	-
101	Chocolate Chips	G1	*	-
102	Chocolate Chips	R	*	-
103	Chocolate Chips	R	*	-
104	Chocolate Chips	R	*	-
105	Chocolate Chips	S	*	-
106	Chocolate Chips	S	*	-
107	Chocolate Chips	S	*	-
108	Chocolate Chips	S	*	-
109	Chocolate Chips	S	*	-
110	Chocolate Chips	S	*	-
111	Chocolate Chips	T	*	-
112	Chocolate Chips	U	*	-
113	Chocolate Chips	U	*	-

⁸ This firm ("G") makes both chocolate bars and chocolate chips (in facility 1); both product categories were collected and tested under this assignment (also see samples 29, 30, and 31 above).

Sample No.	Product Category	Firm ID ²	Analytical Result ³	Follow-Up Action ⁴
114	Chocolate Chips	V	*	-
115	Chocolate Chips	V	*	-
116	Chocolate Chips	V	*	-
117	Chocolate Chips	V	*	-
118	Chocolate Chips	V	*	-
119	Chocolate Chips	V	*	-