



State Access to FACTS

Food and Drug Administration Inspection Report

Summary

Date Assigned: 04/02/2013 **Inspection Start Date:** 03/26/2013 **Inspection End Date:** 03/26/2013
Firm Name & Address : Blue Bell Creameries Inc, 423 N Norton Ave Sylacauga, AL 35150-2009 US
FEI: 1019788 **County:** TALLADEGA **Phone:** (256) 249-6100 **District:** New Orleans District Office

Endorsements

Endorsement

The firm operates as a processor of ice cream and frozen desserts. The current food safety inspection was conducted per contract by the Alabama Department of Public Health on a surveillance basis per FDA Contract. During this inspection the firm was processing ice cream (13AF001). Previous inspection was dated 03/14/12 and was classified as VAI. The firm received a copy of the Food Safety Modernization Act (FSMA) User Free Information Sheet. (b) (4), (b) (7)(E) The firm received printed materials and information on the Reportable Food Registry (RFR) requirements. The firm was aware of bio security measures and Employees First materials were provided. Current inspections found the following violations: #11. Replace or repair leaky valves in (b) (4) pints. #21. Cap all openings on (b) (4) tank during cleaning, clean inside roller (product contact side) on container machine. The firm's labeling is in compliance with NLEA requirements Findings were discussed with management, who agreed to make all necessary corrections. No samples were collected and no refusals were encountered. Inspection time: 6 hours Correspondence should be directed to Ms. Carolyn Suber, Quality Control Manager, at the address or phone number listed above Follow-up: VAI

SCM Remarks for State Inspection

Endorsement Location

<u>Supervisor</u>	<u>Date of Approval</u>
billst	05/08/2013

Registration

<u>Registration Type</u>	<u>Registration Date</u>
Food	12/04/2003
<u>Establishment Type</u>	<u>Industry Code</u>
Manufacturer	13 Ice Cream Prod

Inspection

Inspection Basis: Surveillance

Inspected Processes

<u>PAC</u>	<u>Establishment Type</u>	<u>Products/Process</u>	<u>Inspection Conclusion</u>
CONTRACT FOOD SANITATION INSPECTIONS	Manufacturer	13AFO	Voluntary Action Indicated

Products

Products Covered

<u>Product Code</u>	<u>Establishment Type</u>	<u>Description</u>
13AFO01	Manufacturer	Ice Cream, Regular, Vanilla or Vanillin Flavored; Paper; Pasteurized

Investigator

Investigator Accomplishment Hours

<u>Employee Name</u>	<u>PAC</u>	<u>Establishment Type</u>	<u>Process</u>	<u>Hours</u>
Clinkscales, Mike D	CONTRACT FOOD SANITATION INSPECTIONS	Manufacturer	13AFO	6.0

Results

Inspection Result

Inspection Summary

See endorsement.

Samples Collected

<u>Sample Number</u>	<u>Sample Description</u>
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Consumer Complaints

Consumer Complaint Numbers

56490

56034

Refusals

Refusals

Inspection Refusals

No refusal

Adverse Observations

Adverse Inspectional Observations Issued to the Firm? No

Blue Bell Creameries CF #1019788
423 North Norton Ave.
Sylacauga, AL 35150
Phone # 256-249-6100



This firm was inspected on 3/26/13

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The firm received printed materials and information on the Reportable Food Registry (RFR) requirements.

The firm was aware of bio security measures and Employees First materials were provided.

Current inspections found the following violations:

- #11. Replace or repair leaky valves in (b) (4) pints.
- #21. Cap all openings on (b) (4) tank during cleaning, clean inside roller (product contact side) on container machine.

The firm's labeling is in compliance with NLEA requirements

Findings were discussed with management, who agreed to make all necessary corrections.

No samples were collected and no refusals were encountered.

Inspection time: 6 hours

Correspondence should be directed to Ms. Carolyn Suber, Quality Control Manager, at the address or phone number listed above

Follow-up: VAI

Michael Clinkscales (mcw)

Michael Clinkscales
PHE Mgr.

**DEPARTMENT OF HEALTH AND HUMAN
FOOD GMP INSPECTION REPORT**

FOOD AND DRUG ADMINISTRATION

1. ESTABLISHMENT NAME AND ADDRESS <i>(Include ZIP code)</i> Blue Bell Creameries 423 North Norton Ave. Sylacauga, AL 35150	2. DATE INSPECTED 03/26/2013
	3. PRODUCT(S) INSPECTED Ice Cream
	4. STATE LICENSE OR PERMIT NUMBER 0161
5. NAME AND TITLE OF RESPONSIBLE PLANT OFFICIAL Ms. Carolyn Suber Quality Control Manager	6. TELEPHONE NUMBER <i>(Include Area Code)</i> 256-249-6100
7. NAME AND TITLE OF RESPONSIBLE CORPORATE OFFICIAL Kevin Wood, Plant Manager	8. TELEPHONE NUMBER <i>(Include Area Code)</i> Same

INSTRUCTIONS:

Answer the following questions by checking the appropriate box. Explain "No", answers on continuation sheet(s). Precede each explanation with the item number. Use "N/A" where questions are Not Applicable.

INSPECTION CRITERIA

NO.	PLANTS AND GROUNDS	YES	NO
1.	Are premises free of harborages and/or breeding places for rodents, insects and other pests	X	
2.	Is adequate drainage provided to avoid contamination of facilities and products	X	
3.	Is sufficient space provided for placement of equipment, storage of materials and for production operations	X	
4.	Are floors, walls and ceilings constructed of easily cleanable materials and kept clean and in good repair	X	
5.	Are food and food contact surfaces protected from contamination from pipes, etc., over working areas	X	
6.	Are food processing areas effectively separated from other operations which may cause contamination of food being processed	X	
7.	Are food products and processing areas protected against contamination from breakage of light bulbs and other glass fixtures	X	
8.	Is air quality and ventilation adequate to prevent contamination by dust and/or other airborne substances	X	
9.	Are doors, windows and other openings protected to eliminate entry by insects, rodents and other pests	X	
EQUIPMENT AND UTENSILS			
10.	Are all utensils and equipment constructed of adequately cleanable materials and suitable for their intended uses	X	
11.	Is the equipment designed and used in a manner that precludes contamination with lubricants, contaminated water, metal fragments, etc.		X
12.	Is the equipment installed and maintained so as to facilitate the cleaning of equipment and adjacent areas	X	

INSPECTION CRITERIA			
NO.	SANITARY FACILITIES AND CONTROLS	YES	NO
13.	Is the water supply adequate in quantity and quality for its intended uses	X	
14.	Are the water temperatures and pressures maintained at suitable levels for its intended use	X	
15.	Is the sewage disposal system adequate	X	
16.	Is the plumbing adequately sized, designed, installed and maintained in a manner to prevent contamination	X	
17.	Are adequate toilet rooms provided, equipped and maintained clean and in good repair	X	
18.	Are adequate handwashing and/or sanitizing facilities provided where appropriate	X	
19.	Is all refuse properly stored and protected where necessary from insects, rodents and other pests and disposed of in an adequate manner	X	
SANITARY OPERATIONS			
20.	Is the facility kept clean and in good physical repair	X	
21.	Is cleaning of facilities and equipment conducted in such a manner as to avoid contamination of food products		X
22.	Are detergents, sanitizers, hazardous materials and other supplies used in a safe and effective manner	X	
23.	Are cleaning compounds and hazardous materials kept in original containers, stored separate from raw materials	X	
24.	Are the processing areas maintained free of insects, rodents and other pests	X	
25.	Are insecticides and rodenticides used and stored so as to prevent contamination of food	X	
26.	Are all utensils and equipment cleaned and sanitized at intervals frequent enough to avoid contamination of food products	X	
27.	Are single service articles stored, handled, dispensed, used and disposed of in a manner that prevents contamination	X	
28.	Are utensils and portable equipment stored so as to protect them from splash, dust and other contamination	X	
PROCESSES AND CONTROLS			
29.	Is responsibility for overall plant sanitation specifically assigned to an individual	X	
30.	Are raw materials and ingredients adequately inspected, processed as necessary and stored to assure that only clean, wholesome materials are used	X	
31.	Is ice (where used) manufactured from potable water and stored and handled in a sanitary manner	NA	
32.	Is food processing conducted in a manner to prevent contamination and minimize harmful microbiological growth	X	
33.	Are chemical microbiological or extraneous material testing procedures used where necessary to identify sanitation failures of food contamination	NA	
34.	Are packaging processes and materials adequate to prevent contamination	X	
35.	Are only approved food and/or color additives used	NA	
36.	Are products coded to enable positive lot identification, and are records maintained in excess of expected shelf-life	X	
37.	Are weighing and measuring practices adequate to ensure the declared quantity of contents	X	

INSPECTION CRITERIA

NO.	PROCESSES AND CONTROLS	YES	NO
38.	Are labels of products covered during inspection in compliance (submit violative labels as exhibits)	X	
39.	Are finished products stored and shipped under conditions which will avoid contamination and deterioration	X	

DETAILS OF MANUFACTURING PROCEDURES AND CONTROLS

Provide brief description of manufacturing processes and controls for product(s) inspected. Where appropriate, report times, temperatures, and other critical processing steps. If microbiological or any other type of contamination is suspected or encountered, fully describe the relationship between the routes of contamination and the process. Use flow charts where appropriate. If more space is needed, use continuation sheet.

(b) (4)

NO.	PERSONNEL	YES	NO
40.	Are personnel with sores, infections, etc., restricted from handling food products	X	
41.	Do employees wear clean outer garments, use adequate hair restraints and remove excess jewelry when handling food	X	
42.	Do employees thoroughly wash and sanitize hands as necessary	X	
43.	Do employees refrain from eating, drinking and smoking and observe good food handling techniques in processing areas	X	

CORRECTIONS AND SAMPLES

If any corrections were made as a result of this inspection or made as a result of a previous inspection (including voluntary destructions, capital improvements, etc.), complete Voluntary Correction section of cover sheet Form FDA 481 (E) CG.

If any samples were collected, list sample numbers and briefly describe samples.
No samples collected

DISCUSSIONS WITH MANAGEMENT

Indicate individual with whom inspection was discussed. Identify official (name and title) having authority to authorize corrections. Record any recommendations/warnings given, and management's response.

Ms. Carolyn Suber
Quality Control Manager

Item #:

- 11. Replace or repair leaky valves in (b) (4) pints.
- 21. Clean inside roller on carton machine, cap (b) (4) tank openings during clean up.

(Use additional sheets as appropriate.)

SIGNATURE OF INSPECTOR
Michael Clinkscates PHE Mgr.

Michael Clinkscates *mcw*

DATE
03/26/2013

FOOD PROCESSING PLANT INSPECTIONAL OBSERVATIONS

**Alabama Department of Public Health
Bureau of Environmental Services
Milk and Food Processing Branch**

Name of Individual to whom report issued To: <i>Ms. Carolyn Suber</i>	Date of Inspection <i>3/26/13</i>	C.F. Number <i>1019788</i>
Title of Individual <i>Quality Control Manager</i>	Type of Establishment Inspected (i.e., bakery, cannery) <i>Ice Cream & Frozen Dessert Mfg.</i>	
Firm Name <i>Bluebell Creameries</i>	Name of Firm, Branch or Unit Inspected <i>Same</i>	
Street Address <i>423 N. Norton Ave</i>	Street Address of Premises Inspected <i>Same</i>	
City and State <i>Sylacauga AL 35150</i>	City and State <i>Same</i>	

During an inspection of your firm (I) (We) observed:

- 1) replace or repair leaky valves in **(b) (4)** pints
- 2) opening on **(b) (4)** tank not capped
- 3) Clean inside roller (product contact surface) that touches the bottom of carton (inside) on the carton machine

Employee(s) signature <i>[Signature]</i>	Employee(s) Name and Title (print or type) <i>QA Manager</i>
Employee(s) signature <i>[Signature]</i> <i>PHS-ajr ADPH</i>	