

## REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR #589.2000 BSE CHECKLIST Version 5.0

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FEI# 1682009

Firm (Legal) Name: Blue Bell Creameries Inc

FDA District Office: DAL-DO

Firm (Physical) Address: 1101 S Blue Bell Rd

Date Current Inspection Ended:  
07/16/2009

Brenham, Texas, 77833-4413, United States

Lead Affiliation: State

State Agency: TX FEEDS

Lead Investigator: Sanders, Scott

Name and title of person(s) interviewed: Tommy Supak, Director Quality Control, Doug Middleton Ingredient Processing Manager, Travis Wood Ingredient Processing Manager, Andy Kollman, Quality Manager

Name and title of most responsible person at this site: Tommy Supak, Director Quality Control

Checklist Status: Completed

Checklist Status Date: 08/04/2009

Legacy Checklist? No

Checklist Entered By: Sanders, Scott

Checklist Entered Date: 07/28/2009

Last Modified Date: 08/04/2009

### Section 1 - Complete for ALL firms

1. a) Type of firm inspected?

Feed Mill (not FDA Licensed)

Human Food Processor

b) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of RUMINANT animals? No

c) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of NON-RUMINANT animals? Yes

d) Is the firm aware of the BSE rule, 21 CFR 589.2000? Yes

2. Does the firm RECEIVE feeds or feed ingredients that contain or may contain prohibited material (PM)? No

a) If Question 2 is "Yes, but PM is only in Retail Pet/Lab Feed" or "NO", check all of the following that describe VOLUNTARY safeguards the firm has in place to assure they do not receive prohibited material.

Written assurance from SUPPLIERS that they no longer manufacture/distribute any products containing prohibited materials

Written procedures for the label review of incoming materials

Uses animal proteins only from EXEMPTED sources Milk, Poultry

[If Q2 = No OR Q1a) is ONLY "Feeder of Ruminants," then skip to Section 3]

b) If Question 2 is either "YES, but PM is ONLY in Retail Pet/Lab Feed" or "YES", is imported prohibited material (not originating in the United States) used?

Please list the country/ies of origin for the imported prohibited material

3. Is the RECEIVED product containing prohibited material ONLY intended for further distribution?

4. Does the firm manufacture or process products containing prohibited materials?

5. Are the RECEIVED feeds or feed ingredients containing prohibited materials (referred to in #2 above) labeled with the caution statement, "Do not feed to cattle or other ruminants"?

**Section 2-Complete for ALL firm types EXCEPT: Firms that are ONLY Q1a) Firm Type="Other" OR Firms that are ONLY Q1a) Firm Type="Feeder of Ruminants"**

6. Are the OUTGOING feeds or feed ingredients containing prohibited materials labeled with the caution statement, "Do not feed to cattle or other ruminants"?

7. Describe records the firm maintains in tracking prohibited materials throughout their receipt, processing, and distribution:

- a) Date of receipt or purchase or sale or delivery
- b) Name and address of the seller
- c) Name and address of the purchaser
- d) Identification of the product
- e) Quantity
- f) Copies are available for inspection and copying
- g) Are ONLY RETAIL feed sales involved?
- h) Are ONLY RETAIL feed sales of PET FOOD involved?

8. a) Does the firm manufacture, process, blend or repackage or transport BOTH products containing prohibited materials AND products containing only non-prohibited materials?

b) Does the firm manufacture, process, blend or repackage or transport BOTH products containing prohibited materials AND feeds or feed ingredients that may be used for ruminants?

9. a) Does the firm have a system in place to avoid commingling and cross-contamination?

b) Check all of the following that describe the separation system or clean-out processes and any procedures to avoid commingling and cross-contamination (with the exception of pet food sold at retail and laboratory animal feed).

10. Please describe any additional safeguards that the firm has in place to assure that OUTGOING feeds or feed ingredients containing prohibited material are not shipped to ruminant feeders, (If None, please Enter "None")

**Section 3 - SKIP this section if the firm is ONLY marked as: Q1a) Firm Type="Other" OR Q1a) Firm Type="Transporter (Hauler)"**

- |  |     |
|--|-----|
| 11. a) Are any incoming feeds or feed ingredients transported in bulk form?  | Yes |
| b) Are any incoming feeds or feed ingredients transported in packaged form?  | Yes |
| c) Does the firm utilize its own transportation vehicles for the delivery of any bulk INCOMING feeds or feed ingredients?  | No  |
| d) Does the firm utilize other firms' transportation vehicles for the delivery of any bulk INCOMING feeds or feed ingredients?   | Yes |
| e) If 11(d) is "YES", do ALL INBOUND transporters provide written assurance that they utilize dedicated transport equipment OR utilize measures that adequately prevent commingling or cross-contamination with prohibited material? | Yes |
| 12. a) Are any OUTGOING feeds or feed ingredients transported in bulk form?  | No  |
| b) Are any OUTGOING feeds or feed ingredients transported in bagged/package form?  | Yes |

- c) Does the firm utilize its own transportation vehicles for the delivery of any OUTGOING bulk feeds or feed ingredients? No
- d) Does the firm utilize other firms' transportation vehicles for the delivery of any OUTGOING bulk feeds or feed ingredients? No
- e) If 12(d) is "YES", do ALL OUTBOUND transporters provide written assurance that they utilize dedicated transport equipment OR utilize clean-out measures that adequately prevent commingling or cross-contamination with prohibited material?
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**Section 4 - Complete this section ONLY if the firm is marked as: Q1a) Firm Type="Feeder of Ruminants"**

13. Are ruminant feeders doing the following?

- a) Observing the caution statement on feeds labeled as containing prohibited material(PM)
- b) Maintaining copies of labeling for feeds containing animal protein (AP) (Not including retail pet food for cats and dogs)
- c) Maintaining copies of purchase invoices for feeds containing animal protein (Not including retail pet food for cats and dogs)
- d) Feeding non-ruminant species (Not including cats and dogs)
- e) Feeding non-ruminant species (Not including cats and dogs) feeds which contains or may contain prohibited material
- f) Feeding cats and/or dogs
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**Section 5 - Complete for ALL Firm Types**

14. a) Check ALL deviations that were noted at the time of inspection.

No Deviations Observed

b) If any deviations were noted above, describe the deviations, and the actions and commitments made to correct each deviation,

15. Are you attaching any further descriptions/exhibits/records and/or labeling? Yes