



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

KIRK COLE
INTERIM COMMISSIONER

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Voluntary Regulatory and Public Health Agreement between the Department of State Health Services and Blue Bell Creameries, Inc.

I. JURISDICTION

The Department of State Health Services (DSHS) has jurisdiction to regulate frozen dessert manufacturers as authorized by Chapters 431 and 440 of the Texas Health and Safety Code (HSC) and the Department rules at 25 Texas Administrative Code Chapter 229 which apply to frozen dessert manufacturers. DSHS is also the state public health agency established to protect and promote the health of the people of Texas.

II. SITUATION

Following a series of laboratory results indicating that there was *Listeria monocytogenes (Lm)* present in products and on equipment of the Blue Bell Creameries located in Brenham, Texas (the company), the company voluntarily initiated a national recall of its entire product line and suspended production at the Brenham facilities as well as facilities located in other states. All of the recalled product, except that which has been held for testing and research purposes, has been destroyed or is in the process of being scheduled for destruction. The company is also voluntarily engaged in comprehensive plant sanitation, employee training, and establishment of new or revised policies, procedures, and environmental and product testing programs to ensure that its products, when re-introduced into commerce, do not contain *Lm*.

III. OBJECTIVE

As both the regulatory and state public health agency, it is incumbent that, before Blue Bell Creameries re-introduces food products into commerce in Texas from its Brenham facilities, DSHS has confirmation that the company has:

- thoroughly cleaned and sanitized the facilities, to include all equipment;

- trained all employees on the subject;
- developed and implemented new or revised policies, procedures, and processes to minimize the likelihood of producing any product containing *Lm* in the future;
- completed a trial run of manufacturing an acceptable product as evidenced by negative product samples for *Lm*; and
- notified DSHS at least 2 weeks in advance of their intent to re-introduce food products into commerce in Texas from its Brenham facilities.

IV. TERMS OF AGREEMENT

To achieve confirmation of the steps outlined above, Blue Bell Creameries of Brenham, Texas, voluntarily agrees to:

1. Retain an independent sanitation and/or microbiology expert qualified by background, education, training and experience to determine that the methods, facilities and controls necessary are in place that will prevent the introduction of contamination. This expert should also, to the extent possible based on the best science available, help the company assure that the plant and the equipment are properly prepared, maintained and operated to safely produce products that do not contain *Lm*.
2. Preserve all environmental, product and ingredient testing results and make such results available for DSHS to review upon request.
3. Beginning with the trial run prior to product reintroduction, notify DSHS within 24 hours of receiving a laboratory report of any presumptive positive test result for *Listeria monocytogenes* found in ingredient or finished product samples from the Brenham facilities. If such test result is received by the company on a weekend or holiday, the 24-hour period would expire on the next business day. Such reporting shall continue for a period of 2 years from the date of initial market reintroduction, and may be extended as deemed necessary by DSHS depending on the nature and extent of the test results reported to date.
4. Provide DSHS full access to the Brenham facilities for purposes of collecting ingredient, finished product, or environmental samples. It is understood that DSHS would seek to take any presumptive positive test results for *Listeria species* through to final confirmation for *Lm* and maintain any confirmed *Lm* isolates in the DSHS laboratory in Austin.
5. Conduct root cause analyses for the purposes of identifying potential or actual sources of contamination and allow DSHS to review the documentation.
6. Ensure that the company's Pathogen Monitoring Program (PMP) for *Lm*, includes plans on how the company will respond to presumptive positive tests for *Listeria species* when and where found.
7. Make available for DSHS review upon request:
 - a. Plant deep cleaning and on-going sanitation policies, procedures and records;
 - b. Company staff training curriculum and records, along with plans for re-training of existing staff, new hire orientation, and ongoing training;

- c. Plans for plant modifications made for the purpose of controlling potentially harmful bacteria within the plant operating environment and/or food handling machinery; and
 - d. Start-up procedures prior to initiating production runs for any purpose, up to and including the manufacture of product for entry into commerce.
8. Beginning with the trial run prior to product reintroduction, institute a “test and hold” program for all finished product to be introduced into commerce for a period of one year, or such period as deemed necessary by DSHS in light of the nature and extent of the test results reported under paragraph 3 of this section.

In addition, the company voluntarily agrees that all future food processing and distribution activities will be undertaken pursuant to, or in reflection of, the following industry recognized standards for plant performance:

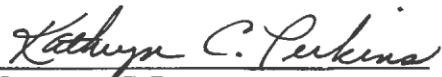
1. Sanitation Standard Operating Procedures (SSOPs);
2. Good Manufacturing Practices (GMPs);
3. a Pathogen Monitoring Program (PMP) for *Listeria Monocytogenes (Lm)*, which includes environmental, ingredient and finished product testing; and
4. a Hazard Analysis and Critical Control Points (HACCP) plan and/or a written Food Safety Plan, including sections on:
 - a. verifiable product trace-back procedures and
 - b. sufficient product recall practices.

The Department of State Health Services agrees, to the greatest extent possible, to:

1. Review items above as they are completed;
2. Conduct reviews and confirmatory sampling at the facilities concurrently with company staff and experts; and
3. Communicate with national and other state regulatory agencies to coordinate activities.

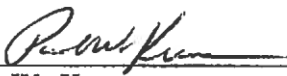
SO AGREED on this 14th day of May, 2015.

TEXAS DEPARTMENT OF STATE HEALTH SERVICES


KATHRYN C. PERKINS
ASSISTANT COMMISSIONER
REGULATORY SERVICES

SO AGREED on this 14th day of May, 2015.

On behalf of Blue Bell Creameries, Inc., as its President and Responsible Individual in Charge, I hereby acknowledge understanding the terms of this Voluntary Agreement; enter into it freely; and accept and agree to its terms and conditions without reservation.


PAUL W. KRUSE
BLUE BELL CREAMERIES, INC.
PRESIDENT & C.E.O.