DFA Dairy Brands Quality Assurance Policy and Procedures

DFA DAIRY BRANDS Dairy Farmers of America **Privileged and Confidential**	**Section:** **Nonconforming Product Control** **Subject:** **Product Recall Procedure**	**Policy Number:** **10.6**	Review Date: November 8, 2021 Supersedes: New Issue Date: November 8, 2021 Page: 1 of 11

POLICY In the event of a product retrieval (recall, withdrawal, etc.) DFA Dairy Brands facilities shall follow the product recall procedures outlined in this policy. When a DFA Dairy Brands product is determined to be in violation of food and drug law or when it presents a risk of illness or injury to the public, the recommendation to remove product from the market SHALL be jointly made by Corporate, Regional, and Plant teams overseeing the manufactured goods. The decisions to remove product from the marketplace can only be made by the SVP of Operations and Quality Assurance.

OBJECTIVE To ensure that all affected product is identified, located, and removed from distribution or from the market as promptly, efficiently, and completely as possible.

SCOPE The procedures outlined in this policy apply to:

1. All DFA Dairy Brands manufacturing locations.
2. All onsite and offsite functions that support DFA Dairy Brands manufacturing locations including but not limited to copackers and Distribution Centers

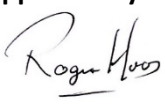
REFERENCES

1. FDA Industry Guidance http://www.fda.gov/Safety/Recalls/IndustryGuidance
2. Policy 10.3 Crisis Management Plan
3. Recall appendices (10.6 A1 to 10.6 A13)

TOPICS Product Recall procedure major subsections are outlined below and are followed by the procedure detailed instructions:

1. Situation Evaluation
2. Recall Coordinator and Other Team Member Responsibilities.
3. Notice to State and Federal Regulators
4. Regulatory Action after Notice from company
5. Recall Strategy
6. Elements of a Recall Strategy

Approved by:



November 8, 2021
Date

Roger Hooi
VP of Quality Assurance, Food Safety and Regulatory

PROCEDURES

In the event a potential health hazard is detected by internal or external means, the following steps shall be followed. Recall considerations demand priority attention and all designated responsibilities must be fulfilled promptly and contemporaneously.

1. Situation Evaluation

1.1 Any product that has been released for distribution which does not conform to established standards of safety, identity, strength, quality, and purity in accordance with the Federal Food, Drug and Cosmetics Act or which labeling does not conform with the Fair Packaging and Labeling Act may be recalled at the discretion of DFA Dairy Brands or by direction of the Food and Drug Administration ("FDA").

1.2 In the event of a recall possibility:

1.2.1 The severity of the situation must be evaluated immediately for appropriate action.

1.2.2 The evaluation process must include the affected Plant, Regional, and Corporate Management Teams.

1.2.3 The recall team shall be led by the Vice President of Quality Assurance, Food Safety and Regulatory or the Vice President, Legal Department in completing the **"Product Recall Cause and Origin Questionnaire" (See Appendix 10.6 A1)**.

1.2.4 The recall teams will consider the degree of risk associated with the situation, including the seriousness of any health hazard relating to consumption of the product.

1.2.5 The recall teams should consider, but not limit considerations to the following factors:

1.2.5.1 Consumer complaints of illness, injury, or adverse reactions.

1.2.5.2 Whether conditions exist that could contribute to the product posing a health hazard.

1.2.5.3 The likelihood of occurrence of the hazard.

1.2.6 All Company resources should be utilized to determine which finished products are involved and which customers are affected.

1.2.7 DFA Dairy Brands facility will identify and trace all affected products by lot codes (i.e., ingredients) or code dates (Sell By, Best By, Best if Used By, etc.).

1.2.8 All Company facilities must report promptly of quantities of affected products that are on hand. Such products should be segregated and isolated and marked with a "Hold" sticker (See Appendix 10.5 A1) to ensure it is not distributed.

1.3 Depth of Recall

The level in the distribution chain to which the recall is to extend will be based on the product's degree of hazard and the extent of distribution. There are three basic options:

1.1.1 The consumer or user level, including any intermediates, wholesale, or retail level. (Recall)

1.1.2 The retail level, including any intermediates, or wholesales level. (Market Withdrawal)

1.1.3 The wholesale levels. (Stock Recovery)

Note: In cases where a health hazard is imminent, the depth of the recall would be to the consumer or user level. The task of determining the appropriate depth of the recall is the joint responsibility of the recall team members.

2. Recall Coordinator and Other Team Member Responsibilities.

2.1 The FDA requires that the company appoint a "Recall Coordinator."

2.2 The DFA Dairy Brands Recall Coordinator is the Vice President of Quality Assurance, Food Safety and Regulatory.

2.3 Since the Recall Coordinator will be the primary contact for regulatory personnel, the Recall Coordinator must be provided the most current knowledge of the relevant facts. The Recall Coordinator should be easily accessible and readily available to all regulatory personnel and be extremely reliable.

2.4 The Recall Coordinator shall function as the Recall Team Director and the Recall Coordinator shall lead the Recall Team through the execution of the product recall.

2.5 The responsibilities of the Recall Coordinator and the various groups and individuals within our Company during a recall event are described generally in **Appendix 10.6 A4. Recall Team Responsibilities**.

3. Notice to State and Federal Regulators

3.1 When the recall teams (Corporate, Regional, and Plant teams) determine that product conditions exist that may cause consumers serious adverse health consequences or death to humans or animals (SAHCODHA), the recall teams may then recommend the removal of the affected product from the market. The decisions to remove product from the marketplace can only be made by the Sr. Vice President of Operations and QA.

3.2 Once the decision to remove product from the market, State and Federal Regulators should be notified as soon as possible. In consultation with the DFA Brands Legal Department, only the VP of Food Safety, Quality Assurance and Regulatory Affairs or a representative under their direction may notify State and / or Federal Regulators. Notification should be made to the State Department of Health (or equivalent) in the state where the affected product was produced, or the FDA, if the affected product was shipped or stored across state boundaries (interstate). **(See Appendix 10.6 A2, List of FDA Regional Offices Phone Numbers).**

3.3 Prior to the notification of State and Federal Regulators or the removal of any product from the market, any Private Label customer whose product is affected by the incident must be notified.

3.4 The VP of Food Safety, Quality Assurance and Regulatory or a representative under their direction will work with State and / or Federal Regulators to determine the need to file the incident into the National Food Registry. If appropriate, the VP of Food Safety,

Quality Assurance and Regulatory Affairs or a representative under their direction will ensure that the incident is filed with the National Food Registry.

4. Regulatory Action after Notice from Company

4.1 The State Department of Health and the FDA will request all necessary information about the product in question (i.e., type, name, code(s), manufacturing facility, reason of withdrawal, distribution, etc.) **(See Appendix 10.6 A3, Information/Documents Needed by FDA for Recalls of Food Products)**.

4.2 The recall team members shall be prepared to provide the required information. It is important that DFA Dairy Brands facility identify a primary contact to manage the recall at the facility. The DFA Dairy Brands facility should provide regulatory with the names, titles and telephone numbers of Company officials who will have a role in the recall, including the Recall Coordinator.

4.3 The FDA will evaluate the information submitted by the company and assign a classification to the recall. This classification will be based on the severity of the situation as defined below:

Class I - is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. (i.e., undeclared allergens in finished products).

Class II - is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (i.e., undeclared food color in finished products).

Class III - is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences. (i.e., incorrect butterfat).

4.4 The FDA will issue a statement on the recall classification to DFA Dairy Brands and to the relevant State Department of Health. The FDA may request the DFA Dairy Brands to initiate a recall when it has determined that a product that has been distributed presents a risk of illness or injury or gross consumer deception and that action is necessary to protect the public health and welfare.

4.4.1 The FDA will advise DFA Dairy Brands that the recall will be published in its weekly FDA Enforcement Report according to its classification.

4.4.2 The FDA may conduct an inspection of the affected plant to collect samples of the product and labeling. A request may also be made for complete distribution addresses, and copies of QA analytical data which supports the decision to recall. It will be the responsibility of the Recall Coordinator to respond to these requests, with the assistance of the Corporate and Regional Quality Assurance personnel.

4.4.3 Failure to conduct an effective recall could result in seizure of the violative product and possibly criminal prosecution.

5. Recall Strategy

5.1 Once it is decided that a recall is necessary and that the product poses a public health risk, the Recall Team is responsible for developing a recall strategy. The strategy must consider the following factors:

5.1.1 Results of the health hazard evaluation.

5.1.2 Ease in identifying the product to the consumer by codes, label names and other means.

5.1.3 The degree to which the product's deficiency is obvious to the consumer.

5.1.4 The geographical area of distribution.

5.1.5 Whether the product remains under the control of the manufacturer or its distributors.

5.1.6 How the affected product can be distinguished so that good product may continue to be made available to consumers.

5.1.7 How will the affected product be collected from our customers, and how reimbursement will be made.

5.2 The FDA may request to review the recall strategy, but DFA Dairy Brands should not wait for FDA approval to begin taking action to recover the product. In its review of the strategy, the agency will recommend any changes it believes will make the plan more effective.

6. Elements of a Recall Strategy

The recall strategy must address the following elements: Public Notification and Effectiveness Checks, Customer Notification / Notification of Consignee, Insurance Notification, Product Return and Disposition, Recall Status Reports, Recall Termination, Recording the Recall, Notification to GFSI, Corrective Actions, and Record Retention.

6.1 <u>Public Notification</u>

6.1.1 The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations (Class I) where other means for preventing consumption of the recalled product appear inadequate. It is the manufacturer's responsibility to issue the press release to the appropriate media outlets that will assure that consumers are alerted to the risk wherever the product is distributed. This task shall be the responsibility of the Vice President of Corporate Communications.

6.1.2 Prior to any public notification pertaining to any Private Label product, the customer whose product is affected by the incident must be notified.

6.1.3 Prior to any public notification pertaining to any DFA Brands product, the customer whose product is affected by the incident must be DFA Brands Consumer Affairs team shall be notified with all pertinent information.

6.1.4 The Recall Team decides to issue a press release it must first be submitted to the appropriate District office of the FDA for review and comment. The FDA will also post their own press release on the FDA's website.

6.1.5 If the recall involves an undeclared food allergen, the FDA also requires the press release to be posted on the Food Allergy & Anaphylaxis Network website (www.foodallergy.org). The Vice President of Corporate Communications shall ensure that the press release is posted on this website.

Food allergy advocacy organizations available:

a. The Food Allergy & Anaphylaxis Network (FAAN)
10400 Eaton Place, Suite 107
Fairfax, VA 22030-2208
800-929-4040 phone
703-691-2713 fax
faan@foodallergy.org

b. Food Allergy Initiative
212-207-1974 phone
917-338-5130 fax
info@faiusa.org

c. Local food allergy organizations
If issue is localized to certain geography, consider contacting a local support group. Reference list here:
http://www.faiusa.org/?page=support_groups

6.1.6 Communications checklist and protocol (**Appendix 10.6 A12**)

6.2 Effectiveness Checks

6.2.1 Effectiveness checks are required to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action. Generally, the FDA will conduct effectiveness checks. Consignees may be contacted by personal visit, telephone, e-mail, mail, or combination of the above.

6.2.2 The level of effectiveness checks that will be conducted will be determined by the recall team or by the FDA.
Level A -100 percent of the total number of consignees to be contacted.
Level B - A specified number above 10 percent of the consignees to be contacted.
Level C -10 percent of the total number of consignees to be contacted.
Level D - 2 percent of the consignees to be contacted.
Level E - No effective checks are required.

6.2.3 In a recall event, a Level A effectiveness check is necessary. In conducting a recall effectiveness check, the "**Effectiveness Questionnaire Form (See Appendix 10.6 A5)** will be used to document acknowledgment of notification from consignees and record the quantity of units they have on hand.

6.2.4 The task of performing the effectiveness checks is the responsibility of the Plant and Regional Sales managers or their designees. Interviewers doing the telephone effectiveness checks should be thoroughly knowledgeable about the background and purpose of the recall and be given a detailed question-by-question review of the questionnaire. The purpose of these questions is to determine whether:

6.2.4.1 Notification of the recall was received.

6.2.4.2 The product involved was handled as instructed in the notice.

6.2.4.3 The consignee before receipt of the return notification further distributed the product involved.

6.2.4.4 If the product was further distributed, were these additional consignees notified.

6.2.5 The plant manager, quality assurance manager, and VP of Sales shall provide periodic status reports to the Corporate and Regional Quality Assurance Directors on the progress of the effectiveness checks. These reports are helpful in determining if there is any problem with the notification process or the questionnaire. Any reports of illness or injury shall be reported to the recall team, the Vice President of Risk Management, and Insurance Company so that arrangements for immediate follow-up can be made.

6.2.6 Documentation of the initial notification to the consignee and all follow up contacts will be documented on the **"Customer Notification and Questionnaire Form" (See Appendix 10.6 A6)**. A separate questionnaire will be used for each consignee, which will substantiate the effectiveness of the notice.

6.2.7 When the last of the recall effectiveness checks have been made, a final tabulation of the results of the contacts and questionnaires shall be made by the Recall Coordinator or their designee. Evaluation of this data will give an estimate of the effectiveness of the recall notice.

6.3 <u>Customer Notification / Notification of Consignee</u>

6.3.1 Each affected direct account (i.e., retail, broker, and distributor) must be notified of the recall immediately. Telephone calls or personal contacts are the quickest method of communication, but such contacts should be confirmed and documented by using the **"Customer Notification and Questionnaire Form" (See Appendix 10.6 A6).** If necessary, a written communication (e-mail or overnight letter) should be sent using the content in **"Sample Customer Notice of Recall Letter/Email" (See Appendix 10.6 A8).** The communication with the customer should be brief and to the point. It should not contain irrelevant qualifications or any statement that may detract from the message.

6.3.2 The following information should be conveyed:

6.3.2.1 The product name, SKU number, quantity, carrier, and lot code number specified which is subject to recall. Include any other pertinent information to enable accurate and immediate identification of the product.

6.3.2.2 Explain concisely the reason for the recall and the hazard involved, if any. **Further sale of any remaining products should cease immediately**.

6.3.2.3 The direct account should notify its customers who received the product. The same information should be conveyed to its consignees.

6.3.2.4 Instructions should be given regarding what to do with the detained product (i.e., segregate for pick-up; do not destroy).

6.3.2.5 Record whether customer has any of the products, how much it has in stock, and how much it has distributed.

NOTE: Customers who were not available when first contacted must be re-contacted until notified about the recall.

6.4 Insurance Notification

The insurance carrier covering the recall must be notified of the recall event at this time. This task shall be the responsibility of the Vice President of Risk Management. Insurance coverage and claim processes are fully described in the attached **"Product Recall Insurance Claim Process "(See Appendix 10.6 A10)**.

6.5 Product Return and Disposition

6.5.1 As delivery drivers return affected products to the facility; the Plant Manager, Distribution Manager, or designee, will record the detailed information about the returned products and periodically report the quantities of returns to the Corporate and Regional Quality Assurance Managers.

6.5.2 Upon receipt, all returned products must be segregated and tagged in a confined/controlled area to await disposition upon completion of the return per Policy 10.5 Hold and Release Program.

6.5.3 The Recall Coordinator will make the final decision of the disposition of the affected product. If the disposition of product is destruction, then the actual destruction must be witnessed and an "Affidavit of Product Destruction" is to be completed and signed. **See Appendix 10.6 A9 for "Affidavit of Product Destruction".**

6.6 Recall Status Reports

Periodic status reports must be submitted to the appropriate FDA District office as requested, so the FDA can assess the progress of the recall. The FDA will determine the reporting interval based on the determined urgency of the recall.

The recall report shall contain the following information:

6.6.1 The number of consignees notified of the recall, the date and method of notification.

6.6.2 The number of consignees contacted regarding the recall and quantity of products on hand.

6.6.3 The number of products returned by each consignee contacted and the quantity of products accounted for.

6.6.4 The number and results of effectiveness checks that were made.

6.7 Recall Termination

A recall will be terminated when the FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subjected to the recall has been removed and the proper disposition or correction has been accomplished. **(See Appendix 10.6 A7, Information Needed by FDA to Terminate a Recall)**.

6.7.1 The FDA will send written notice to DFA Dairy Brands when the recall is terminated.

6.7.2 DFA Dairy Brands may request termination of a recall by submitting a written request to the appropriate FDA District office stating that the recall is effective in that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and it is reasonable to assume that the product has been removed and the proper disposition or correction has been accomplished. Included with this request will be:

6.7.2.1 The most current recall status report.

6.7.2.2 A description of the disposition of the recalled product.

6.8 Recording the Recall

6.8.1 The task of summarizing the recall event shall be the responsibility of the VP of Quality Assurance, Food Safety and Regulatory with assistance with the Vice President, Legal Department.

6.8.2 The **"Product Recall Investigative Report" (See Appendix 10.6 A11)** shall be completed within thirty days after the recall is terminated.

6.9 Notification to GFSI

The Recall Coordinator will advise the Regional Quality Director to notify the SQF Certification Body and SQFI in writing at foodsafetycrisis@sqfi.com within twenty-four hours of the recall (only for Class I or II) initiation of receipt of a regulatory warning letter.

6.10 Corrective Actions

6.10.1 DFA Dairy Brands shall perform a root cause analysis and determine corrective actions to reduce the likelihood of reoccurrence of a non-compliance event for any incident that leads to a recall or market withdrawal.

6.10.2 Circumstances evaluated will be led by the local plan with the assistance of the regional team to ensure corrective actions developed are effective.

6.11 Record Retention

6.11.1 The Recall Coordinator is responsible for ensuring that records are systematically organized, indexed, and stored appropriately.

6.11.2 Documents that are to be retained include product-related information, communications, instructions, forms, and all recall documentation.

6.11.3 The minimum program necessary to meet Company and federal record retention requirements is six years plus current year.

6.11.4 The timing and mechanics of record destruction is the responsibility of the Recall Coordinator who must assure that retention requirements are met, and destruction is complete.

CHANGE HISTORY

No.	Nature of Change	Date
1	New consolidated policy from both legacy DFA Dairy Brands and legacy Dean Foods	November 8, 2021
2		
3		