APPLIED FOOD SCIENCES, INC.
675-B Town Creek Road, Kerrville, Texas 78028
Customer Service: 512-306-9660 Toll Free: 800-345-9666
Customer Service Fax: 512-306-9580

| **PRODUCT RECALL PROGRAM** | | | |
|---|---|---|---|
| POL-01-001 | Revision: 06 | Effective Date: 07/12/2023 | |
| Originated By: | Chris Fields | Approved By: | Blake Dixon |
| Title: | VP Scientific Affairs | Title: | Quality Manager |
| Date: | 08/2013 | Date: | 07/12/2023 |

## POLICY

It is the policy of Applied Food Sciences ("AFS") to respond to food product safety concerns and issues in an effort to protect the health, safety, and welfare of the public consuming one of the AFS products and / or ingredients.

## PURPOSE

The purpose of this Product Recall Program is to prevent food related health risks to all persons consuming Applied Food Sciences products by establishing procedures for an immediate and appropriate response to food product recall notices and suspect foods.

## DEFINITIONS

Classes of Recall Notice: Ranking of personal health risk associated with food product recall. Class 1 is defined as a reasonable probability of health risk. Class 2 has a remote probability of health risk. Class 3 does not cause adverse health consequences.

Hazardous Analysis Critical Control Points (HACCP): A proactive system AFS employs for achieving food safety based on seven essential steps that identify and control physical, chemical, and biological hazards.

AFS Customers: All distributors, retailers, brokers, manufacturers, and formulators who receive an AFS product.

## RESPONSIBILITIES

1. All AFS employees are responsible for promptly responding to notifications of food product recalls or concerns about the wholesomeness of food products.
2. The Quality Manager or the VP Scientific Affairs are responsible for verifying the Mock Recalls were completed.
3. The Quality Department and the VP Scientific Affairs are responsible for validating this program as defined on this procedure.

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RECALL PROCEDURES

1. If an AFS product is suspected to be contaminated, mislabeled, adulterated or out of specification a Quality Deficiency Notice form (FOR-01-002) will be completed by personnel following the procedures described on SOP-01-002.
2. A recall situation could also come from a supplier of AFS products or components.
3. The QDN will be forwarded to the VP of Scientific Affairs. If an AFS product is to be recalled or may need to be recalled, the recall team will be contacted. VP of Scientific Affairs serves as the Recall Coordinator.
4. The Recall Team consists of Executive Leadership Team. See FOR-05-001 Contact List for contact numbers roles and responsibilities.
5. The situation will be investigated and the possible recall situation classified (see Class I, II, III definitions). The decision to recall will be determined by the Recall Team and in coordination with legal counsel. The FDA may be notified of Class I recall situations. FOR-05-001 contains contact information for the FDA. If the FDA is to be notified the following information will need to be provided to the FDA (see http://www.fda.gov/safety/recalls/industryguidance):
    a. Product name, lots, item numbers
    b. AFS contact information
    c. Supplier/manufacturer name and address
    d. Recall reason, health assessment, recall classification and why
    e. Recall strategy – to what level of distribution; list of customers; how they will be contacted; how product is to be returned
    f. Method for determining effectiveness of the recall strategy – how to determine if recall notification have been received and acted upon.
6. SQFI and the certification body will be notified in instances of a food safety incident of a public nature or product recall for any reason.
7. If a recall is needed:
    a. All Recall Team meetings and decisions will be documented.
    b. Inventory and shipping records will be reviewed.
    c. Product in inventory will be quarantined and marked “recall or suspect recall”.
    d. Product that has been shipped to customers will be identified by lot, quantity and customer.
    e. The level of the recall will be determined. AFS customers will be notified, but it will need to be determined if the recall should be extended beyond this level of distribution. The determination may be made after AFS customers are notified. If the customer still retains the product then the recall may not need to be extended.
    f. The customer will be notified:
        i. Customers will be notified by email, writing or by phone.
        ii. Documentation must be kept of the method and contacts made.
        iii. Sample letters are attached in Appendix A and B that may be used for notifying customers.
        iv. AFS may also call the customer and complete the documentation

indicating the lots and quantities in question. If AFS is completing the documentation for the customer that should be noted.

v. All notifications will be documented (copies of letters and email saved, phone calls documented).

vi. The customer will be asked to provide a response regarding the recalled product. Appendix B contains an example response letter. The response letter will detail what happened to the AFS product shipped to that customer. AFS may complete this information on behalf of the customer if AFS receives this documentation over the phone.

g. Returned product will be handled according to SOP-01-005.

h. All returned product will be quarantined and labeled "recall".

i. Product should be accounted for to 100% or as close as possible. Recall Coordinator will maintain inventory accounting in an organized fashion. Confirmed Recall Accountability Form FOR-03-011 can be used to document the accountability.

j. The situation will be investigated and a root cause determined. Corrective Actions will be documented and implemented.

k. Termination of the recall will be documented. Recall termination occurs when:

i. If the FDA has been notified, recall termination will only happen after notification from the FDA and

ii. All product is accounted for and destroyed.

1. Product that is destroyed as part of a recall situation will be documented on the Destruction Log FOR-03-007. Product will not be destroyed until notification has been received from the FDA (if applicable).

## VERIFICATION AND VALIDATION ACTIVITIES

1. Mock Recalls
   - 1.1. Mock recalls will be conducted at least once per year according to this procedure.
   - 1.2. FOR-03-011 will be used to document the Mock Recall exercise.
   - 1.3. All documents should be clearly marked MOCK RECALL. The completed forms will be recorded in the Dropbox folder "PRP Quality Deficiency and Product Recall".
   - 1.4. Notification outside of AFS is not required for the mock recall exercise.
   - 1.5. Mock recalls may be conducted on products sold, incoming product or components in order to evaluate all process streams.
   - 1.6. Mock recalls will be documented and should be considered effective if 90-105% of product is accounted for within 4 hours. Shorter time durations may be considered for mock recall completed on domestic only sales.
2. Validation of the Program
   - 2.1. Mock recalls will be reviewed annually to assess the effectiveness of the program. The review will be documented on FOR-01-009 Pre-requisite Program Validation Form.

2.2. Improvements to the recall program will be documented as corrective actions and implemented.

ATTACHMENTS

I. Appendix A – Example of Letter for Customer Notification of Recall
II. Appendix B – Example of Response Letter for Customer to Complete and Return Immediately

REFERENCES

SOP-01-002 Quality Deficiency Notice (QDN) Program
FOR-01-002 Quality Deficiency Notice Form
FOR-05-001 Contact List
SOP-01-005 Returns
FOR-03-011 Confirmed Recall Accountability Form
FOR-03-007 Destruction Log
FOR-01-009 Pre-requisite Program Validation Form

Revision History

| Date | Revised By | Rev No. | Reason for Revision |
|---|---|---|---|
| 11/15/2014 | Molly | 01 | Renumbered the document from AFS Form 300 – 1B to POL-01-001 |
| 06/05/2016 | Ana P. Craig | 02 | Added References, added Revision History, formatted. |
| 07/27/2017 | Ana P. Craig | 03 | Added "SQFI will be notified of food safety incidents" (6). |
| 01/04/2018 | Ana P. Craig | 04 | Added Validation Activity. Updated responsibilities. |
| 03/19/2019 | Blake Dixon | 05 | Changed time line for mock recalls from 24 hours to 4 hours. Updated acceptable percentage for mock recalls. |
| 07/12/2023 | Blake Dixon | 06 | Updated business address |

END OF DOCUMENT

## APPENDIX A – Example of Letter for Customer Notification of Recall

CUSTOMER NOTIFICATION OF RECALL <issue on company letterhead>
URGENT: <Product Name and Code> RECALL

Date: <Date>
Applied Food Sciences
675-B Town Creek Road
Kerrville, Texas 78028
Dear:
<Business Name>
<Business Address>
<Contact Person>

**This is to inform you of a product recall involving:**
**<Product/Label>, <Lot Number>, Expiration Date>**
This recall has been initiated due to <problem>. The consumption of this product:

| |
|---|
| □ HAS A REASONABLE PROBABILITY OF CAUSING SERIOUS, ADVERSE HEALTH CONSEQUENCES OR DEATH (CLASS I) |
| □ MIGHT CAUSE TEMPORARY HEALTH CONSEQUENCES & SLIGHT THREAT OF SERIOUS NATURE (CLASS II) |
| □ IS UNLIKELY TO CAUSE ADVERSE HEALTH CONSEQUENCES (CLASS III) |

**According to our records, your business received <quantity> of this product, shipped on <date>, <invoice number>.**
We request your assistance in the removal of this production from distribution.
1. We request that you review our products in your inventory. Segregate and hold products.
2. A representative of our company will contact you to arrange retrieval of the product. Arrangements are being made to ship replacement products as soon as possible.
3. If you have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.
**4. Please return the enclosed response letter as soon as possible.**

If you have any questions, call <Phone>
This recall is being made with the knowledge of the Food and Drug Administration.

Sincerely,
<Responsible person print name> <Responsible person signature>
<Title>
<Address>
<Phone>

**APPENDIX B - Example of Response Letter for Customer to Complete and Return Immediately**

CUSTOMER NOTIFICATION OF RECALL RETURN RESPONSE FORM <issue on company letterhead>

Please complete and return this letter, regarding the product recall involving <insert Product/Label>, <insert Lot Number>, immediately to Applied Food Sciences, even if you do not have any product on your stock.

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the <date> letter.

□ I have checked my stock and have quarantined inventory consisting of _____ <units>.

Indicate disposition of recalled product:

□ Returned (specify quantity, date and method), or ☐ held for return;

□ Relabeled/repackaged (specify quantity and date);

□ Quarantined (specify quantity);

□ Sold (specify date and quantity);

□ I have identified and notified my customers that were shipped or may have been shipped this product by (specify date and method of notification); ☐ Attached is a list of customers who received/may have received this product. Please notify my customers.

Any adverse events associated with recalled product? □ Yes □ NO

If yes, please explain: _____

Customer Representative Name: _____

Title: _____

Tel. number: _____

Company name: _____