Document #: **SOP# 30**	Title: **30. PRODUCT RECALL- MOCK RECALL**	Print Date: **27/06/2025**
Rev #: **1.8**	Reviewed By: **Nguyen Thi Thuy Trang**	Date Reviewed: **27/06/2025**
Effective Date: **27/06/2025**	Approved By: **Nguyen Pham Thanh**	Date Approved: **27/06/2025**
Standard(s): **FDA 101: PRODUCT RECALL & BRC STANDARD (Issue 9, August 2022)**		

Purpose: To ensure effective recall procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the good from the market.

To regularly test mock recall product by tracing in a manner that is appropriate to ensure their effective operation which traceability can be determined from raw material to finished product and vice versa.

Scope: This procedure applies for product recall and mock recall.

Responsibilities:

- HACCP Food Safety Team *and/ or* QC/ QA Department
- Processing/ Warehouse Department
- General Director
- Marketing Department

Procedures:

I. RECALL CLASSIFICATIONS:

Based on the *"FDA 101: Product Recalls*", these guidelines categorize all recalls into one of three classes, according to the level of hazard involved:

- ***Class I:*** Dangerous or defective products that predictably could cause serious health problems or death, such as a food found to contain botulinum toxin, food with undeclared allergens…
- ***Class II:*** Products that might cause a temporary health problem, or pose only a slight threat of a serious nature, such as food under-strength but is not used to treat life-threatening situations.
- ***Class III:*** Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws, such as a minor container defect and lack of English labeling in a retail food.

II. PRODUCT RECALL

1. General Director designates recall team of company to handle if there is any recall occurred.
2. If there is any problem that might affect food safety hazard, buyer or distributor or consumer, etc. will send a telephone and email/ fax or telex to Marketing Department of the company for investigation and actions. The contact information 24/ 7 are as below:
   - ***Marketing Department for Export Sales***

     Mr. Nguyen Pham Thanh

     Tel: +84 274 3 790201/ Mobile: +84 903 913107

     Email: npthanh@highlanddragon.com.vn
   - ***Marketing Department for Local Sales***

     Ms. Ta Nu Viet Ha / Marketing Manager

     Tel: +84 274 3 790201/ Fax: +84 274 3 790210

     Email: Vietha@highlanddragon.com.vn
3. Marketing Department distributes reply to Chairman of Management Board *(for information)* and to General Director for investigation. The contact information 24/ 7 are as below:
   - ***Chairman of Management Board***

     Mr. Richard Fowler Email: kingtuna42@gmail.com

❖ ***General Director***

Mr. Nguyen Pham Thanh

Tel: +84 274 3 790201

Mobile: +84 903 913107

Email: npthanh@highlanddragon.com.vn

4. General Director calls a meeting *(In some case the email & calling were used to inform the problem)* with all Managers of Quality Control Department, Production Department, Warehouse Department and Marketing Department to search for more information.
5. From raw material to finished product and vice versa such as the can code, dates of production, production line, all materials used such as fish, ingredients, empty cans and lids, labels and cartons, shipment…and other involved information are able to be traced back.
6. For Marketing Department, they shall check the following details of the problem code of product and then inform to related departments and General Director.
   a. Can code list that found problem
   b. Details of problem
   c. Brand and Label Name
   d. All distributed locations and the amount distributed to each location
7. For QC/ QA and Production Department shall review records detail if they related to the product problem same as ***item 4 & 5 of SOP# 31.***
8. For Warehouse Department, they shall check quantity of product produced of the same code as the product in question shipped and available in the warehouse to take into account stock requisition and recovery. If product available, they shall segregate and inform to QC Dept.
9. If there is any available stock of the product code that found problem, QC/ QA will take some samples to evaluate. If evaluation/ analysis could be done by internal lab, it will do internally. If it could not be done by lab, QA sent samples to analyze by outside competent laboratory.
10. Production Department and Warehouse Department shall send all the related information to QC/ QA Department for assessment.
11. QC/ QA Manager concludes the cause of the problem together with proposing corrective actions then submits to related Manager, Technical Advisor and/ or General Director.
12. General Director discuss with HACCP Food Safety Team/ QC-QA Manager and Marketing Manager in order to get conclusion if product poses health hazard or only quality problem.
13. The final disposition for the problem product is any of the following:
    a. Handle as normal complaint if the problem is not of health hazard concern, *or*
    b. The product may release if the findings show evidence that the rest product is safe for consumption, *or*
    c. Destroy the products if the findings show evidence that product is unsafe for consumption.
14. If a product recall is initiated, the HACCP Food Safety Team will have a meeting with all involved departments in order to identify and fix the problem. QC Department has to follow up the corrective actions and reports to General Director routinely. The General Director will make a report about final disposition of the product and send to Managing Director for approval and to Marketing Department.
15. Upon approval of final disposition, Marketing Department has to take further steps of action. If the case is considered as normal complaint, Marketing Department will proceed according to consumer complaint procedures. If the case is considered as a recall, Marketing Department should do the following:
    a. Notify the customers/ buyers/ distributors about the problem products (code list, quantity, label, and problem) and corrective actions that the factory will solve this problem, and/ *or*
    b. Withdraw all problem product from distributors and shelves, and/ *or*
    c. Destroy the problem product, and/ *or*
    d. Compensate all expenses incurred to the customers/ buyers/ distributors, and/ *or*

e. Notify mass media of the recall for public warnings of provincial, city and related agencies and organizations in accordance with the law on consumer protection if necessary, *and,*

f. Notify in writing the recall of food to the competent food safety authority. The owner of the establishment must clearly state: name and address of the production establishment; food names; packaging specifications, production batches, production dates and expiry dates; quantity, reason for recall, list of places to gather and receive recalled food; recovery time.

g. In the event of a significant food safety, authenticity or legality incident, including a product recall, regulatory food safety non-conformity or food safety-related withdrawal, the certification body issuing the current certificate for the site shall be notified within 3 working days. The company shall then provide sufficient information to enable the certification body to assess any effects of the incident on the ongoing validity of the current certificate within 21 calendar days. As a minimum, this shall include corrective action, root cause analysis and a preventive action plan.

h. Methods of handling unsafe food after recall & report on food handling results after recall: Comply with Articles 13 and 14 of Circular 17/2021/TT-BNNPTNT dated Dec. 20, 2021.

i. If the recall is happened at US, notify the local FDA district office no later than 24 hours on the FDA's RFR home page: www.fda.gov/reportableFoodRegistry.

16. The certification body and regulatory authority will be notified as following list:

a. ***Global Standard for the Food Safety authority***:

Certification body: SGS VIETNAM LTD.,

Address: Floor 4th, Nguyen Kim Building, 198 Nguyen Thi Minh Khai, Ward 6, District 3, HCMC, Vietnam

Contact person: Mr. Nguyen Hong Trung

Tel: 0971111269

Email: trung.nguyen@sgs.com

b. ***Southern Region of Quality, Processing and Market Development***

Contact person: Mr. Nguyen Dinh Thu - Managing Director

Tel: +84 (28) 3.6228822 Mobile: +84 913398994

Email: cc_clcb_nb@mae.gov.vn

Effectiveness Checks if Product Recall

- ❖ HACCP Food Safety Team evaluates whether all reasonable efforts have been made to remove or correct a product. A recall is considered complete after all of the corrective actions are reviewed by HACCP Food Safety Team and deemed appropriate.
- ❖ After a recall is completed, HACCP Food Safety Team makes sure that the product is destroyed or suitably reconditioned, and investigates why the product was defective in the first place. Root cause analysis and implementing ongoing improvements, to avoid recurrence.

Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions, and which may present a similar hazard to public health, should be evaluated for safety and may need to be withdrawn. The procedures for investigation and actions are the same as mentioned previously.

III. MOCK RECALL *or* TRACEABILITY TEST

1. On an annual basis, the Company shall verify the effective operation of recall procedures by conducting two (2) mock recall exercises.
2. Mock recalls shall follow the same procedures specified in **SOP# 30**: ***"Product Recall"***.
3. To test traceability from finished product to raw materials, the Food Safety Team shall initiate a *"Mock Recall"* by notifying the Quality Control (QC) Manager, of a lot of finished product that requires tracing due to an unspecified problem.

4. To test traceability from raw materials to finished product, the Managing Team shall initiate a *"Mock recall"* by notifying to the Quality Control (QC) Manager the lot of incoming materials that requires tracing due to an unspecified problem.
5. The traceability of raw material usage and final product packing records to substantiate claims shall undertake documented mass balance tests at a frequency to meet the particular scheme requirements *or* at least ***every 6 month*** in the absence of a scheme-specific requirement.
6. All required information for product traceability regarding material, products and records shall be located and relayed to the Food Safety Team Leader/ General Director with time limit ≤ four (4) hours and % recoveries ≥ 99.5% from the time notification. ***(See * 1).***
7. If the above time requirement is not met, or the required information is incomplete or incorrect, the frequency of mock recalls *or* traceability test shall be increased to quarterly.
8. Frequency shall revert to normal after two consecutive successful mock recall *or* traceability exercises have been completed.
9. Mock recall *or* product traceability performance shall be documented and kept on file.

(*1) *Food Plant/GMP/ HACCP/ Security check list – FAI: G.4.1*

Records:

- All of records of Item # II.7
- Product Traceability Report
- Recall/ Mock recall report *(Information from Warehouse)*

Revision History:

Revision	Date	Description of changes	Requested By
0.0	25/04/2008	Initial Release	Chris Lord
0.1	12/05/2008	Modified target of recovery min. 99.5% for recall/ mock recall and record.	Chris Lord
0.2	09/04/2009	Changed time of mock recall for located and relayed to the Food Safety Team Leader with time limit ≤ 4 hours.	Management team
0.3	09/04/2010	Changed authorized of technical advisor by the Food Safety Team Leader/ General Director.	Management team
0.4	19/05/2010	Modify the contact list of certification body and regulatory authority will be notified if product recall.	Management team
0.5	02/07/2011	Modify the contact information of ***FAI*** certification body of Global Standard for the Food Safety authority will be notified if product recall & record.	Management team
0.6	27/12/2011	Modify the limit time will be informed to certification body if product recall. (Based on 3.11.4 of BRC Issue 6 – July 2011)	Management team
0.7	19/02/2013	- Modify the Recall Classification (definition of Class I, II, III) and effectiveness checks if product recall. - Modify the contact information of ***FAI*** certification body of Global Standard.	Management team
0.8	19/02/2014	Modify the records will be checked if product recall. Modify the contact information of ***NAFIQUAD 4*** certification body of *National Agro-forestry-Fisheries Quality Assurance Department-Branch 4* for the Food Safety authority will be notified if product recall.	Management team

Revision	Date	Description of changes	Requested By
0.9	19/06/2014	- Modify the contact information Global Standard for the Food Safety authority certification body of CERT ID EUROPE LTD will be notified if product recall. - Modify the records will be checked if product recall base on SOP# 31.	Management team
1.0	19/03/2015	Modify the contact information Global Standard for the Food Safety authority certification body of CERT ID EUROPE LTD will be notified if product recall.	Management team
1.1	09/05/2016	- Modify the contact information Global Standard for the Food Safety authority certification body of NSF CERTIFICATION will be notified if product recall. - Modify procedure to test the traceability of raw material usage and final product packing with mass balance to meet the particular scheme *or* at least every 6 months. *(Based on 5.4.4 of BRC Issue 7 – July 2015)*	Management team
1.2	19/07/2017	Modify the contact information of NAFIQAD & Vietnam city code will be notified if product recall.	Management team
1.3	12/03/2018	Modify the name of Vietnam regulatory authority.	Mgmt. team
1.4	12/12/2018	Modify the contact person of Marketing Department for Export Sales.	Mr. Thanh
1.5	10/07/2020	Modify contact information Global Standard for the Food Safety authority certification body as SGS VIETNAM	Mgmt. team
1.6	27/09/2022	Modify some contents on the recall of Seafood products that do not ensure quality and/ or safety according to Circular 17/2021/TT-BNNPTNT dated Dec. 20, 2021 & item 3.11.4 of BRC 9.	NAFIQAD – SRA Mgmt. team
1.7	27/06/2024	Modify the name of Vietnam Regulatory Authority.	Mgmt. team
1.8	27/06/2025	Modify the email & name of Vietnam Regulatory Authority.	Mgmt. team