



Quality Assurance Procedure

TITLE: Non-Conforming Product Recall,
Market Withdrawal or Stock
Recovery and Mock Recall
Procedure

Procedure No. CQAP 3
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Effective Date: March 15, 2011

1. PURPOSE

To provide a procedure for the removal from commerce a product judged not to be in compliance with the quality standards established by the following:

- 1.1. Innophos' Manufacturing Specifications, primarily in the areas of chemical, foreign particle or microbiological contamination.
- 1.2. Compendia under jurisdiction of the Food and Drug Administration
 - 1.2.1. United States Pharmacopoeia
 - 1.2.2. National Formulary
 - 1.2.3. Food Chemicals Codex

2. DEFINITIONS

- 2.1. Non-Conforming Product is any product, which is:
 - 2.1.1. "adulterated", misbranded or otherwise not in compliance with any applicable governmental regulation or,
 - 2.1.2. Not in accord with an established specification and/or standard of identity whether adopted by Innophos a customer, governmental agency, or other body.
- 2.2. Product Recall is the removal or correction of non-conforming product which has entered channels of distribution outside of the Company's direct control where the product is in violation of governmental statute, rule, or regulation. Three classes of Product Recall are recognized which indicate the relative degree of health hazard presented by the product being recalled:
 - 2.2.1. Class I Recall is a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death.



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2.2.2. Class II Recall is a situation in which use of or exposure to product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequence is remote.

2.2.3. Class III Recall is a situation in which use of or exposure to a product is not likely to cause adverse health consequences.

2.3. Market Withdrawal is a removal of non-conforming product which has entered channels of distribution outside of Innophos' direct control from said channels, when the product is not in violation of any governmental statute, rule or regulation or when, if such a violation exists, the infraction is minor and would not subject Innophos to legal action by any governmental body under its existing compliance policy.

2.4. Stock Recovery is a removal from channels of distribution of non-conforming product which has not left the direct control of Innophos, irrespective of the physical location of the product in question.

2.5. Innophos is Innophos, Inc. and all its subsidiaries.

3. PROCEDURE

3.1. All Innophos employees or agents promptly convey all customer complaints and warnings of non-conforming product within the scope of this procedure to the **EMERGENCY COMMUNICATIONS TEAM 24/7 NUMBER 615-386-7816**.

3.2. The Manager, Regulatory Affairs & Product Stewardship investigates and, if applicable, confirms the validity of any report of a non-conforming product, and summarizes such findings for the following personnel:

- Chief Executive Officer
- Vice President Operations
- Vice President & General Counsel
- Vice President, Specialty Phosphates Business
- Vice President, Research & Development



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- Manager, Commercial Development & Technical Services
 - Appropriate Business Manager
 - Appropriate Plant Manager

3.3. The Manager, Regulatory Affairs & Product Stewardship recommends to either:

- Initiate a Product Recall
- Initiate a Market Withdrawal
- Initiate a Stock Recovery
- Close the case.

3.4 The Vice President, Specialty Phosphates Business decides to initiate a Product Recall, Market Withdrawal or Stock Recovery.

3.5 The Chief Executive Officer:

3.5.1. Approves the initiation of a Product Recall, Market Withdrawal or Stock Recovery.

3.5.2. If appropriate and applicable, reports or announces the decision to initiate a Product Recall, Market Withdrawal or Stock Recovery.

3.5.3. Oversees the execution of the product recall action.

3.6 The Vice President & General Counsel

3.6.1. If applicable, informs the appropriate governmental agencies of the recall action taken, and advises the Manager, Regulatory Affairs & Product Stewardship of the information which needs to be submitted to these agencies.

The British Retail Consortium (BRC) Registration body, AIB-CB as well as the appropriate ISO Registration bodies (NSF-ISR or SAI Global) will be notified of the product recall and this will be recorded.



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- 3.6.2 Advises management of their legal rights under statutory proceedings and recommends actions to avoid violations of the law.
 - 3.6.3 Accesses all customer or carrier claims related to the Product Recall, Market Withdrawal or Stock Recovery.
 - 3.6.4 Coordinates all external communications, i.e., press releases and verbal discussion with the news media.
- 3.7. The Manager, Regulatory Affairs & Product Stewardship:
- 3.7.1 Directs all Product Recall, Market Withdrawal and Stock Recovery Actions:
 - a. Determines the locations of the coded material released for shipment, and the total quantity returned to the designated manufacturing plant.
 - b. Directs the location and conditions of isolated storage and disposal or rework of all non-conforming product in the manufacturing plant.
 - c. Ensures that none of the material will re-enter the distribution chain, without having first been brought into compliance.
 - d. Coordinates the plant's investigation into the cause of the shipment of non-conforming product, and recommends corrective/preventive action to eliminate its re-occurrence.
 - 3.7.2 Provides status reports on actions taken to appropriate Innophos personnel.
 - 3.7.3 Maintains all necessary records. Refer to Appendix A.
 - 3.7.4 Maintains a directory of names and telephone numbers of key personnel responsible for handling a Product Recall, Market Withdrawal or Stock Recovery Action. Refer to Appendix B.



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3.8. The Vice President Operations:

- 3.8.1. Advising the Plant Manager responsible for the production of the product being recalled of the recall action taken.
- 3.8.2. Places a hold on the shipment of all suspected non-conforming products from a plant or warehouse until a clarification of the situation has been received.
- 3.8.3. Makes available all personnel and facilities required by the Manager, Regulatory Affairs & Product Stewardship to direct the recall action.

3.9. Vice-President, Specialty Phosphates Business:

- 3.9.1. Forwards all sales reports and written complaints concerning the non-conforming product to the Quality Assurance Manager, and advises appropriate sales personnel of the recall action to be taken..
- 3.9.2. Coordinates the development of a recall notification letter to Customers, in conjunction with Manager, Regulatory Affairs & Product Stewardship and General Counsel.

3.10. Plant Management:

The Plant Manager and/or his delegates assist the Manager, Regulatory Affairs & Product Stewardship in the recall process by providing information on the amount of material produced, inventory on hand, quantity shipped to customers, names and addresses of all consignees, as well as, plant and laboratory records related to the non-conforming material.

4. MOCK RECALL PROCEDURE



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- 4.1. Each manufacturing location shall develop a mock recall procedure, with the following elements to be included:
- a. Selection of products, lot numbers and type of contamination.
 - b. Notification of plant personnel, as well as, the Manager, Regulatory Affairs & Product Stewardship who will coordinate and direct the recall process.
 - c. Review of inventory and distribution records to account for all products in question.
 - d. Development of Recall Notice for submission to customers.
 - e. Review and evaluation of all raw material, in-process and finished product records for the lot numbers in question.
 - f. Investigation of possible causes of contamination, as well as, corrective and preventive actions.
 - g. Summary reporting outlining all aspects of the recall.
- 4.2. Each manufacturing location implements a mock recall on a semi-annual basis.



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APPENDIX A

PRODUCT RECALL RECORDS

(Not applicable to Market Withdrawal or Stock Recovery)

1. PRODUCT RECALL DATA

- A. Identity of products involved.
- B. Description of the deficiency or possible deficiency in the product and date and circumstances under which it was discovered; including verification data of customer and/or Innophos samples.
- C. Total quantity produced and the time span of the production.
- D. Total amount estimated to be in distribution channels.
- E. Distribution information, including identity of all consignees.
- F. Evaluation of the risk associated with the deficiency or possible deficiency.

2. PRODUCT RECALL STATUS REPORTS

- A. Number of consignees notified of the Product Recall and date and method of notification.
- B. Number of consignees responding to the Product Recall communication and the quantity of products on hand at the time it was received.
- C. Number and identity of consignees that did not respond.
- D. Quantity of product returned or corrected by each consignee contacted.
- E. Reconciliation of the quantity of products accounted for and the amount estimated on the market.
- F. Time frames for completion of the recall.



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APPENDIX B

DIRECTORY OF KEY PERSONNEL

<u>NAME</u>	<u>POSITION</u>	<u>PHONE</u>
Randy Gress	Chief Executive Officer	609-366-1201
Louis Calvarin	Vice President, Operations	609-366-1206
Bill Farran	Vice President & General Counsel	609-366-1232
Joe Golowski	Vice President, Specialty Phosphates Business	609-366-1205
Russ Kemp	Vice President, Research & Development	609-366-1222
Roy Lyon	Manager, Regulatory Affairs & Product Stewardship	609-366-1282
Rosaleen Doherty	Manager, Commercial Development & Technical Service	609-366-1292



Innophos, Inc.
259 Prospect Plains Road ♦ Building A
Cranbury, NJ 08512-3706
Telephone: (609) 495-2495
Fax: (609) 860-0138
www.innophos.com

January 1, 2014

To Whom It May Concern:

Please be advised that none of Innophos' products contain latex.

Please advise if you have any questions or need further information regarding this matter.

Regards,

A handwritten signature in blue ink, appearing to read "Ray S. For".

Quality/Regulatory Affairs Manager



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TO WHOM IT MAY CONCERN:

Please be advised that Innophos has adopted a new General Format for Lot Code Identification on Innophos' Product and it is as follows:

Lot XXXXXX XXX, where XXXXXX is a sequential six digit lot number, and XXX is the sequential three digit pallet number within the lot. This identification appears on individual pallet labels

The Certificate of Analysis which accompanies each lot in the shipment contains the manufacturing date and the retest (shelf life) date. The lot number on COA's is six digits XXXXXX, followed by a pallet range of 6 digits XXXXXX: the first 3 digits are the first pallet in the lot and the next 3 digits are the last pallet in the lot.

Please advise if you have any questions or need further information regarding this matter.

Regards,

A handwritten signature in blue ink, appearing to read "Roy Lyon".

Roy Lyon
Quality/Regulatory Assurance Manager



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APPROVAL:

Louis Calvarin

Louis Calvarin
Vice President, Operations

Roy Lyon
Mgr. Regulatory Affairs & Product
Stewardship

CHANGE RECORD

Revision No.	Page(s)	Description of Change	Effective Date
0		Original	March 27, 1986
1	1 - 11	General Revision	November 15, 2000
2	1 -10	General Revision	April 16, 2003
3	1 - 8	General Revision	September 1, 2006
4	1 - 8	General Revision	March 30, 2007
5	1 - 8	General Revision	April 30, 2010
6	1 - 9	General Revision	March 15, 2011