Procedure for Recalls and Traceability

Scope: Any product that may cause risk of injury, is deceptive, or is otherwise defective and any product that undergoes a traceability exercise

Purpose: To outline how the company handles recall of produced product after it has been distributed to customers

Procedure:

1. The Quality and Regulatory Department must first decide a recall is necessary
2. Decide whether the recall is a Class I, II, or III.

Class	Description
Class I	Involves a health hazard situation in which there is a reasonable probability that eating the product will cause health problems or death
Class II	Involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food
Class III	Involves a situation in which eating the food will not cause adverse health reactions

3. Contact the FDA Office and the Recall Coordinator to receive assistance and advisement on recall efforts.
4. In addition, contact required Certification Bodies and the appropriate regulatory bodies to notify them of a food safety event that requires public notification.
5. Employees will check the production date on the Master Label and compare it to the product label to ensure that the recall notification is valid.
6. The team consisting of Quality, Operations Shipping, and Upper Management personnel with gather the facts surrounding the recall.
7. The records of production for the product will be received from the company's computer records to see if there were any abnormalities or compliance issues.
8. Stored goods of the recalled material will be identified with "NOT TO BE SHIPPED UNTIL FURTHER NOTICE" and the amount in stock will be recorded.
9. The team will determine product disposition and/or instructions for disposal.
10. The team will then assess the remaining inventory and trace all the shipments.
11. With the aid of Macola, the records of customers who have received the recalled product will be contacted within 24 hours by phone, email, or a hard copy.
12. The recalled product will them have arrangements made to be returned to Koster Keunen,

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Inc. or there will be disposal instructions provided.

13. A CAPA will be written up in accordance with the recall to confirm all material has been accounted for.
14. On an annual basis, perform a Mock Recall as part of the Annual Traceability Audit.
15. All documentation will be stored in the appropriate files.