

DLA Office of the Inspector General

Audit of Subsistence and Nonprescription Drug Recalls

Audit Report: DAO-10-13      February 06, 2012

Recommendation 1

Update the recall notification procedures associated with DLA Regulation 4155.26 to include document retention controls that ensure source documents are retained for each distributed ALFOODACT message.

DLA Troop Support Response:

Concur. DLA Regulation 4155.26, Recall Notification Procedures changes will be reviewed and updated via a Change Sheet. The Change Sheet will then be linked to current 4155.26 and available via the Subsistence Directorate website by 03/30/2012.

ECD for DLAR Change Updates: 03/30/2012

Concur. The Subsistence Food Safety Officer has already worked with appropriate Troop Support personnel. Source retention folders have been created to store both source documents and DMS/AMHS confirmation emails in the DLA Troop Support, K-drive, under ALFOODACT "Continuity Book".

ECD for Document Retention: Completed

Recommendation #2

Create formal recall management operating procedures associated with DLA Regulation 4155.26 to document the process used to manage recalled products outside of EBS.

Concur. Mr. Michael Killian (US Army VETCOM liaison) is in process of revising DLAR 4155.26 (AR 40-660, NAVSUPINST 10110.8C, AFR 161-42, and MCO 10110.38C) including Formal Recall Management Operating Procedures. He will be visiting Troop Support in April 2012.

ECD for complete revision of DLAR 4155.26: 03/01/2013

NOTE: Since the actual conducted DLA Audit, some procedures have already changed. One change is that a DMS Access Request is no longer generated to transmit the ALFOODACT message. This process has been automated, when an ALFOODACT message is disseminated.

DLA REGULATION  
No. 4155.26

02 July 08

DoD HAZARDOUS FOOD AND NONPRESCRIPTION DRUG  
RECALL SYSTEM

(No further Supplementation is authorized)

I. PURPOSE AND SCOPE. To prescribe policy guidance and assign responsibilities within the DoD to be followed when recalls of hazardous, tampered or suspected tampering of foods or nonprescription drugs, nonprescription medical devices, and health and beauty aids (hereinafter collectively called hazardous food and nonprescription drugs) are issued by the Food and Drug Administration (FDA), U.S Department of Agriculture (USDA), U.S. Department of Commerce (USDC), Defense Supply Center- Philadelphia (DSCP), or other Government or nongovernmental agencies, which concern foods or non-prescription drugs that are or may be expected to be in military accounts. As commissaries, exchanges, and other activities stock and distribute non-prescriptive drugs, non-prescriptive medical devices, and health and beauty aids; this recall system will be utilized to disseminate information on Class I and Class II recalls (i.e. based on FDA policy and as listed under paragraph III. B.), concerning these types of products in accordance with the Joint Readiness Clinical Advisory Board (JRCAB), such notification is designed to supplement the customary recall information notices issued by the Military Medical Field Offices.

This publication is applicable to HQ DLA; DSCP; Defense Supply Centers (DSCs) with depot operations; Defense Depots (DDs); Army, Navy, Air Force, and Marine Corps communications facilities; and those activities of the Military Services including Reserve Forces (hereinafter referred to as the Services) involved in the contracting, inspection, administration, shipment, storage, distribution, issue, sale, preparation for feeding of food supplies, and use or sale of nonprescription drugs, nonprescription medical devices, and health and beauty aids. This publication implements policy of the Office of the Under Secretary of Defense for Research and Engineering for the establishment of a hazardous food and nonprescription drug recall system. It has been coordinated with and concurred in by the JRCAB and the Services.

This DLAR supersedes DLAR 4155.26, AR 40-660, NAVSUPINST 10110.8B, AFR 161-42, MCO **10 110.3** 813, 14 November 03.

II. POLICY.

A. HQ DLA, through its primary level field activity, DSCP, will act as the sole agent for DoD to coordinate all hazardous, tampered or suspected tampering of food and nonprescription drug recalls which may involve the Services.

B. By direction of the Commander, DSCP, Directorate of Subsistence, Food Safety Office, (DSCP-FTW) shall act as the agent for all recalls as stated above and shall appoint a Consumer Safety Officer (CSO) and sufficient alternate CSOs to administer the recall system.

C. The Directorate of Medical Material (DSCP-M) will assist the Subsistence designated CSO in handling nonprescription medical/drug items.

NOTE: In this role, the agent will evaluate hazardous food and nonprescription drug recalls for DoD involvement, taking appropriate actions to protect the health of military personnel and their dependents, as well as the financial interests of DoD. DSCP will also advise the Military Medical Field Offices and DDs, as appropriate, of recall information on medical items. Retail activities, in addition, will be notified of Class I and Class II food and non-prescriptive drug recalls when there is definite knowledge that the items were procured for the exchanges and commissaries.

III. DEFINITIONS.

A. Authorized Medical/Food Inspection Personnel

1. Army - Assigned veterinary service food inspection personnel.
2. Air Force - Assigned Public Health service personnel.
3. Navy and Marine Corps - Assigned medical inspection personnel in the absence of Army

B. Class of Recall

1. Class I Recall - Reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
2. Class II Recall - Reasonable probability that the 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.

C. Communicators. Individuals responsible for the receipt, transmission, and delivery of messages from one person or place to another.

D. Food and/or Drug Accountable/Responsible Personnel. Individuals having accountability and/or responsibility for food and/or nonprescription drugs and their proper custody, care, and safekeeping while in the accounts of troop feeding facilities; while located at DDs, DSCs, and Supply Points; also those individuals with similar obligations at commissary stores, exchanges, clubs; and other appropriated or non-appropriated fund activities.

E. Food and Nonprescription Drugs Recalls. Announcements or alerts of emergency or priority situations involving the removal from the marketplace of hazardous foods or nonprescription drugs or suspect hazardous foods or non-prescription drugs, the consumption or use of which could produce consequences that would be immediate or long-range, life threatening, or hazardous to health.

F. Hazardous Foods or Non-Prescription Drugs. Foods or nonprescription drugs not free or suspected of not being free from disease or noxious elements, or conditions which would render them a health hazard or unfit for human consumption or use.

G. Military Medical Field Offices. The primary medical field offices are the U.S. Army Medical Material Agency (USAMMA), the Naval Medical Logistics Command (NAVMEDLOGCOM) and the Air Force Medical Logistics Office (AFMLO) all based within Ft. Derrick, Frederick, MD 21701-5001.

H. Non-Prescription Drugs. Over-the-counter drugs, health and beauty aids, and nonprescription medical devices that do not require a physician's prescription

I. Tampering. Deliberate introduction or substitution of an adulterant, unwholesome material, or toxic substance to or the alteration of a food or nonprescription drug or health and beauty aid or its packaging or labelling, the consumption or use of which may result in death or serious bodily harm.

IV. SIGNIFICANT CHANGES. This publication has been updated to include Prime Vendor programs, (Dining Facilities and Naval Ships), and current terminology.

#### V. RESPONSIBILITIES

##### A. HQ DLA

1. The Logistics Policy and Acquisition Management (J-33) will provide policy for and exercise staff supervision of the recall of DLA-managed food and nonprescription drug supplies and assure that the supply aspects of this regulation pertaining to the recall of DLA-managed items are administered efficiently and effectively.

##### B. Field Activities

1. The Directorate of Subsistence Food Safety Office (DSCP-FTW) will:

- a. Sole POC with FDA, USDA, USDC, and other sources for all matters pertaining to recalls in furtherance of the policy stated in paragraph II above.
- b. Determine if any DLA-managed stocks are involved by the recall.
- c. Determine location of involved food/nonprescription drug items managed by DLA.
- d. Determine whether or not the hazardous item may be in the accounts of food/nonprescription drug accountable/responsible personnel.
- e. Evaluate, in conjunction with responsible Federal agencies, reports of hazardous foods or nonprescription drugs or suspected hazardous food or nonprescription drug items received from food or nonprescription drug accountable/responsible personnel, authorized military inspection personnel, medical personnel, or other sources; determine whether or not a hazardous food and nonprescription drug recall message should be dispatched to all users; and coordinate with FDA to determine if a military recall should be expanded to include the civilian community.

f. Prepare initial message for transmission by the Defense Messaging System (DMS), which will be routed direct to user installations and activities worldwide, or only to specific location(s) stocking the item when this is known. As a minimum, these messages will contain the following:

(1) The Defense Communications Agency (DCA) approved collective address designator code - All Food/Drug Activities (ALFOODACT).

(2) The applicable message serial number as taken from a sequence that begins and ends within a calendar year; e.g., the first message during CY 2002 would be numbered 01-02. The first message of the calendar year will summarize the previous calendar year ALFOODACT message activity and list open/unresolved recalls.

(3) Specific description of hazardous food or nonprescription drug and National Stock Number (NSN) or Local Stock Number (LSN), if applicable.

(4) Brand name, if applicable.

(5) Name and address of processor/manufacturer, and country of origin if an imported item.

(6) Contract number, if applicable.

(7) Date of pack, container code or product code.

(8) An advisory statement to users to place the hazardous food/nonprescription drug immediately in a "hold status" which will suspend its sale, issue, and use. If appropriate, advise Base/Post Public Affairs Office to notify general population of the installation to return the suspected hazardous food/nonprescription drug items to place of purchase.

(9) Final disposition instructions if known at this time; e.g., return product to recalling firm through local distributor.

g. Assign "priority" precedence to ALFOODACT messages.

h. As necessary, prepare interim messages to users to advise of the progress of recall actions or status of the hazardous items involved.

i. Advise users by message of final disposition of the recalled item.

j. Maintain a summary log of hazardous food/nonprescription drug recalled items that as a minimum will include the following:

(1) Message number/ALFOODACT number.

(2) Item identification.

(3) Contract number, if applicable.

k. Prepare and transmit ALFOODACT test messages whenever a 90-day period of time has elapsed during which no message has been transmitted.

2. The Directorate of Subsistence Food Safety Office (DSCP-FTW) will:

- a. Act as DPSC focal point for all recalls.
- b. Determine the necessity of issuing recalls.
- c. Prepare recall for all messages.
- d. This assignment will be accomplished by the CSO.

3. The Medical Quality Assurance responsibility under (DSCP-MB) which will provide assistance and advice to Food Safety Office (DSCP-FTW) in determining necessity for issuing recalls and in preparation of messages involving nonprescription drug items.

C. Communicators will assure:

1. That ALFOODACT messages are processed in a manner appropriate to the "priority" communications precedence assigned.
2. Delivery of ALFOODACT messages to food or nonprescription drugs accountable/responsible personnel of DDs, DSCs, supply points, commissary stores, food service offices, exchanges, clubs, open messes, authorized military inspection personnel, and veterinary/medical personnel.
3. Maintain a file of ALFOODACT messages by message serial number for a minimum of 1 year and provide a copy of messages to supported activities on request.

D. Food and/or Drug Accountable/Responsible Personnel will:

1. Upon notification, immediately act to identify stocks of hazardous food or nonprescription drugs that may be on hand, segregate those present, and secure the items in a hold status to preclude their immediate further issue sale, and use. Responsible depot/supply point/non-appropriated fund activity personnel will notify the end users of hazardous food or nonprescription drug items in those instances when issue has been made prior to receipt of a DPSC message that has been directed only to that specific depot/supply point. Authorized food inspection or medical personnel may be requested to assist in all of these matters involving food recalls. In cases of nonprescription drug recalls advice may be obtained from the responsible medical activity.
2. As appropriate, notify parent commands of the amounts of hazardous items on hand.
3. Retain hazardous food or nonprescription drug items in a hold status until final disposition instructions have been received from DSCP.
4. Notify the Commander, DSCP, ATTN: Food Safety Office (DSCP-FTW) whenever hazardous foods or nonprescription drugs have been identified through local determination as being on hand in a local supply account. An information copy of such notification will be forwarded to the department headquarters of the Service, which originates the notification, and will be noted to the attention of medical and food service staff at department level.
5. In the event any DoD activity finds a condition of food that may require a hazardous recall, the

hazardous recall will be reported to Food Safety Office (DSCP-FTW) to the CSO via priority message which is to contain, as a minimum, the following:

- a. Specific description of hazardous item, and NSN/LSN, if applicable.
- b. Brand name, if applicable:
- c. Name and address of manufacturer/processor.
- d. Contract number, if applicable.
- e. Lot numbers (from case) or package/can codes.
- f. Activity that supplied material (Depot/Supply Center, DoD).
- g. Date material received at using activity.
- h. Amount received and amount in stock.
- i. Description of hazardous condition.
- j. Symptoms of illness or death attributed to or suspected to be caused by the item, number of persons affected, and contact point for medical authority cognizant of the incident.
- k. Laboratories to which samples have been submitted for test/analysis, date shipped, and mode of shipment.
- l. Laboratory test/analysis results when available.

6. In addition to the above procedure for reporting a suspected hazardous nonprescription drug item, report and process medical materiel complaints in accordance with the appropriate Service regulations (DLAR 4155.28: BUMEDINST 6710.63; AR 40-61; AFM 67-1, Vol V, Chap 19).

7. In addition to the above procedures for reporting a suspected hazardous food item, report and process subsistence material complaints in accordance with the appropriate Service regulations (DLAR 4155.3/AR 30-12/NAVSUPINST 4355.2/AFR 74-5/MCO 10110.21).

8. Retain copies of ALFOODACT messages for a minimum period of 1 year or until final disposition, whichever is later.

9. Conduct inspections and submit samples to laboratories for testing as required

## VI. PROCEDURES.

- A. During normal duty hours, recall or alert notification will normally be made available directly to the Consumer Safety Officer (CSO) or alternate within the Food Safety Office (DSCP-FTW), extension 2922/2911 or e mail [dscpconsafofc@dla.mil](mailto:dscpconsafofc@dla.mil) when suspected hazardous food or nonprescription drug/medical device messages are received from military activities. Action will be taken through regular staff coordination on a priority basis by all participating elements at DSCP.

B. During other than normal duty hours. Class I. FSIS/FDA Recall Notifications - The Consumer Safety Officer (CSO) has been authorized a Laptop for use during after duty hours as well as during Temporary Duty (TDY) periods in order to remain current on alerts and recalls. During leave periods, the alternate CSO will assume stated duties. Upon notification of a Class I recall via e-mail, the CSO will, at the earliest opportunity, adhere to normal protocol/procedures, to include steps outlined in Paragraph V.D. above.

1. All telephone calls and other informal means of communication/information received relating to alerts, recalls, or potentially hazardous foods will be referred to the CSO. If the CSO or alternate is unable to be contacted, the party shall report the information to Food Safety Officer (DSCP-FTW), Building 6, 6C073, extension 2922 or 2911, by 0800 hours the following duty day.

2. Any questions concerning the nature of any action to be taken on any drugs (e.g., whether the item is a prescription or nonprescription drug or medical devices, or health and beauty aid) will be referred to the DSCP Medical Directorate personnel cited in DSCP Regulation No. 4140.1.

C. Upon determination that potentially dangerous items do exist at locations within the military supply system, the CSO will take continuous aggressive action to obtain the necessary information in coordination with appropriate federal agencies (FDA, USDA, USDC), other DoD activities, and applicable DLA/DSCP Prime Vendor Distributors to permit expeditious release of an ALFOODACT message. This will include action to the contracting officer, as necessary, to return product to contractor under warranty, recovery, or other appropriate clauses of the contract. Interim advice will be furnished every 30 days pending final resolution of the recall.

VII. PUBLICATION MAINTENANCE: This document will be maintained by Subsistence Support Office, DSCP-HXL.

BY ORDER OF THE DIRECTOR

Colonel, USA  
Staff Director, Administration



COORDINATION: DLA-KS, DLA-LP, DLA-LR, DLA-PP, DLA-OW, DRSO-M, Army (DALO-TST), Navy (NAVFSSO(SV)), Air Force (SGPA), Marine Corps (LFS-4), JRCAB

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