DHA-MSR 6025.01 ARMY REGULATION 40-660 DLAR 6025.01 NAVSUPINST 10110.8D AIR FORCE INSTRUCTION 48-161_IP MARINE CORPS ORDER 10110.38D 6 SEPTEMBER 2018 DOD HAZARDOUS FOOD AND NONPRESCRIPTION DRUG RECALL SYSTEM

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

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THE DEFENSE HEALTH AGENCY AND THE DEPARTMENTS OF THE ARMY, THE NAVY, AND THE AIR FORCE

6 September 2018

UNCLASSIFIED

Defense Health Agency Headquarters Departments of the Army, the Navy, and the Air Force Falls Church, VA 6 September 2018

DHA-MSR 6025.01 AR 40-660 DLAR 6025.01 NAVSUPINST 10110.8D AFI 48-161_IP MCO 10110.38D Effective 6 September 2018

DHA VS

SUBJECT: DoD Hazardous Food and Nonprescription Drug Recall System

References: See Enclosure 1.

1. <u>PURPOSE</u>. This Defense Health Agency-Multi-Service Regulation (DHA-MSR), based on the authority of References (a) through (c), and in accordance with the guidance of References (d) through (h) and (j):

a. Establishes the Defense Health Agency's (DHA) procedures to be followed when recalls (All Food and Drug Activity (ALFOODACT) messages) are issued for hazardous food, nonprescription drugs, dietary supplements, nonprescription medical devices, health and beauty aid items, and pet food which may be in military accounts (hereinafter referred to as "hazardous food and nonprescription drugs").

b. Ensures the expeditious identification, segregation, and reporting of recalled items is performed at all applicable DoD food supply levels.

c. Cancels and replaces AR 40-660/DLAR 4155.26/NAVSUPINST 10110.8C/AFR 161.42/MCO 10110.38C, "DoD Hazardous Food and Nonprescription Drug Recall System," all editions (Reference (i)).

2. <u>APPLICABILITY</u>. This DHA-MSR applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the DoD, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively here as "DoD Components").

3. <u>POLICY IMPLEMENTATION</u>. It is DHA's instruction, pursuant to Reference (e), to:

a. Provide veterinary and public health services focused on food protection to ensure wholesome subsistence in support of military planning, operations, and force health protection.

All applicable Service Component food safety and public health personnel are required to assist in the investigation, product handling, reporting, and disposition of recalled hazardous food and nonprescription drugs to prevent usage and further distribution of these items within the military supply system.

b. Establish the DoD's procedures for the investigation and notification of recalled hazardous food and nonprescription drugs under the recall classification designation (Class I and Class II).

4. <u>RESPONSIBILITIES</u>. See Enclosure 2.

5. <u>PROCEDURES</u>. See Enclosure 3.

6. <u>RELEASABILITY</u>. **Cleared for public release**. This DHA-MSR is available on the Internet from the DHA SharePoint Site at: http://www.health.mil/dhapublications.

7. EFFECTIVE DATE. This DHA-MSR:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with DHA-Procedural Instruction 5025.01 (Reference (d)).

VADM, MC, USN Director

Enclosures

- 1. References
- 2. Responsibilities
- 3. Procedures

Appendix Glossary

DHA-MSR 6025.01 September 6, 2018

Coordination: DLA Army (DAS (MP&QL)) Marine Corps (LFS4) Navy (DAS (MM&P)) Air Force (DAS (RA&AR)) Joint Staff Acting DASD (HRP&O)

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ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5101.10E, "DoD Executive Agent (EA) for Subsistence," October 26, 2015, as amended
- (b) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
- (c) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
- (d) DHA-Procedural Instruction 5025.01, "Publication System," August 21, 2015, as amended
- (e) DoD Directive 6400.04E, "Veterinary Public and Animal Health Services," June 27, 2013, as amended
- (f) DoD Instruction 4715.05, "Environmental Compliance at Installations Outside the United States," November 1, 2013, as amended
- (g) DoD Instruction 6055.01, "DoD Safety and Occupational Health (SOH) Program," October 14, 2014
- (h) Code of Federal Regulations, Title 48
- (i) AR 40-660/DLAR 4155.26/NAVSUPINST 10110.8C/AFR 161.42/MCO 10110.38C, "DoD Hazardous Food and Nonprescription Drug Recall System," August 15, 1986 (hereby cancelled)
- (j) DoD Manual 4160.21, Volume 1, "Defense Materiel Disposition: Disposal Guidance and Procedures," October 22, 2015, as amended

ENCLOSURE 2

RESPONSIBILITIES

1. <u>DIRECTOR, DHA, DIRECTOR, DEFENSE LOGISTICS AGENCY (DLA), SECRETARY</u> OF THE ARMY, SECRETARY OF THE NAVY, AND SECRETARY OF THE AIR FORCE.

The Director, DHA, Director, DLA, and the Secretaries of the Services/Military Departments, will:

a. Oversee the implementation of this DHA-MSR to ensure consistent application across the DoD.

b. Provide clarifying guidance, as needed, to all applicable parties regarding issues related to the implementation of the hazardous food and nonprescription drug recall system.

c. Ensure the enforcement of this DHA-MSR in place of cancelled regulations.

2. <u>DEFENSE LOGISTICS AGENCY TROOP SUPPORT (DLA-TS) DIRECTORATE OF</u> SUBSISTENCE. The DLA-TS Directorate of Subsistence will:

a. Provide policy for and exercise staff supervision of the recall of applicable DoD hazardous food and nonprescription drugs.

b. Ensure government funds spent on recalled stocks of DLA-managed items are recouped properly.

c. Ensure disposal of DLA-owned items classified as hazardous waste complies with Reference (j).

d. Comply with applicable DoD Instructions and Code of Federal Regulations, as well as the applicable federal, state, or host nation laws regarding the hazardous food and nonprescription drug recall system.

e. Act as the sole agent for DoD to coordinate recalls of all hazardous, tampered with, or suspected tampered food and nonprescription drugs which may involve the Service Components.

f. Designate the DLA-TS Food Safety Office to act as the agent for all recalls, as stated above, and appoint a U.S. Army Veterinary Corps Officer (VCO) as the Consumer Safety Officer and sufficient alternate Consumer Safety Officer (also a VCO) to administer the recall system.

g. Advise the Surgeons General (SG), as appropriate, of recall information on hazardous food and nonprescription drugs.

3. CONSUMER SAFETY OFFICER, DLA-TS. The Consumer Safety Officer, DLA-TS, will:

a. Serve as the DLA focal point for all subsistence recalls.

b. Communicate directly with the Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), U.S. Department of Commerce, other government agencies, and commercial vendors or manufacturers for matters pertaining to hazardous food and nonprescription drug recalls.

c. Prepare subsistence recall messages, and coordinate with Defense Logistics Agency Troop Support-Medical Materiel (DLA TS-M) in preparing recall messages for nonprescription drugs.

d. Work in close coordination with Veterinary Service Information Management System (VSIMS) Support to ensure a current roster of message recipients is maintained. Confirm process validity at least annually.

4. <u>GENERAL ENGINEER, DLA TS-M</u>. The General Engineer, DLA TS-M, will assist the designated Consumer Safety Officer in handling the recalls of nonprescription drug items.

5. SG, DEPARTMENT OF THE ARMY. The SG, Department of the Army, will:

a. Assign active duty U.S. Army VCOs to DLA-TS to serve as Consumer Safety Officers to manage and execute the hazardous food and nonprescription drug recall program for the DoD.

b. Ensure policies, systems, and processes are in place within all Veterinary units worldwide to execute the hazardous food and nonprescription drug recall mission accurately and expeditiously.

c. Report any communication problems regarding ALFOODACT messages expeditiously to DLA-TS and the Defense Health Agency Veterinary Service (DHA VS) Branch.

6. <u>SG, DEPARTMENT OF THE NAVY</u>. The SG, Department of the Navy, will:

a. Ensure policies, systems, and processes are in place within all Navy and Marine Corps units worldwide to execute the hazardous food and nonprescription drug recall mission accurately and expeditiously.

b. Coordinate hazardous food and nonprescription drug recall mission efforts with the U.S. Army VS as needed or requested.

c. Report any communication problems regarding ALFOODACT messages expeditiously to DLA-TS and DHA VS.

7. SG, DEPARTMENT OF THE AIR FORCE. The SG, Department of the Air Force, will:

a. Ensure U.S. Air Force (USAF) public health personnel manage and execute the hazardous food and nonprescription drug recall program for the USAF.

b. Ensure policies, systems, and processes are in place within all USAF MTFs worldwide to execute the hazardous food and nonprescription drug recall mission accurately and expeditiously.

c. Report any communication problems regarding ALFOODACT messages expeditiously to DLA-TS and DHA VS.

8. <u>COMMANDER, NAVAL SUPPLY SYSTEMS COMMAND</u>. The Commander, Naval Supply Systems Command, will:

a. Ensure policies, systems, and processes are in place for Naval Vessels afloat to execute the hazardous food and nonprescription drug recall mission accurately and expeditiously.

b. Coordinate hazardous food and nonprescription drug recall mission efforts with the U.S. Army VS as needed or requested.

c. Report any communication problems regarding ALFOODACT messages expeditiously to DLA-TS and DHA VS.

9. CHIEF, DHA VS BRANCH. The Chief, DHA VS Branch, will:

a. Ensure inspection and reporting processes for hazardous food and nonprescription drug recalls are completed accurately and efficiently in collaboration with the Service Components.

b. Provide oversight across Service Components to ensure central reporting systems (VSIMS) are functional and being utilized.

c. Create and manage metrics to measure the effectiveness of the hazardous food and nonprescription drug recall program across the Service Components.

10. <u>ALFOODACT MESSAGE COMMUNICATORS</u>. ALFOODACT message communicators will:

a. Ensure that ALFOODACT messages are processed in a manner appropriate to the assigned "priority" communications precedence.

b. Deliver ALFOODACT messages to all food establishments on military installations including, but not limited to, Defense Depots; Defense Supply Centers; Defense Commissary Agency; and Exchange retail convenience stores (Express and mini-marts, for example); food

service offices; clubs; open messes; theaters; DoD Dependents Schools; military MTFs; surface and sub-surface vessels; all other DoD facilities that sell, serve, or otherwise provide food; and medical food inspection personnel.

c. Maintain records of ALFOODACT messages by message serial number in accordance with DoD, DHA, DLA, and Service policies on records retention, and provide a copy of messages to supported activities upon request.

11. <u>FOOD SAFETY OFFICER, MILITARY LABORATORIES</u>. The Food Safety Officer, military laboratories, will:

a. Immediately transmit laboratory test results from ALFOODACT items to the Consumer Safety Officer, DLA-TS.

b. Upload laboratory test results from ALFOODACT items to the Laboratory Submissions & Sample Management module within the VSIMS application and email the results to:

(1) Army Public Health Center Food Protection & Public Health Sanitation Directorate, Approved Sources Manager;

(2) Food Safety Officer of the requesting organization; and

(3) Other points of contact identified on the test request form, in accordance with the current laboratory protocol and standard operating procedure.

ENCLOSURE 3

PROCEDURES

1. DLA-TS PROCEDURES

a. The ALFOODACT recall system will be utilized to disseminate information on Class I and Class II recalls of hazardous food and nonprescription drugs. The ALFOODACT recall system does not disseminate information on Class III recalls.

b. Recalls must be evaluated for DoD involvement, taking appropriate actions to protect the health of military personnel and communities, as well as the financial interests of DoD.

c. ALFOODACT messages for DoD will be coordinated and posted on the DLA-TS Subsistence Food Safety web page, as well as the Subsistence Recalls module of the VSIMS application.

d. Food recalls and product alerts are received daily from the FDA, USDA, and FoodTrack Incident Alerts. If the product is not immediately identified in the DoD supply system, the Consumer Safety Officer will generate a food recall query and transmits it to the appropriate internal program recipients.

e. After receiving the hazardous food and nonprescription drug recall query information, the Consumer Safety Officer will:

(1) Determine the necessity of issuing recalls. Any guidance on nonprescription drug matters will be obtained from the DLA TS-M.

(2) Determine if any DLA, Defense Commissary Agency, Service Component, and nonappropriated fund-managed stocks are affected by the recall.

(3) Determine the location of recall-involved hazardous food and nonprescription drugs managed by DLA.

(4) Determine whether or not an ALFOODACT message should be dispatched to all users.

(5) Coordinate with the appropriate Federal agencies to determine if a DoD-generated recall should be expanded to include civilian communities.

(6) Upon determination that potentially dangerous items do exist at locations within the DoD supply system, take proactive measures to obtain the necessary information in coordination with appropriate Federal agencies (FDA, USDA, U.S. Department of Commerce), FoodTrack,

other DoD activities, and applicable DLA Prime Vendor Distributors to permit expeditious release of an ALFOODACT message.

(7) Ensure the correct recall classification designation (Class I or Class II) is assigned to each ALFOODACT message.

(8) As necessary, prepare interim messages to users to advise on the progress of recall actions or status of the hazardous food and nonprescription drugs involved.

(9) Advise users by message of the disposition instructions for the recalled item.

(10) Refer any questions concerning the nature of any action to be taken on any drugs (for example, whether the item is a prescription or nonprescription drug, medical device, or health and beauty aid), to DLA TS-M personnel. Include whether items are classified as hazardous waste under federal, state, or host nation laws.

2. ACCOUNTABLE MEDICAL FOOD INSPECTION PERSONNEL PROCEDURES

a. Upon notification, act immediately to identify stocks of hazardous food and nonprescription drugs that may be on hand, and segregate those present. Medical food inspection personnel will secure the items in a medical hold status to preclude their immediate further issue, sale, and use.

b. Provide clarifying guidance, as needed, to all applicable parties regarding issues related to the implementation of the hazardous food and nonprescription drug recall system.

c. Medical food inspection personnel will assist in ALFOODACT recalls. Medical food inspection personnel will:

(1) Notify parent commands of the amounts of recalled items on hand as appropriate.

(2) Retain hazardous food and nonprescription drugs in a medical hold status until final disposition instructions have been received from the DLA-TS Consumer Safety Officer.

(3) Input ALFOODACT investigation results, to include the amount of product, into the Subsistence Recalls module of the VSIMS application.

(4) Conduct inspections and, as necessary, submit a laboratory request in the Laboratory Submissions & Sample Management module of the VSIMS application, and then send the samples to the nearest military laboratory. Include a request to furnish DLA-TS with a copy of results on a priority basis.

(5) Physically visit all MTFs (hospitals, clinics, satellite pharmacies, etc.) when recalls involve nonprescription drugs.

3. ACTIONS TO BE TAKEN TO INITIATE AN ALFOODACT REQUEST

a. In the event that any DoD organization or agency identifies a food or health safety condition which may warrant the initiation of an ALFOODACT message, local medical food inspection personnel will be contacted.

b. Local medical food inspection personnel will conduct an inspection, and report findings through appropriate channels to the DLA-TS Consumer Safety Officer. Where necessary, local medical food inspection personnel will submit samples to the appropriate military reference laboratory.

c. The DLA-TS Consumer Safety Officer will review inspection findings and laboratory results, and determine if an ALFOODACT message will be initiated.

4. MEDIA INTERACTION

a. All media queries and public announcements regarding ALFOODACTs will be coordinated with the DLA-TS Public Affairs Office (PAO). No direct contact with the media is authorized unless coordinated in advance and approved by the DLA-TS PAO.

b. The DLA-TS PAO will coordinate with the DHA and the Services to develop risk communication messaging as needed.

APPENDIX

RECORDS MANAGEMENT - AIR FORCE

1. <u>RECORDS MANAGEMENT</u>. Ensure that all Air Force records created as a result of processes prescribed in this DHA-MSR are maintained in accordance with Air Force Manual 33-363, Management of Records and disposed of in accordance with Air Force Records Disposition Schedule located in the Air Force Records Information Management System Publications and Forms Management, Table 1.1, for a description of the authorities associated with Tier 0. Submit requests for waivers through the chain of command to the Air Force Publication Office of Primary Responsibility for consideration. Supplementation of this regulation and establishment of command and local forms are prohibited without prior approval from The Surgeon General, 7700 Arlington Boulevard, Falls Church, VA 22041-5143.

2. <u>WAIVER AUTHORITY</u>. All compliance items in this DHA-MSR are determined by respective non-Air Force authority (for example, Media Interaction) to be Tier 0 compliance items. See AFI 33-360, Publications and Forms Management, for a description of the authorities associated with the Tier 0. Submit requests for waivers through the chain of command to the appropriate Tier waiver approval authority, or alternately, to the Publication Office of Primary Responsibility for non-tiered compliance items.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ALFOODACT	All Food and Drug Activity
DHA DHA-MSR DHA VS DLA DLA-TS DLA TS-M	Defense Health Agency Defense Health Agency-Multi-Service Regulation Defense Health Agency Veterinary Service Defense Logistics Agency Defense Logistics Agency-Troop Support Defense Logistics Agency Troop Support-Medical Materiel
FDA	Food and Drug Administration
MTF	medical treatment facility
NAVSUP	Naval Supply Systems Command
PAO	Public Affairs Office
SG	Surgeon General
USAF USDA	U.S. Air Force U.S. Department of Agriculture
VCO VS VSIMS	Veterinary Corps Officer Veterinary Service Veterinary Service Information Management System

PART II. DEFINITIONS

<u>accountable personnel</u>. Managerial personnel in operational charge of sites on an installation that sell, serve, or otherwise dispense food and nonprescription drugs.

<u>ALFOODACT message communicators</u>. Individuals responsible for the receipt, transmission, or delivery of ALFOODACT messages from one person or place to another.

<u>Class I Recall</u>. A health-hazard situation where there is a reasonable probability that the use of, or exposure to, the food or medical item will cause serious adverse health consequences or death.

<u>Class II Recall</u>. A health-hazard situation where the use of, or exposure to, the food or medical item may cause temporary health consequences or when there is a remote probability of serious adverse health consequences from use of the food or medical item.

<u>Class III Recall</u>. A situation where the use of, or exposure to, the food or medical item will not cause adverse health consequences.

<u>food recall query</u>. The preliminary request for information sent to key individuals within an organization only, on a particular food recall, to determine whether this recall should become an ALFOODACT message. A food recall query becomes an ALFOODACT if one or more key individuals respond positively to the query.

<u>Food Safety Officer, military laboratories</u>. A position located at the DoD Food Analysis and Diagnostic Laboratory filled by a Veterinary Services Warrant Officer (640A). In other military laboratories, if a Warrant Officer is not assigned, the functions of this position are performed by other assigned personnel as determined by the particular military laboratory Director.

<u>FoodTrack</u>. A food safety network that dispatches recall and alert messages occurring real time worldwide to the DLA-TS food safety team, on a continual basis. This network provides manned incident surveillance and preemptive reporting of product recalls, outbreaks, tampering incidents, and food safety issues that may ultimately impact the DoD food supply chain.

<u>hazardous food and nonprescription drugs</u>. Food, pet food, dietary supplements, nonprescription drugs (over-the-counter drugs), nonprescription medical devices, and health and beauty aid items.

Medical Food Inspection Personnel. Army VS or Air Force Public Health inspection personnel.

<u>pet food</u>. Food and treats purchased in the DoD system for government-owned animals and privately-owned animals (pets), including but not limited to dogs, cats, birds, etc.

<u>recall</u>. The removal or correction of a marketed food or medical item from commerce when there is reason to believe that such product is adulterated, misbranded, defective, or a safety concern for the consumer.

<u>recall classification</u>. The numerical designation, i.e., I, II, or III, assigned to a particular food or medical item recall to indicate the relative degree of health hazard presented by the product being recalled.

<u>responsible medical activity</u>. The military hospital or MTF located at the installation for which the ALFOODACT recall is being conducted.

<u>VSIMS</u>. The primary system providing information management for VS personnel at over 400 locations around the world, supplying immediate information availability to the entire chain of command and all appropriate customers. VSIMS' Subsistence Recalls module serves as the central reporting system across the Services for ALFOODACTs.