DLA TROOP SUPPORT 4155.6	*
SUBSECTION 212.6	
DLA TROOP SUPPORT-FTRE	*
SEPTEMBER 2011	*
ASSISTANCE TO CONTRACTING OF FICERS	

Suspected Violations of FDA, USDA and USDC Regulations And Reporting Rejections to FDA, USDA, USDC, and DLA Troop Support

I. <u>PURPOSE AND SCOPE</u>. The Subsection prescribes procedures for reporting suspected violations of FDA, USDA and DLA Troop Support regulations and for reporting rejections of items due to violations of those regulations. This Subsection is applicable to Government Quality Assurance Representatives (QARs) assigned to DLA Troop Support contracts.

II. <u>BACKGROUND</u>.

- A. The Food and Drug Administration (FDA), Department of Health and Human Services is the sole agency responsible for investigation and enforcement of the Federal Food, Drug and Cosmetic Act. It has authority to investigate and bring action for violations of the Act, including introduction into interstate commerce of any food, drugs, medical devices, biologics, cosmetics and animal products & feed commodities, which are short weight, mislabeled, adulterated or impure. The USDA has authority to investigate and bring action for violations of the Federal Meat Inspection Act and Poultry Products Inspection Act. The USDC has authority to act on violations of the Agricultural Marketing Act of 1946 and regulations promulgated thereunder, as related to waterfoods inspected by the National Marine Fisheries Service.
- B. The majority of DLA Troop Support Subsistence contracts contain a Federal Food, Drug and Cosmetic Act clause, which entitles the Government to certain rights, even though the supplies are not shipped in interstate commerce and even though the FDA takes no action in the particular case. It is also the intent that all DLA Troop Support subsistence procured in accordance with the wholesomeness and labeling provisions of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Agricultural Marketing Act of 1946 (as amended). Accordingly, it is important that suspected violations be reported promptly to permit the contracting officer to take action to preserve the Government's rights. These instructions are not to be confused with reports of suspected fraud or misconduct (see Subsection 212.5). There may or may not be a suspicion of fraud in a case where there is suspicion of violation. If fraud is also suspected, then both suspected violations shall be reported.

III. <u>PROCEDURES</u>.

A. <u>Reporting Suspected Violations</u>.

1. When there is a suspected violation of the Federal Food, Drug and Cosmetic Act, the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Agricultural Market Act of 1946 (as amended) and regulations promulgated thereunder (e.g., short

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weights, swelled cans, quality below standards of identity of FDA, USDA or USDC, high mold count, misleading labels, slack fill of container), the QAR shall telephone his/her inspection office (DO NOT USE THE CONTRACTOR'S TELEPHONE) for evaluation of the information. If the Chief, Inspection Office decides that the suspicion warrants reporting to the contracting officer, he/she shall immediately telephone the Contract Quality Assurance element (CQAE) of the applicable DLA Troop Support Subsistence Contracting Element (SCE) issuing the contract. The CQAE shall obtain all necessary information for evaluation and present the matter to DLA Troop Support Consumer Safety Officer, (DLA Troop Support-FTW; 215-737-2922), so the appropriate Federal agency can be notified. The telephone report shall be confirmed in writing by QAR on MEDCOM Form 817 (Quality Assurance Representative's Correspondence). The written report, in triplicate, shall be distributed as follows: one copy to applicable SCE, ATTN: CQAE; one copy to QAR's assigned office, and one copy retained for file. The report shall be narrative in form and include the following information:

- a. Name, title, grade or rank, station and address of person making the report.
- b. Contract or purchase order number(s), lot number, name of contractor, location, and USDA/USDC establishment or plant number.
- c. Complete nomenclature of the commodity.
- d. Date, time, place, and a detailed description of the alleged violation.
- 2. The QAR shall not advise the contractor that a report has been made nor shall he/she discuss the alleged violation with anyone other than the individuals authorized to further the investigation. QARs shall insist on suitable identification of such personnel.
- 3. The QAR shall then continue with the inspection after the report has been submitted unless otherwise directed by the inspection office or CQAE.
- 4. Surveillance inspectors shall report these observations to DLA Troop Support- * FTW.
- 5. Copies of all reports and communications concerning suspected violations of Federal Acts shall be stamped or plainly marked "For Official Use Only" at the bottom of each page or document.
- B. <u>Reporting Rejections</u>. Inspectors at ration assembly plants or at destination sites shall advise the appropriate CQAE of all rejections. In addition, a report shall be made in those instances when the vendor elects to withdraw a lot in lieu of requesting a waiver. Security measures indicated in paragraph III.A. shall be observed.
- C. <u>Request for Sampling and Testing</u>. QARs may receive requests from Federal agencies for samples of Government-owned products when violations have been suspected. Details pertaining to the request for and the furnishing of samples to these agencies shall be reported promptly to the CQAE and guidance shall be requested.