



DEPARTMENT OF THE NAVY
NAVAL SUPPLY SYSTEMS COMMAND
5450 CARLISLE PIKE
PO BOX 2050
MECHANICSBURG PA 17055-0791

TELEPHONE NUMBER
COMMERCIAL
AUTOVON
IN REPLY REFER TO

0056 '03 DEC 31 P1:29

DEC 23 2003

Mr. Joseph McCallion
Deputy Director, Division of Import Operations and Policy
Food and Drug Administration
5600 Fishers Lane, Room 12-38
Rockville, MD 20857

Dear Mr. McCallion,

The implementation of the Bioterrorism Act of 2002, and Interim Final Rule, has generated uncertainties within the Navy departments under my cognizance. Key to addressing these uncertainties is the Food and Drug Administration's (FDA) interpretation and application of the Bioterrorism Act and the Interim Final Rule, on Department of Defense (DoD) activities. The areas that have my immediate concerns are U.S. Navy Food Service, Household Goods, and Postal Service, however I would advocate and welcome your support in establishing a dialogue for all U.S. Navy concerns.

My staff has consolidated our specific issues and I'm providing them as a separate attachment. To better assess the impact of any new oversight implementation, I'm requesting your office review the concerns identified and provide granularity where uncertainty exists.

Your assistance is greatly appreciated. My point of contact is: LTC Paul E. Whippo, DVM, USA, 5450 Carlisle Pike, P.O. Box 2050, Mechanicsburg, PA 17055-0791, telephone 717-605-7445.


A. DUNNE-HAYES
Captain, SC, USN
Deputy Commander
Navy Family Support

02N-0278

0284

1. What procedures under the Interim Final Rule will apply to the United States Navy (USN) ships returning to port from outside United States territorial waters? FDA Policy Guide December 2003 states that food entering and then leaving the port area is not subject to prior notice. Does this include US Naval Bases, and what is the definition of port area?
 - a. How will subsistence that does not leave the returning ship or that is cross decked to other ships headed out to sea be viewed under the Interim Final Rule?
 - b. How will subsistence that is placed in temporary storage at the pier/dock while the subsistence hold and/or freezers are being cleaned or treated for infestation or the ship is in being repaired/refitted be viewed under the Interim Final Rule?
2. Submarines and ships based in the United States go out to sea for periods of time ranging from days to four (4) months without putting into foreign ports and then return to United States ports/bases where subsistence is taken off the ship sorted and distributed to other submarines or ashore galleys within the port area. How will this subsistence be viewed under the Interim Final Rule?
3. How will food produced or processed in the U.S., which is still in its original packaging and has been in continental US food distribution channels or under DoD control/DoD contracted distributors control, be viewed under the Final Interim Rule? Can it be considered to have never left the U.S.?
4. US Fleet ships have always been considered US territory. Does this affect the application of the Act and the Interim Final Rule?
5. Since the Supply Officer on board a US Navy Ship is accountable for food products and responsible for its utilization and disposal, can all food products on board ship be considered "for use by the intended owner?" Food products are purchased and held with government funds for the use of the ship's crew and are not intended for resale to parties outside the US Navy.
6. Will subsistence turned in to the Defense Re-utilization Management Office to be sold or disposed, be affected under the Interim Final Rule?
7. Military members returning from overseas have their house hold goods (HHG) packaged in wooden crates that have security seals placed on the crates at the service members residence before the crates are removed. Can these crates which have been sealed for customs purposes be considered to continue in the service members possession
8. How will the Final Interim Rule apply to the military postal service, a subsidiary of the United States Postal Service that operates overseas?