GENERAL REVIEW AND ENFORCEMENT POLICIES

DIVERSION OF UNFIT FOOD TO ANIMAL USE

Sections 402(a)(3) and (4) of the Federal Food, Drug, and Cosmetic Act (FFDCA) have been interpreted to allow different standards for food intended for human use and food intended for animal use. For example, there are tolerances for filth in human foods but none for the same food when intended for animal use. Accordingly, FDA has authorized the salvage of food unsafe or unfit for one use by the diversion of that food to an acceptable use, e.g., diversion of insect-contaminated rice to animal use. Diversion requests have involved USDA-detained meats containing illegal drug or chemical residues; food or feed under voluntary industry recall or quarantine; and, as is principally the case, foods presenting unacceptable aesthetic conditions by virtue of their contamination with filth. To assist in handling certain specific types of diversion requests, the Center has developed Compliance Policy Guides 7126.10 and 7126.14. No single set of criteria, however, can be prepared to cover diversion requests in general. This guideline remedies this lack of structure in the diversion request process by providing procedures for submitting requests to the Agency for authorization to divert foods.

1. Purpose:

   This guide establishes procedures for processing requests for the diversion of unsafe or unfit human foods to animal use.

2. Criteria for Consideration of Requests:

   Diversion requests will continue to be handled on an ad hoc basis. The Center will consider the requests for diversion of food rendered unfit for human use by virtue of any of the following causes:

   a. Pesticide contamination in excess of the permitted tolerance or action level.

   b. Pesticide contamination where the pesticide involved is unapproved for use on a food or feed commodity.

   c. Contamination by industrial chemicals.

d. Contamination by natural toxicants.

e. Contamination by filth.

f. Microbiological contamination.

g. Aesthetic unfitness for food.

h. Over tolerance or unpermitted drug residues.

3. Procedures for Submitting Requests:

Written requests for diversion should be submitted to the appropriate FDA District Office and transmitted to the Division of Compliance, Center for Veterinary Medicine, HFV-230. Each request should include the following information:

a. Name and address of the requestor, and the name and address of the owner of the subject articles.

b. The precise physical location of the product.

c. A precise identification of the product (including lot numbers, amount of articles in each lot, etc.).

d. The reason by which the articles are rendered unsafe or unfit for their originally intended food uses.

e. The levels, on a lot-by-lot basis, of any adulterant; all analytical data regarding such levels of an adulterant, and the methodology used in determining the levels of the adulterant.

f. The cause of adulteration or unfitness.

g. The proposed disposition of and, if required, reconditioning procedure for the food.

h. The name and address of the proposed consignee.

i. The denaturing procedure or, if not denatured, a legally enforceable assurance (bond)

that the products will move under seal and be sold to the appropriate approved consignee.

j. The proposed labeling as well as written information, or instructions to accompany the product.

k. All special restriction information, i.e., is the product under detention by the USDA; and therefore requiring an official correspondence between agencies regarding the approval of the diversion.

l. The intended use of the Food. This will include complete description of the class of animals involved, whether they are food or non-food producing; the part of the country in which the food will be used, and all assurances have been secured that indeed the food will be used as described in the written request.

m. All available information on the safety of the adulterant for the intended animal use and, where appropriate, for the consumption of the edible products of the animals.

n. Information sufficient for a determination whether disposition of such article, including packaging material, will result in the release of a toxic substance into the environment.

4. Clarification of Diversion Policy:

Several misconceptions regarding the diversion policy must be dispelled.

a. A seizure action and a voluntary request for diversion are two separate processes. A seizure action and a request for diversion cannot legally be processed simultaneously. No diversion request submitted under this guideline will be considered once a seizure recommendation has been forwarded to headquarters. If a seizure recommendation is withdrawn and if the requirements of this policy are met, a diversion request may be entertained. Naturally, a diversion-based means of reconditioning seized articles may be an appropriate means of meeting the requirements of a court-ordered consent decree arising from a seizure.

b. Diversion may only be allowed where legally appropriate. This would peclude, for example, considering a request for a diversion of goods for which there is no legally enforceable assurance that the unsafe or unfit foods will not be placed into interstate

commerce before the request is approved and the products appropriately diverted (i.e., meats not under USDA detention, but nevertheless containing illegal residues, would be appropriate for seizure but not diversion if the meats were already shipped in interstate commerce).

c. Where diversion is legally appropriate, data are required to demonstrate that the diverted use poses no safety hazards to the animals consuming the diverted food and to the public who may be exposed to edible tissues.

d. The diversion policy does not sanction or authorize the blending of unsafe or unfit foods, e.g., the policy does not authorize the diluting of an adulterated product below a tolerance or action level.

5. Preparation of Response:

When all the information requested in item 3 of this guide has been received by the Center for Veterinary Medicine, a safety review will be promptly conducted. The Center's written response will ordinarily be issued from the Division of Compliance. That response will not issue without the appropriate concurrences from the responsible units within the Center for Veterinary Medicine.