

§2.19

when, after opportunity for presentation of views following such notice, it determines that no other such notice, and no case under the act, is or will be based on such sample;

(4) Any official sample or part thereof when the sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample;

(5) Any official sample or part thereof if the article is perishable;

(6) Any official sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for analysis;

(7) That part of any official sample which is in excess of three times the quantity it estimates to be sufficient for analysis.

[42 FR 15559, Mar. 22, 1977, as amended at 63 FR 51299, Sept. 25, 1998]

§2.19 Methods of analysis.

Where the method of analysis is not prescribed in a regulation, it is the policy of the Food and Drug Administration in its enforcement programs to utilize the methods of analysis of the AOAC INTERNATIONAL (AOAC) as published in the latest edition (13th Ed., 1980) of their publication "Official Methods of Analysis of the Association of Official Analytical Chemists," and the supplements thereto ("Changes in Methods" as published in the March issues of the "Journal of the Association of Official Analytical Chemists"), which are incorporated by reference, when available and applicable. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. In the absence of an AOAC method, the Commissioner will furnish a copy of the particular method, or a reference to the published method, that the Food and Drug Administration will use in its enforcement program. Other methods may be used for quality control, specifications, contracts, surveys, and similar non-

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regulatory functions, but it is expected that they will be calibrated in terms of the method which the Food and Drug Administration uses in its enforcement program. Use of an AOAC method does not relieve the practitioner of the responsibility to demonstrate that he can perform the method properly through the use of positive and negative controls and recovery and reproducibility studies.

[42 FR 15559, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 54 FR 9034, Mar. 3, 1989; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

Subpart B—Human and Animal Foods

§2.25 Grain seed treated with poisonous substances; color identification to prevent adulteration of human and animal food.

(a) In recent years there has developed increasing use of poisonous treatments on seed for fungicidal and other purposes. Such treated seed, if consumed, presents a hazard to humans and livestock. It is not unusual for stocks of such treated food seeds to remain on hand after the planting season has passed. Despite the cautions required by the Federal Seed Act (53 Stat. 1275, as amended 72 Stat. 476, 7 U.S.C. 1551 *et seq.*) in the labeling of the treated seed, the Food and Drug Administration has encountered many cases where such surplus stocks of treated wheat, corn, oats, rye, barley, and sorghum seed had been mixed with untreated seed and sent to market for food or feed use. This has resulted in livestock injury and in legal actions under the Federal Food, Drug, and Cosmetic Act against large quantities of food adulterated through such admixture of poisonous treated seeds with good food. Criminal cases were brought against some firms and individuals. Where the treated seeds are prominently colored, buyers and users or processors of agricultural food seed for food purposes are able to detect the admixture of the poisonous seed and thus reject the lots; but most such buyers, users, and processors do not have the facilities or scientific equipment to determine the presence of the poisonous

chemical at the time crops are delivered, in cases where the treated seeds have not been so colored. A suitable color for this use is one that is in sufficient contrast to the natural color of the food seed as to make admixture of treated, denatured seeds with good food easily apparent, and is so applied that it is not readily removed.

(b) On and after December 31, 1964, the Food and Drug Administration will regard as adulterated any interstate shipment of the food seeds wheat, corn, oats, rye, barley, and sorghum bearing a poisonous treatment in excess of a recognized tolerance or treatment for which no tolerance or exemption from tolerance is recognized in regulations promulgated pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act, unless such seeds have been adequately denatured by a suitable color to prevent their subsequent inadvertent use as food for man or feed for animals.

(c) Attention is called to the labeling requirements of the Federal Hazardous Substances Act, where applicable to denatured seeds in packages suitable for household use.

§2.35 Use of secondhand containers for the shipment or storage of food and animal feed.

(a) Investigations by the Food and Drug Administration, the National Communicable Disease Center of the U.S. Public Health Service, the Consumer and Marketing Service of the U.S. Department of Agriculture, and by various State public health agencies have revealed practices whereby food and animal feed stored or shipped in secondhand containers have been rendered dangerous to health. Such contamination has been the result of the original use of these containers for the storage and shipment of articles containing or bearing disease organisms or poisonous or deleterious substances.

(b) The Commissioner concludes that such dangerous or potentially dangerous practices include, but are not limited to, the following:

(1) Some vegetable growers and packers employ used poultry crates for shipment of fresh vegetables, including cabbage and celery. Salmonella organisms are commonly present on dressed

poultry and in excreta and fluid exudates from dressed birds. Thus wooden crates in which dressed poultry has been iced and packed are potential sources of Salmonella or other enteropathogenic microorganisms that may contaminate fresh vegetables which are frequently consumed without heat treatment.

(2) Some potato growers and producers of animal feeds use secondhand bags for shipment of these articles. Such bags may have originally been used for shipping or storing pesticide-treated seed or other articles bearing or containing poisonous substances. Thus these secondhand bags are potential sources of contamination of the food or animal feed stored or shipped therein.

(c) In a policy statement issued April 11, 1968, the Food and Drug Administration declared adulterated within the meaning of section 402(a) of the Federal Food, Drug, and Cosmetic Act shipments of vegetables or other edible food in used crates or containers that may render the contents injurious to health. This policy statement is extended so that the Food and Drug Administration will regard as adulterated within the meaning of section 402(a) of the act shipments of vegetables, other edible food, or animal feed in used crates, bags, or other containers that may render the contents injurious to health.

Subparts C–E [Reserved]

Subpart F—Caustic Poisons

§2.110 Definition of ammonia under Federal Caustic Poison Act.

For the purpose of determining whether an article containing ammonia is subject to the Federal Caustic Poison Act, the ammonia content is to be calculated as NH₃.