MOU number: 225-72-2009

Memorandum of Understanding

Between
The Agricultural Marketing Service

and

The Food and Drug Administration

Concerning the Inspection and Grading of Food Products 1

The Food and Drug Administration (FDA) of the Department of Health, Education and Welfare is charged with the enforcement of the Federal, Food, Drug, and Cosmetic Act. In fulfilling its responsibilities under the Act, FDA's activities are directed toward the protection of the public health of the nation by insuring that foods are safe and wholesome and that products are honestly and informatively labeled. This is accomplished by inspecting the processing and distribution of foods and examining samples thereof to assure compliance with the Act. FDA also promulgates under the Act mandatory standards of identity, quality, and fill of container for food products after appropriate notices and hearings.

The Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture, under the authority of the Agricultural Marketing Act of 1946, carries out certain voluntary service functions designed to aid in the efficient marketing of agricultural products. These include the development of commercial grade standards and specifications for foods, and furnishing inspection and grading services, including the issuance of certificates of quality and/or condition, to producers, processors, shippers, buyers, or other interested parties. The major purpose is to assist producers in preparing better quality of wholesome products and to provide objective information by means of official certification concerning the grade, quality, or condition of a product which will be of maximum assistance to all interested parties engaged in marketing functions.

The two agencies have certain related objectives in carrying out their respective regulatory and service activities. Therefore, it is believed desirable from the standpoint of public interest to set forth in this Memorandum of Agreement the working arrangements which are being followed or adopted in the interest of each agency discharging as effectively as possible its responsibilities related to inspection and standardization activities for food products.

The Agricultural Marketing Service will:

(1) Supply to FDA, headquarters, a complete list of all food processing and packing plants which are operating under AMS continuous or other resident-type inspection or grading contracts. This list will set forth the type of service provided and the food products involved. AMS will immediately advise the appropriate FDA field office of those plants subject to withdrawal or suspension of service, termination of contract or denial of inspection services because of sanitation or other current good manufacturing practice deficiencies.

(2) Investigate any report from FDA to the effect that a processor or packer operating under contract with AMS has not corrected objectionable conditions found to exist by FDA, and will take action in accordance with AMS regulations and contracts.

(3) Decline to inspect or grade samples of products which have been seized by FDA, or which are known to be involved in formal FDA actions. This does not preclude reinspection of legally authorized samples by AMS if the FDA seizure or other actions involved products which had previously been inspected or graded by AMS.

(4) Decline to assign a U.S. grade or permit the use of Government official marks or other approved identification on a food product which is considered adulterated under the Federal Food, Drug, and Cosmetic Act, of such type and/or in such amounts so as to result in the food product being subject to regulatory action by FDA or is otherwise found to be not suitable for grade assignment. AMS will make such examinations and tests as are reasonably feasible for those materials and substances that would be likely to contaminate the product.

(5) Report to the appropriate FDA field office information on any lot of produce which, upon inspection, AMS declines to assign a grade unless such product is so reconditioned as to comply with FDA requirements

Ex. 105

and/or qualify for grade assignment, or is segregated and disposed of for nonfood use or otherwise lawfully shipped or sold.

(6) Furnish FDA headquarters on request, with any pertinent information concerning the grade or quality determination relative to specific lots of products inspected or graded by AMS that have been processed against or are being considered for action by FDA.

(7) Report on the inspection certificate any pertinent codes or other marks that will serve to identify the specific goods which are inspected or graded.

(8) Inform FDA headquarters whenever it has information that an employee or USDA-licensed inspector is to be or has been subpoenaed as a witness at judicial proceedings involving FDA action and advise FDA of the nature of his proposed testimony.

The Food and Drug Administration will:

(1) Recognize that the AMS service provided in connection with the voluntary contract inspection of fruit and vegetable processing establishments contributes to protection of consumers and aids FDA in enforcement of pertinent statutes. The AMS inspection service will not diminish FDA authority to inspect but should minimize FDA inspections in establishments under AMS contract inspection. In this regard AMS inspectors will routinely advise contract establishments of pertinent FDA requirements, advise them on how to comply and provide advice on compliance. AMS inspectors may not act as FDA inspectors but their inspections and consultations with FDA should reduce the necessity for FDA inspections.

(2) Invite the AMS inspector stationed at a plant which is operating under AMS inspection to accompany the FDA inspector during his inspection of such plant. The FDA inspector will point out or discuss with the AMS inspector and conditions noted which may result in violations of the Federal Food, Drug, and Cosmetic Act.

(3) Request AMS headquarters for any pertinent information concerning the grade or quality determinations relative to specific lots of products that have been proceeded against or are being considered for action by FDA and are known or believed to have been inspected by AMS. FDA will take into consideration the results of AMS inspection certificates and other available data unless it has evidence that the product does not meet legal requirements as a food or has deteriorated to such an extent, subsequent to AMS inspection, as to make it unacceptable as food.

(4) Immediately notify the appropriate AMS field office concerning the details of objectionable conditions whenever such conditions are found to exist in processing or packing plants where AMS is currently conducting inspection of products, or in other food plants, when FDA believes such information would be of value to AMS in its inspection and grading activities.

(5) Whenever possible mark the claimant's samples of seized products in such a manner that AMS inspectors or graders will recognize such post-seizure samples.

(6) Discuss with AMS headquarters the criteria used by FDA in order to provide the maximum assurance that AMS does not classify a food as acceptable which FDA would consider actionable under the Federal Food, Drug, and Cosmetic Act.

(7) On request of AMS review labels, legends, stamps, and other official marks for products packed under the various inspection services of AMS from the stand-point of possible conflict with the misbranding provisions of the Federal Food, Drug, and Cosmetic Act.

It is mutually agreed that:

(1) Both agencies will maintain close working relations with each other, both in headquarters as well as in the field.

(2) Proposed regulations by either agency establishing or amending any food products standard will be referred to the other agency for review and comment prior to issuance.

(3) Both agencies will cooperate jointly and with industry in the improvement of sanitation and food handling practices in processing plants. Both agencies will mutually exchange data and cooperate in the development of sampling plans, methodology and guidelines for determining natural and unavoidable defects common to products inspected and graded by AMS.

(4) Both agencies will work with industry toward greater efficiency in connection with improvement in coding methods.

(5) Both agencies will cooperate in the handling of those cases of misbranding which also come under the provisions of the Perishable Agricultural Commodities Act of 1930, as amended.

(6) Each agency will designate to the other a central contact point to which communications dealing with this agreement or matters affected thereby may be first referred for attention.

(7) Nothing in this Agreement modifies other existing agreements, nor does it preclude entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by such special agreement.

(8) The provisions of this memorandum may be modified at any time by mutual agreement.

Effective Date: This agreement becomes effective_____ (date of publication in the FEDERAL REGISTER) and supersedes Memorandum of Understanding dated August 28, 1973.

1. This agreement does not apply to egg products, inspection of which is covered by the Egg Products Inspection Act, nor to grains, including rice, dry beans, peas, or lentils, which will be covered by a separate memorandum of agreement between AMS and FDA.

Approved and Accepted
for the Agricultural Marketing Service

Signed by: E.L. Peterson, Administrator
Agricultural Marketing Service

Date: June 25, 1975

Approved and Accepted
for the Food and Drug Administration

Signed by: A. Schmidt, Commissioner
Food and Drug Administration

Date: June 9, 1975
