United States Department of Agriculture
Agricultural Marketing Service
Federal Grain Inspection Service

Directive

FGIS 9060.2 March 31, 2025

IMPLEMENTATION OF THE FGIS-FDA MEMORANDUM OF UNDERSTANDING

CONTENTS

1. PURPOSE

This directive transmits procedures for implementing the Memorandum of Understanding (MOU) between the Federal Grain Inspection Service (FGIS) and the Food and Drug Administration (FDA).

2. REPLACEMENT HIGHLIGHTS

This directive supersedes FGIS Program Directive 9060.2, Implementation of the FGIS-FDA Memorandum of Understanding, dated 5-1-97. This directive is updated to reflect organizational changes, current actionable criteria, updated FDA compliance references, and to clarify reporting of actionable lots. Representatives from FDA's Human Foods Program (HFP), Center for Veterinary Medicine (CVM), and Office of Inspections and Investigations (OII) aided in the update and its release.

The following is a list of changes from the previous version of this directive:

a. Updated contact information for FDA personnel.

b. Added instructions to identify and monitor actionable lots after reporting.

c. Added requirement to send copies of reports to FGIS Policies, Procedures, and Market Analysis Branch (PPMAB) for central reporting.

d. Provided language that allows for the shipment of grain that does not meet US requirements if the exporter can show that the requirements in section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) are met.

e. Added provision in Section 9 for allowing applicants to take minor cleaning steps prior to waiting for FDA approval in certain circumstances.

f. Updated actionable criteria in Sections 5, 6, and 7 to include only criteria that are covered by FDA Compliance Policy Guides (CPGs).

    (1) Specified that animal filth only applies to wheat in Section 4. The current CPG Sec. 578.300 only covers animal filth in wheat.

    (2) Clarified classification of actionable lots for commodities at storage and warehouse facilities based on CPG Sec. 580.100.

    (3) Moved the following criteria to a newly created Section 8, which covers when deleterious conditions exist that may render the grain or commodity unsafe for consumption but are not specifically covered by CPGs.

        (a) Castor beans and crotalaria seeds.

        (b) Commercially objectionable foreign odors (COFO).

        (c) Distinctly Low Quality (DLQ).

g. Removed Attachment 2: Written Report Format in favor of guidelines detailing what information must be reported.

3. POLICY

FGIS and FDA have certain mutual objectives in carrying out their respective service and regulatory functions. While FGIS is responsible for making quality determinations on lots of grain, FDA is responsible for ensuring the safety of the U.S. food supply. In accordance with the FGIS-FDA MOU (Attachment 1), FGIS must report to FDA officially sampled lots of grain, rice, pulses, or processed commodities which may be considered adulterated or misbranded under the Act.

Lots of grain or commodities are considered actionable by FGIS when they exceed the criteria set forth by FDA or when other deleterious conditions exist that may render the grain or commodity unsafe for consumption. See Sections 4, 5, and 6 for a list of criteria and references established by FDA which identify action levels in commodities and Section 7 for criteria that require FDA consultation.

In accordance with Section IV.B.4. of the MOU, official personnel must report any officially sampled lots that meet any of the actionable criteria listed in this directive. **Do not report submitted samples**.

4. ACTIONABLE CRITERIA FOR GRAIN AND GRADED COMMODITIES

The following criteria provides action levels for contaminants or information on adulteration in grain and graded commodities that must be reported to FDA when found in officially sampled lots of grain and other graded commodities. The criteria are based on the relevant FDA Compliance Policy Guides (CPGs).

a. Animal Filth in Wheat.
(FDA CPG Sec. 578.300 Wheat – Adulteration by Insects and Rodent Filth)

b. Insect Damaged Kernels in Wheat.
(FDA CPG Sec. 578.300 Wheat – Adulteration by Insects and Rodent Filth)

Any lot of wheat that grades U.S. Sample Grade due to insect damaged kernels based on the three-stage inspection process.

c. Toxic Substances in Grain, Rice, and Pulses.
(FDA CPG Sec. 578.400 Treated Grain Seed, Mercury Residue)

Any lot of grain or other commodity that grades U.S. Sample Grade due to toxic material (treated seeds).

d. Aflatoxin.
(FDA CPG Sec. 555.400 Foods – Adulteration with Aflatoxin and Sec. 683.100 Action Levels for Aflatoxins in Animal Food)

Any lot of grain or other commodity that exceeds 20 ppb aflatoxin is considered adulterated if the intended use is for human food, pet food, or to be fed to dairy animals and/or young animals. A lot of grain containing between 20 and 300 ppb aflatoxin may be distributed for an appropriate animal food use per action levels listed in CPG 683.100 without contacting the FDA, as long as the certificate representing the product in distribution and the product is labeled for use only in the approved species and class of animal.

e. Deleterious Foreign Matter.
(FDA CPG Sec. 555.500 All Food Sanitation (Including Bacteriological) Inspections – Classification of Establishment; CPG Sec. 585.575 Peas and Beans; Dried – Adulteration Involving Storage, Insect Damage, Rocks; and CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects)

(1) Grain: Any lot of grain that meets the criteria for U.S. Sample Grade (DLQ) due to metal fragments or glass.

(2) Rice and Pulses: Any lot of rice or pulses that meets the criteria for U.S. Sample Grade (DLQ) due to metal fragments, glass, or stones.

f. Insects and Insect Filth in Pulses.
(FDA CPG Sec. 585.225 Black-Eyed Peas (Cow Peas, Field Peas); Dried – Adulteration with Bug Damage and CPG Sec. 585.575 Peas and Beans; Dried – Adulteration Involving Storage, Insect Damage, Rocks)

Any lot that meets the requirements for U.S. Sample Grade on account of live or dead insects, insect webbing, or insect refuse.

g. Additives.
(FDA CPG Sec. 578.600 Unapproved Additives for Exported Grains)

The application of any additive for the purposes of insect and fungi control, dust suppression, or identification must be approved by FDA or the Environmental Protection Agency (EPA). For further information on additives, see the Grain Inspection Handbook, Book IV, Chapter 3. If an applicant intends to add any substances to grain for these purposes, contact FDA before loading begins to ensure compliance. Report any lot that has had any unapproved additive applied.

5. ACTIONABLE CRITERIA FOR AMA NONGRADED COMMODITIES

The following section provides information on adulteration in nongraded commodities that when found in officially sampled lots of nongraded commodities sampled under the Agricultural Marketing Act (AMA) of 1946 must be reported to FDA. The criteria are based on the relevant FDA CPGs.

a. Any Commodity.
(FDA CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects)

Any lot that contains any number of stones, metal fragments, or pieces of glass.

b. Wheat Flour (All Types Except Durum).
(FDA CPG Sec. 578.450 Wheat Flour – Adulteration with Insect Fragments and Rodent Hairs)

Any lot that contains either of the following (or equivalent):

(1) 75 or more insect fragments per 50 grams.

(2) One or more rodent hairs per 50 grams.

c. Macaroni and Noodle Products, Durum, and Farina.
(FDA CPG Sec. 505.500 Macaroni and Noodle Products – Adulteration Involving Insect Fragments and Rodent Hairs)

Any lot that contains either of the following (or equivalent):

(1) Average of 225 or more insect fragments per 225 grams.

(2) Average of 4.5 or more rodent hairs per 225 grams.

d. All Corn Meal.
(FDA CPG Sec 578.200 Corn Meal - Adulteration by Insect and Rodent Filth | FDA)

Any lot that contains any of the following (or equivalent).

(1) Average of 25 or more insect fragments per 25 grams.

(2) Average of 1 or more whole insects per 50 grams.

(3) Average of 1 or more rodent hairs per 25 grams.

(4) Average of 1 or more fragments of rodent excreta per 50 grams.

6. ACTIONABLE CRITERIA FOR COMMODITIES AT STORAGE AND WAREHOUSE FACILITIES

The following criteria apply to rice, pulses, and processed products stored at warehouses. All are based on FDA CPG Sec. 580.100 Food Storage and Warehousing – Adulteration – Filth (Domestic and Import).

a. Rodent Contamination:

(1) If the storage is rodent infested, and any of the following apply:

(a) Three or more of the bags in the lot are rodent gnawed.

(b) At least five of the bags in the lot bear either rodent urine stains at least 1/4 inch in diameter or two or more rodent pellets.

(c) The commodity in at least one container in the lot contains rodent-gnawed material or rodent excreta or urine.

(2) Whether or not the warehouse is rodent infested, if any of the following apply:

(a) At least three bags bear rodent urine stains of at least 1/4 inch in diameter which penetrates to the product even though the commodity cannot be demonstrated to have been contaminated.

(b) At least two bags are rodent gnawed and at least five bags bear either rodent urine stains at least 1/4 inch in diameter, with or without penetration to the product, or two or more rodent pellets.

(c) The commodity in at least one bag in the lot contains rodent-gnawed material or rodent excreta or rodent urine, and at least five bags bear either rodent urine stains at least 1/4 inch in diameter or two or more rodent pellets.

b. Insect Contamination.

(1) The lot contains either of the following:

(a) One live insect in each of two or more immediate containers, or one dead insect in each of three or more immediate containers, or three live or dead insects in one immediate container.

(b) Similar live or dead insect infestation present on or in the immediate proximity of the lot.

(2) The lot contains one or more live insects in each of three or more immediate containers.

(3) The lot contains two or more dead whole insects in at least five of the immediate containers.

Note: This situation may follow fumigation and vacuuming of the exteriors of the bags of a lot.

(4) The commodity is in cloth or burlap bags and two or more live or dead insects are present on at least five of the containers.

c. Bird Contamination.

If the lot is in permeable containers (paper, cloth, burlap, etc.) and any of the following apply:

(1) The lot contains bird excreta in one or more containers and is stored in an insanitary condition.

(2) Bird excreta is present on the exteriors of at least five of the containers, and the lot contains bird excreta in one bag.

(3) At least 30 percent of the bags examined, but at least five bags, are contaminated with bird excreta; and at least three of the bags bear excreta stains which penetrate to the product, even though the product cannot be demonstrated by chemical analysis to have been contaminated.

7. OTHER CRITERIA

When other deleterious conditions exist that may render the grain or commodity unsafe for consumption, but are not covered by CPGs, consult with FDA staff to determine if action must be taken on the lot. If FDA requests, follow through with the procedures detailed in Section 4. Examples of other criteria include:

a. Toxic Substances in Grain, Rice, and Pulses.

Any lot of grain or other commodity that grades U.S. Sample Grade due to castor beans or crotalaria seeds.

b. Commercially Objectionable Foreign Odors (COFO).

Any lot with a COFO other than fumigant odors.

c. Distinctly Low Quality (DLQ).

Any lot that grades as DLQ based on flood damage or other unusual conditions that affect the safety of the grain or commodity.

Note: Large animal excreta is not considered actionable in grains other than wheat. Do not report lots of other grains that grade as DLQ based on large animal excreta.

8. PROCEDURES

Note: Only report officially sampled lots. Actionable criteria does not apply to submitted samples.

Upon finding a lot actionable based on any of the above criteria, official personnel must take the following steps to ensure compliance with the MOU.

a. Immediately inform the applicant that the lot is considered actionable by FDA and explain the process or provide them with a copy of this directive for their information.

b. Inform the applicant that any further disposition of the lot is subject to FDA oversight. Report any unauthorized movement or commingling of the actionable lot with other lots of grain or commodities to FDA.

c. If the lot is still located at the applicant's facility, ensure that it is easily locatable and identifiable by the most appropriate means, whether by physical locks, security seals, physical observation, or some other method.

d. If the actionable lot has left the applicant's facility, record the identity of the carrier and destination for tracking purposes.

e. Perform all requested review inspections of the lot in accordance with FGIS Directive 9170.15.

    (1) If the results of a review inspection determine that the lot is free from actionable criteria, consider the lot as not actionable. The applicant is free to handle it without further FDA intervention.

    (2) If the applicant requests no review inspection or the results of all review inspections confirm the actionable criteria, proceed with the next step of the process.

f. If the lot is actionable based on machine-separable material or aflatoxin, allow the applicant to take minor cleaning steps as detailed in Section 10 of this directive. Officially sample and inspect the cleaned grain for the actionable criteria only. Review inspections are not allowed.

    (1) If the cleaned lot is free from actionable criteria, consider the cleaned lot as not actionable. The applicant is free to handle it without further FDA intervention.

    (2) If the cleaned lot still contains actionable criteria, consider the cleaned lot as actionable and proceed with reporting to FDA.

    (3) In either case, consider the screenings as actionable and proceed with reporting to FDA.

g. If any lot of grain, commodity, or screenings is still considered actionable, ask the applicant if the lot is intended for human or animal food. If the applicant is unsure, report the lot as if it were intended for human food. Report actionable lots to FDA according to Section 9 of this directive.

h. If the applicant requests a review inspection after an actionable lot has been reported to FDA, notify the applicant and FDA of the results immediately upon completion of the review.

i. Maintain records at the facility, field office, or official agency office to keep track of actionable lots.

j. Report any unauthorized movement or commingling of actionable lots to FDA.

9. MINOR CLEANING

Applicants may take minor cleaning steps to remove easily separable actionable criteria from lots without prior FDA approval. For the purposes of this section, “minor cleaning steps” is defined as screening, aerating, or similar methods of mechanical separation. If an applicant wishes to take such minor cleaning steps, official personnel must take the following steps while observing the cleaning:

Monitor the movement of the grain or commodity and all relevant diversion points to ensure the identity of the lot.

a. Ensure that the applicant isolates the lot and screenings from other grains or commodities in the facility.

Note: The applicant may add the screenings to a bin with other grain screenings. In this case, the entire bin will be considered actionable.

b. Officially sample and inspect the cleaned lot (and screenings, if possible) to determine if the actionable criteria is still present.

Note: The purpose of this inspection is only to determine if the cleaning removed the actionable criteria from the grain. It is not a new original inspection of the lot.

c. If the results of the subsequent inspection show that the actionable criteria is no longer present in the cleaned lot, the applicant is free to use that cleaned lot without further action. If unable to further test the screenings, consider them to still contain the actionable criteria.

d. If the lot was originally actionable based on aflatoxin, official personnel must sample the screenings using the most practical procedures available and test the screenings for aflatoxin contamination.

e. If the lot remains actionable after minor cleaning, the applicant is responsible for working with FDA to submit and execute a reconditioning plan with meaningful changes from the minor cleaning procedure.

f. Report the results of the cleaning process to FDA as detailed in Section 10. Make sure to include the results of the inspection and location of any still actionable lots and screenings.

10. REPORTING ACTIONABLE LOTS

a. Reports.

After determining that a lot is at or exceeds the actionable criteria level, report the results to the applicant for inspection and to the appropriate FDA Office as outlined below, as determined by the intended use of the lot:

(1) Animal Food.

If the lot of grain is intended for domestic use in animal food, contact the Center for Veterinary Medicine (CVM), Division of Food Compliance (DFC), Field Operations and Investigations Branch (FOIB) at CVMDFCFOIB@fda.hhs.gov.

(2) Human Food.

For lots of grain intended for human food, contact the Office of Inspections and Investigations (OII), Division of Field Enforcement (DFE) at SubmitRPInfo@fda.hhs.gov.

(3) Special Circumstances for Export Lots.

If a lot is intended for export and the applicant can provide documentation required by 21 CFR 1.101(b), the lot may still be exported under section 801(e) of the Act. In accordance with section 801(e)(1) of the Act, food that might not meet U.S. requirements may be exported to another country as long as it meets the requirements of the importing country. If official personnel identify a lot of grain that does not meet U.S. requirements, but which does meet the requirements of the foreign purchaser, that lot may be released if the exporter can provide documentation showing that this lot of grain meets the importing country's requirements, is labeled for export only, and is not sold or offered for sale in the U.S.

If a lot cannot be exported under section 801(e), the applicant should be allowed to perform reconditioning or divert the grain to animal food as described in paragraph d below.

b. Lot Identification.

Ensure that the actionable lot is easily locatable and identifiable by the most appropriate means, whether by physical locks, security seals, physical observation, or some other method. Maintain records at the facility, field office, or official agency office to keep track of actionable lots. Inform the applicant that any further disposition of the lot is subject to FDA oversight. Report any unauthorized movement or commingling of the actionable lot with other lots of grain to FDA.

c. Written Reports.

The written report notifying the FDA of an actionable lot should include as many of the following details as possible:

(1) Date of sampling/inspection

(2) Elevator or loading location, including address

(3) Commodity

(4) Carrier identification (including sublot number if relevant)

(5) Quantity of lot

(6) Destination

(7) Intended use (human or animal, if known)

(8) Actionable condition(s)

(9) Details of minor cleaning steps taken by applicant and results of inspection of cleaned lots

(10) Current location of lot, including any bin numbers, seals, or other identifying information

Send copies of the written report to the FDA representative (as noted in 10(a)), the applicant, and to the FGIS Policies, Procedures, and Market Analysis Branch at FGISPoliciesProceduresMarketAnalysisBranch@usda.gov. Employees of designated agencies or designated or delegated States must also forward a copy of their report and a copy of the certificate to the supervising FGIS field office. Upon FDA request, include the worked portion of the sample with the written report.

d. Reconditioning.

The applicant is responsible for working with FDA to submit and execute a reconditioning plan for actionable lots.

For lots that are still deemed to be actionable after minor cleaning, or for actionable screenings resulting from minor cleaning or reconditioning, the applicant has the option to divert to animal food if possible. Diversion proposals should be submitted to CVM, DFC per CPG 675.200, Diversion of Adulterated Food to Acceptable Animal Feed Use. Send inquiries or requests to CVMDFCFOIB@fda.hhs.gov. When necessary, FGIS may assist with sampling and testing the reconditioned lot to ensure FDA approval of the final product.

For lots that are deemed to be actionable after minor cleaning, and the applicant would still like to market the grain for human consumption, the applicant should reach out to OII, DFE at SubmitRPInfo@fda.hhs.gov for additional reconditioning guidance.

Attachment 1

MEMORANDUM OF UNDERSTANDING

Between The

FEDERAL GRAIN INSPECTION SERVICE
U.S. DEPARTMENT OF AGRICULTURE

And The

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

1. PURPOSE

This agreement sets forth the working arrangements between the Federal Grain Inspection Service (FGIS) and the Food and Drug Administration (FDA) regarding their respective responsibilities in the inspection and standardization of grain, rice, pulses, and food products. *

II. BACKGROUND

This Memorandum of Understanding revises and replaces the Memorandum of Agreement on this subject which went into effect on April 15, 1980.

III. STATUTES RELATING TO THE AGREEMENT

A. The Food and Drug Administration of the Department of Health and Human Services enforces the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (the Act). In fulfilling its responsibilities under the act, FDA ensures that foods, including animal food, are safe and wholesome and are labeled in a truthful, non-misleading manner. FDA accomplishes this in part, by inspecting facilities that process, hold, and distribute grain, rice, pulses, and similar food. FDA also examines samples of inspected food to determine whether the food is adulterated or misbranded within the meaning of the act. FDA also promulgates, under the act, standards of identity, quality, and fill of container for food products.

B. The Federal Grain Inspection Service of the U.S. Department of Agriculture under the authority of (1) the U.S. Grain Standards Act (7 U.S.C. 71 et seq.) and the regulations thereunder (7 CFR Part 800 through 810), and (2) the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) and the regulations thereunder (7 CFR Part 68), performs voluntary and mandatory inspection and weighing services designed to aid in the efficient marketing of agricultural products. These services include developing specifications and standards; furnishing inspection, grading, and weighing services; and issuing certificates of quantity, quality, and condition of producers, processors, shippers, buyers, and other interested parties. An FGIS certificate provides reliable commercial information concerning the quantity, quality, and condition of agricultural products.

* This agreement applies only to those commodities assigned to FGIS by the Secretary of Agriculture.

IV. SUBSTANCE OF AGREEMENT

A. When performing functions under the act that relate to agricultural products, persons, and facilities that are also subject to the laws and regulations administered by FGIS, FDA will:

1. During FDA inspection of a facility that processes, packs, or holds agricultural products, request the FGIS inspector or FGIS licensee stationed at a facility to accompany the FDA inspector during the inspection. The FDA inspector will discuss with the FGIS inspector or FGIS licensee any conditions that the FDA inspector believes may result in violations of the act.

2. Request FGIS to furnish information concerning quality determinations of specific lots of products against which FDA has taken or may take action. When involved in such an action, FDA will consider the results of official FGIS inspection certificates and other available data provided the information is relevant to the current condition of the product and the nature of the violation charged.

When an FDA action is to be based on an analysis by FGIS or an FGIS licensee and FDA has not received the results of an appeal analysis, FDA through its appropriate field office will contact the designated FGIS field liaison person (see IV.B.4.), confirm that an appeal analysis is being conducted and request an oral report of the results of the analysis as soon as possible.

3. Notify FGIS concerning details of objectionable conditions found by FDA to exist in processing plants, packing plants, grain elevators, or any other facilities where FGIS provides official services.

4. Notify FGIS of the criteria FDA uses to determine whether FDA should consider an action under the act against an agricultural product. Notification will ensure that FGIS does not classify an objectionable commodity as acceptable.

5. Upon request of FGIS, review for possible conflict with the misbranding provisions of the act the following: labels, legends, stamps, and other marks on products that are packed under the various official services.

B. When performing functions under the laws and regulations administered by FGIS that relate to agricultural products, persons, and facilities that are also subject to the act, FGIS will:

1. Promptly notify FDA of the facilities that are subject to withdrawal or suspension of service, termination of contract, or denial of official FGIS services because of insanitary conditions or other processing deficiencies.

2. Investigate any report from FDA that a processor, packer, merchandiser, or facility operator using official FGIS services has not corrected objectionable conditions found by FDA. Upon completion of this investigation, FGIS will initiate appropriate action and notify FDA of the action taken.

3. Refuse to inspect products which have been seized by FDA, or which are known to be involved in formal FDA actions. This does not preclude official reinspection of authorized samples if the FDA action involves products which have been officially inspected.

4. Promptly report to FDA the results of any inspection or analysis (including results of any appeal analysis, when available) for any product that may be actionable under the act. Such report shall include information to assist in locating and identifying the product and the name of an appropriate field liaison person in FGIS.

5. Furnish FDA, upon request, any pertinent information concerning the grade or quality of FGIS inspected specific lots of products, against which FDA has taken or may take action.

C. It is mutually agreed that:

1. Field liaison will be maintained between FDA District offices and FGIS designated field liaison persons as indicated in IV.B.4. General matters involving this agreement may be referred to the agencies' liaison officers as indicated in VI.A. and VI.B.

2. Proposed regulations initiated by either agency which affect, establish, or amend food standards or other products covered by this agreement will be referred to the other agency for review and comment before the proposed regulations are published for broader comment.

3. Both agencies will cooperate with industries in improving sanitation and food handling practices in processing plants, packing plants, or other facilities.

4. Both agencies will exchange data and cooperate in developing sampling plans, methodology, and guidelines for determining natural and unavoidable defects common to products officially inspected.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

A. Federal Grain Inspection Service
U.S. Department of Agriculture
14th St. and Independence Ave.,
Washington, DC 20250.

B. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857.

VI. LIAISON OFFICERS

A. For the Food and Drug Administration:

Director, Office of Compliance,
(currently, John M. Taylor),
Center for Food Safety and Applied Nutrition (HFF-300),
200 C St. SW.,
Washington, DC 20204,
202-485-0160.B. For the Federal Grain Inspection Service:

Director, Field Management Division,
(currently, John W. Marshall),
Federal Grain Inspection Service,
14th St. and Independence Ave.,
Washington, DC 20250,
202-382-0228

VII. PERIOD OF AGREEMENT

This agreement, when accepted by both parties, will be effective indefinitely. It may be modified by mutual consent or terminated by either party upon a 30-day written notice.

APPROVED AND ACCEPTED FOR THE FEDERAL GRAIN INSPECTION SERVICE	APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION
BY: / S /	BY: / S /
K.A. Gilles	Joseph P. Hile
TITLE: Administrator Federal Grain Inspection Service	TITLE: Associate Commissioner for Regulatory Affairs
DATE: October 9, 1985	DATE: Nov. 8, 1985