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

Directive

9060.2 May 1, 1997

IMPLEMENTATION OF THE FGIS-FDA MEMORANDUM OF UNDERSTANDING

Contents

1. PURPOSE

This directive transmits procedures for implementing the Memorandum of Understanding (MOU) between the Agricultural Marketing Service (AMS), Federal Grain Inspection Service (FGIS), U.S. Department of Agriculture, and the Food and Drug Administration (FDA), Department of Health and Human Services.

2. REPLACEMENT HIGHLIGHTS

The directive supersedes FGIS Program Directive 906.2, Implementation of the FGIS FDA Memorandum of Understanding, dated 2-26-93, and issuance change dated 4-19-96. This directive is updated to reflect organizational changes, new numbering system, and new format but does not revise policy.

3. POLICY

FGIS and FDA have certain mutual objectives in carrying out their respective service and regulatory functions. In accordance with the FGIS-FDA MOU (attachment 1), FGIS reports to FDA certain lots of grain, rice, pulses, or food products which are considered actionable under the Federal Food, Drug, and Cosmetic Act.

These are considered actionable when they exceed the action levels and guidelines set forth by the FDA. See sections 5, 6, and 7 of this directive.

4. REPORTING ACTIONABLE LOTS

a. General. In accordance with the FGIS-FDA MOU, official personnel will report lots that exceed action levels as follows:

(1) Officially sampled domestic and export lots.

(2) Auxiliary sample results for officially sampled carriers.

NOTE: Submitted samples are not reported.

If a review inspection (reinspection, retest, appeal, or Board appeal) is performed on an actionable lot before the original result is reported and the review inspection result is no longer actionable, it is not necessary to contact FDA regarding either result.

Whenever an actionable lot is reported to FDA and a subsequent review inspection is completed, the applicant and FDA must be promptly notified of the results.

b. Telephone Reports. After determining that a lot is at or exceeds the action level, report the results to the applicant for inspection and to the FDA district office nearest to the location of the lot in question (attachment 3). Telephone calls to FDA should be made collect only when FTS is not available.

c. Written Reports. Promptly confirm telephone reports in writing using the guidelines in attachment 2. Upon request of FDA, the work portion of the sample may accompany the written report. The inspection certificate shall be forwarded to the applicant which serves as the applicant's written report. Agencies making written responses to FDA, must forward a copy of their report and a copy of the certificate to the appropriate FGIS field office.

5. ACTION LEVELS FOR GRADED COMMODITIES

a. Animal Filth in Wheat, Rye, Rice, and Pulses.
(FDA Compliance Policy Guide 7104.03)

(1) Bird droppings: two or more droppings per 1,000 grams.

(2) Rodent pellets: two or more rodent pellets per 1,000 grams or 9 mg or more rodent excreta pellets and/or fragments of rodent excreta pellets per 1,000 grams.

(3) A combination of filth types: one or more bird droppings and one or more rodent pellets per 1,000 grams.

b. Insect Damaged Kernels in Wheat.
(FDA Compliance Policy Guide 7104.03)

Insect damaged kernels: 32 or more kernels per 100 grams.

Lots which exceed U.S. Sample grade criteria on a three-stage inspection process are considered actionable. (Grain Inspection Handbook, book II, chapter 13, section 13.22).

c. Toxic Substances in Grain, Rice, and Pulses.
(FDA Compliance Policy Guides 7104.05, 7126.15, and 7126.33)

(1) Castor beans: two or more per 1,000 grams.

(2) Crotalaria seeds: three or more per 1,000 grams.

(3) Treated seeds:

(a) Rice and pulses: four or more per 1,000 grams.

(b) Grain: 20 or more per 1,000 grams.

(4) Aflatoxin: more than 20 ppb.

d. Objectionable Odor in Grain, Rice, and Pulses. Lots having an objectionable foreign odor are considered actionable.

e. Deleterious Foreign Matter.
(FDA Compliance Policy Guides 7114.15, 7120.24)

(1) Grain:

(a) Metal fragments: two or more in the lot as a whole or in the original sample.

(b) Glass fragments: two or more in the lot as a whole or in the original sample.

(2) Rice and Pulses:

(a) Metal fragments: one or more in the lot as a whole or in the original sample.

(b) Glass fragments: one or more in the lot as a whole or in the original sample.

(c) Stones:

1 All rice except rough rice: more than 0.1 percent by weight.

2 Pulses: more than 0.3 percent by weight.[1]

f. Insects and Insect Filth in Rice and Pulses.
(FDA Compliance Policy Guides 7114.05 and 7114.15)

A determination of U.S. Sample grade or of meeting the requirements for U.S. Sample grade on account of live or dead insects, insect webbing, or insect refuse.

g. Distinctly Low Quality (Grain and Rice). A determination of the special grade Distinctly Low Quality (DLQ)

h. Other Defects.
(FDA Compliance Policy Guide 7104.08)

The application of any additive not approved by FDA. For further information on additives, see the Grain Inspection Handbook, Book IV, chapter 3. If a question arises about an additive, contact the local FDA office for a ruling.

[1] Lots in consumer size packages which contain sharp and jagged rocks, even if the amount of these rocks is below the limit in the USDA grade, are actionable

6. ACTION LEVELS FOR NONGRADED COMMODITIES

a. Wheat Flour (All Types Except Durum).
(FDA Compliance Policy Guide 7104.06)

(1) Insect fragments: 75 or more in 50 grams.

(2) Whole insects and/or larvae: two or more in 50 grams.

(3) Rodent hairs: one or more in 50 grams.

(4) Rodent excreta fragments: two or more in 50 grams.

b. Macaroni and Noodle Products, Durum, and Farina.
(FDA Compliance Policy Guide 7102.06)

(1) Insect fragments: 225 or more in 225 grams; or, 50 or more in 50 grams.

(2) Whole insects and/or larvae: two or more in 50 grams.

(3) Rodent hairs: two or more in 50 grams.

(4) Rodent excreta fragments: two or more in 50 grams.

c. All Corn Meal and Grits, Oat Products, Sorghum Products, Soy-Fortified Rice, and Corn-Soy Blend.
(FDA Compliance Policy Guide 7102.02)

(1) Insect fragments: 50 or more in 50 grams.

(2) Whole insects and/or larvae: one or more in 50 grams.

(3) odent hairs: two or more in 50 grams.

d. Bulgur and Soy-Fortified Bulgur, Wheat Soy Blent, and Sweetened Wheat Soy Blend.

(1) Insect fragments: 50 or more in 50 grams.

(2) Whole insects and/or larvae: five or more in 50 grams.

(3) Rodent hairs: three or more in 50 grams.

(4) Rodent excreta fragments: two or more in 50 grams.

7. ACTION LEVELS FOR COMMODITIES AT STORAGE AND WAREHOUSE FACILITIES

The following action levels apply to rice, pulses, and processed products stored at warehouses. (FDA Compliance Policy Guide 7103.01)

a. Rodent Contamination:

(1) If the storage facility has any live rodents, and:

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

(b) Five or more bags in the lot bear either rodent urine stains or least 1/4 inch in diameter or two or more rodent pellets; or

(c) The food in one or more containers in the lot contains rodentgnawed material or rodent excreta or urine.

(2) If the storage facility does not have any live rodents, but:

(a) Two or more bags are rodent gnawed and at least five bags bear either rodent urine stains at least 1/4 inch in diameter or two or more rodent pellets; or

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

b. Insect Contamination.

(1) External infestation only. The product is in cloth or burlap bags and two or more live insects are present on at least five of the containers.

(2) External and internal infestation. The product contains 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 or more live or dead insects in one immediate container and similar live or dead insects are present on or in the immediate proximity of the lot.

(3) Internal infestation only.

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

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

c. Bird Contamination. If the product is in permeable containers (paper, cloth, burlap, etc.):

(1) The product contains bird excreta in one or more containers.

(2) Bird excreta is present on the exteriors of five or more of the containers, and the product contains bird excreta in one bag.

Attachments

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 insures that foods, including animal feed, are safe and wholesome and are labeled in a truthful, nonmisleading 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.

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* 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 willbcontact 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

BY: / S /
K.A. Gilles

TITLE: Administrator
Federal Grain Inspection Service

DATE: October 9, 1985

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

BY: / S /
Joseph P. Hile

TITLE: Associate Commissioner
for Regulatory Affairs

DATE: Nov. 8, 1985

WRITTEN REPORT FORMAT

SUBJECT: Confirmation of Telephone Report

TO: Food and Drug Administration
District Office

CXX

This will confirm our telephone report of (date) regarding the following inferior lot of (product).

Item	Remarks
Commodity :	
Contract No. :	
Carrier	
Identification :	
Lot No. :	
Sampling Date :	
Plant/Elevator :	
Location :	
Amount :	
Destination :	
Actionable Condition(s) :	

Field Office Manager/Agency Manager
Field Office/Agency

cc: Office of the Director, FMD/Field Office

FDA DISTRICT OFFICIALS
Telephone and Address List

Report actionable lots to one of the following individuals in the preference order listed.

1. DIB - Director, Investigations Branch

2. DCB - Director, Compliance Branch

3. DD - District Director

DISTRICT OFFICE	TITLE	PHONE NUMBER	FAX NUMBER
ATLANTA	DIB	(404) 347-3151	(404) 347-1913
60 Eighth Ave., N.E.	DCB	(404) 347-3162	(404) 347-1913
Atlanta, GA 30309	DD	(404) 347-4344	(404) 347-4206
Hours 8:00 AM - 4:30 PM (Eastern)			
BALTIMORE	DIB	(410) 962-4099	(410) 962-2307
900 Madison Ave.	DCB	(410) 962-4040	(410) 962-2307
Baltimore, MD 21201	DD	(410) 962-4012	(410) 962-2307
Hours 7:45 AM - 4:15 PM (Eastern)			
BOSTON	DIB	(617) 279-1675	(617) 279-1742
One Montvale Ave., 4th. Floor	DCB	(617) 279-1675	(617) 279-1742
Stoneham, MA 02180	DD	(617) 279-1675	(617) 279-1742
Hours 8:00 AM - 4:30 PM (Eastern)			
BUFFALO	DIB	(716) 846-4461	(716) 846-4470
599 Delaware Ave.	DCB	(716) 846-4461	(716) 846-4470
Buffalo, NY 14202	DD	(716) 846-4461	(716) 846-4470
Hours 8:00 AM - 4:30 PM (Eastern)			
CHICAGO	DIB	(312) 353-5863	(312) 886-3280
300 S. Riverside Plaza	DCB	(312) 353-5863	(312) 886-3280
5th. Floor, Suite 550 South	DD	(312) 353-7379	(312) 886-3280
Chicago, IL 60606			
Hours 8:00 AM - 4:30 PM (Central)			

DISTRICT OFFICE	TITLE	PHONE NUMBER	FAX NUMBER
CINCINNATI	DIB	(513) 684-3501	(513) 684-2905
1141 Central Parkway	DCB	(513) 684-3501	(513) 684-2905
Cincinnati, OH 45202-1097	DD	(513) 684-3504	(513) 684-2905
Hours 8:00 AM - 4:30 PM (Eastern)			
DALLAS	DIB	(214) 655-5310	(214) 655-5331
3310 Live Oak Street	DCB	(214) 655-5317	(214) 655-5331
Dallas, TX 75204	DD	(214) 655-5315	(214) 655-5331
Hours 8:00 AM - 4:30 PM (Central)			
DENVER	DIB	(303) 236-3000	(303) 236-3100
P.O. Box 25087	DCB	(303) 236-3000	(303) 236-3100
6th. & Kipling Sts.	DD	(303) 236-3000	(303) 236-3100
Denver, CO 80225-0087			
Hours 8:00 AM - 4:30 PM (Mountain)			
DETROIT	DIB	(313) 226-2253	(313) 226-3717
4560 E. Jefferson Ave.	DD	(313) 226-6260	(313) 226-3076
Detroit, MI 48207			
Hours 8:00 AM - 4:30 PM (Eastern)			
KANSAS CITY	DIB	(913) 752-2423	(913) 752-2413
11630 W. 80th. St.	DCB	(913) 752-2101	(913) 752-2111
Lenexa, KS 66214-3338	DD	(913) 752-2144 (	913) 752-2111
Hours 8:00 AM - 4:30 PM (Central)			
LOS ANGELES	DCB	(714) 798-7612	(714) 851-7849
1990 MacArthur Blvd., Suite 300	DD	(714) 252-7714	(714) 851-7849
Irvine, CA 92715-2445			
Hours 8:00 AM - 4:30 PM (Pacific)			
MINNEAPOLIS	DIB	(612) 334-4120	(612) 334-4134
240 Hennepin Ave.	DCB	(612) 334-4114	(612) 334-4134
Minneapolis, MN 55401	DD	(612) 334-4102	(612) 334-4134
Hours 8:00 AM - 4:30 PM (Central)			
NASHVILLE	DIB	(615) 781-5378	(615) 781-5383
297 Plus Park Blvd.	DCB	(615) 781-5388	(615) 781-5383
Nashville, TN 37217	DD	(615) 781-5392	(615) 781-5383
Hours 8:00 AM - 4:30 PM (Central)			

DISTRICT OFFICE	TITLE	PHONE NUMBER	FAX NUMBER
NEWARK	DIB	(201) 645-6230	(201) 645-3848
Waterview Corporate Center	DCB	(201) 645-2177	(201) 645-3848
10 Waterview Blvd., 3rd. Floor	DD	(201) 645-3023	(201) 645-3848
Parsippany, NJ 07054			
Hours 8:00 AM - 4:30 PM (Eastern)			
NEW ORLEANS	DIB	(504) 589-7181	(504) 589-4666
4298 Elysian Fields Ave.	DCB	(504) 589-7166	(504) 589-6360
New Orleans, LA 70122	DD	(504) 589-2401	(504) 589-6360
Hours 8:00 AM - 4:30 PM (Central)			
NEW YORK	DIB	(718) 965-5300	(718) 965-5117
850 3rd. Ave.	DCB	(718) 965-5300	(718) 965-5117
Brooklyn, NY 11232-1593	DD	(718) 965-5300	(718) 965-5117
Hours 8:00 AM - 4:30 PM (Eastern)			
ORLANDO	DIB	(407) 648-6913	(407) 648-6881
7200 Lake Ellenor Drive, Suite 120	DCB	(407) 648-6823	(407) 648-6881
Orlando, FL 32809	DD	(407) 648-6995	(407) 648-6881
Hours 8:00 AM - 4:30 PM (Eastern)			
PHILADELPHIA	DIB	(215) 597-4390	(215) 597-6649
U.S. Customhouse	DCB	(215) 597-4390	(215) 597-8212
2nd. & Chestnut Sts., Room 900	DD	(215) 597-4390	(215) 597-6649
Philadelphia, PA 19106			
Hours 8:00 AM - 4:30 PM (Eastern)			
ST. LOUIS	DIB	(314) 645-1167	(314) 645-2969
808 North Collins	DCB	(314) 645-1167	(314) 645-2969
Lacledes Landing	DD	(314) 645-1167	(314) 645-2969
St. Louis, MO 63102			
Hours 8:00 AM - 4:30 PM (Central)			
SAN FRANCISCO	DIB	(510) 769-3050	(510) 769-3002
1431 Harbor Bay Parkway	DCB	(510) 769-3040	(510) 769-3003
Alameda, CA 94502-7070	DD	(510) 769-3020	(510) 769-3001
Hours 8:00 AM - 4:30 PM (Pacific)			

DISTRICT OFFICE	TITLE	PHONE NUMBER	FAX NUMBER
SAN JUAN	DIB	(809) 729-6854	(809) 729-6809
466 Fernandez Juncos Ave.	DCB	(809) 729-6829	(809) 729-6809
San Juan, PR 00901-3223	DD	(809) 729-6842	(809) 729-6809
Hours 8:00 AM - 4:30 PM (Eastern)			
SEATTLE	DIB	(206) 483-4941	(206) 483-4915
22201 23rd. Drive S.E.	DCB	(206) 483-4971	(206) 483-4996
P. O. Box 3012	DD	(206) 483-4950	(206) 483-4996
Bothell, WA 98041-3012			
Hours 8:00 AM - 4:30 PM (Pacific)			