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Mycotoxin Handbook

United States Department of Agriculture
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Program Handbook

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Mycotoxin Handbook

Foreword

The Mycotoxin Handbook illustrates step-by-step procedures for sample preparation and for certifying grain and commodities for mycotoxins, as well as safety information for testing and storing test chemicals. All official inspection personnel authorized or licensed to perform official mycotoxin testing shall reference this Handbook for procedures.

This handbook has been updated to incorporate FGIS's agency move to AMS, the inclusion of Policy Bulletin Board #275 Mycotoxin Testing in Grain: Sample Preparation Guidance, the removal of qualitative testing, updated test kit ranges, as well as general revisions and formatting. In addition, definitions, tables, and processes were updated to the current standards. The specific technical updates are listed in Chapter 7 of this handbook.

This handbook supersedes the Mycotoxin Handbook, dated June 28, 2016.

The mention of firm names or trade products does not imply that they are endorsed or recommended by the U.S. Department of Agriculture over other firms or similar products not mentioned. Except for the FGIS-approved mycotoxin test kits, equivalent equipment may be used in place of the items listed.

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CHAPTER 1

GENERAL INFORMATION

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1.1 PURPOSE

This handbook establishes official procedural information for sample preparation for determining the quantity of mycotoxins (aflatoxin, deoxynivalenol (DON), fumonisin, zearalenone, and ochratoxin A) in grain and processed commodity products. The handbook also provides information on how to certify the official results and comply with safety and environmental regulations involved in the testing process.

1.2 BACKGROUND

Mycotoxins are toxic substances naturally produced by fungi (molds) that may contaminate agricultural commodities. They are most likely to occur in grain or feed grown when environmental conditions of temperature and humidity are favorable for the growth of specific fungi. Some fungi favor heat, high moisture, and humidity; while others favor cool, wet climates. Most toxic fungi attack plants in the field, while some others proliferate in grain or feed during storage. These fungi result in a variety of dangerous mycotoxins, some of which are known carcinogens.

The appearance of mold can indicate an increased possibility of toxins; however, the absence of visible mold does not necessarily assure that toxins are not present. The worldwide increase in mycotoxin regulations has driven adoption of tests that are accurate, repeatable, and easy to use.

Official personnel must adhere to proper testing protocol, follow safety and health precautions, adhere to environmental regulations for hazardous waste disposal, and document and certify all mycotoxin results according to official procedures.

1.3 OFFICIAL CRITERIA

The Agricultural Marketing Service's (AMS), Federal Grain Inspection Service (FGIS) provides mycotoxin testing services as official criteria for corn, sorghum, wheat, barley, oats, rye, and soybeans under the United States Grain Standards Act (USGSA), as amended. Testing is also provided for rice, popcorn, distillers dried grains, corn grits, corn meal, corn gluten meal, corn/soy blend, wheat middlings, and other processed commodity products under the authority of the Agricultural Marketing Act (AMA) of 1946, as amended.

Fee-based mycotoxin testing services are available nationwide upon request, using rapid test kits approved by FGIS.

Individuals requesting an official mycotoxin testing service should contact the nearest FGIS field office, delegated or designated state, or designated official agency service provider.

To further assist the grain industry, FGIS also provides, on a limited basis, mycotoxin testing using reference methods based on high-performance liquid chromatography (HPLC) coupled with fluorescence or mass spectrometric detection. FGIS performs reference method testing upon applicant request for Board appeal inspections under the USGSA or for original inspections under the AMA. Contact FGIS’s Technology and Science Division (TSD) for more information.

All official mycotoxin testing is performed as prescribed in this handbook by authorized employees of FGIS or of delegated or designated official service providers.

1.4 MANDATORY TESTING

The 1990 Farm Bill (Food, Agriculture, Conservation, and Trade Act of 1990, P.L. 101-624) amended section 5 of the USGSA to “require that all corn exported from the United States be tested to ascertain whether it exceeds acceptable levels of aflatoxin contamination, unless the contract for export between the buyer and seller stipulates that aflatoxin testing shall not be conducted.” The Food and Drug Administration (FDA) uses the term “action level” to specify a precise level of contamination at which the FDA is prepared to take regulatory action. Consult chapter 6 of this handbook for more information on FDA procedural guidelines.

1.5 TESTING SERVICES

FGIS evaluates the conformance of quantitative mycotoxin test kits to FGIS-established design specifications and performance criteria. Only test kits that conform to all the criteria are approved for use in official testing.

Table 1.1 below shows the standard ranges covered by FGIS-approved test kits. In some instances, test kits are approved to cover a larger range. Refer to the FGIS-issued test kit instructions to verify the range approved by FGIS.

Table 1.1. Standard Test Kit Ranges

Aflatoxin	DON	Fumonisin	Zearalenone	Ochratoxin A
5 – 300 ppb	0.5 – 30 ppm	0.5 – 30 ppm	100 – 1,000 ppb	5 – 100 ppb

A result in the test kit range can be certified quantitatively (e.g., 10 ppb aflatoxin). If a result is outside the test kit’s range, a qualitative certification is used. For example, if an aflatoxin test kit range is 5 – 300 ppb a result above the range would be certified as >300 ppb aflatoxin.

Only quantitative test kits are available for official mycotoxin testing. An applicant may request a qualitative statement for certification. When requesting service, applicants

must specify on the load order whether they want qualitative or quantitative certification of test results. Applicants must specify on the load order the maximum limit for certification prior to receiving official service. Applicants may not change load order specifications without presenting written agreement of buyer and seller to FGIS. Applicants may not change the kind of certification (qualitative to quantitative) after testing is completed.

Before performing official testing, technicians must verify that FGIS-issued instructions are available, that the test kit in use is approved for the requested grain or commodity, and that the test kit's range applies to the applicant's request.

Note: TSD maintains a current list of performance verified test kits and instructions for official use on the FGIS website [Mycotoxin Test Kit Evaluation page](#).

An applicant's request for mycotoxin testing service for the commodity **rice** must specify the test basis (e.g., milled, rough rice, brown rice) prior to official testing. If the applicant does not specify a test basis, official personnel must analyze the rice for mycotoxin according to the type of rice as indicated on the official certificate or according to the approved test basis for the test kit in use. Test kits approved for milled rice may only be used officially for testing and certification on the milled rice basis. For more information on testing, consult Chapter 4 of this handbook.

The three types of mycotoxin testing services available are as follows:

a. Submitted Sample Service.

Analysis based on a sample submitted by the applicant for service.

b. Official Sample-Lot Service.

Analysis based on an official sample obtained and analyzed by official personnel.

1. Single lot inspection.

Obtain and test samples on either an individual carrier basis or a composite sample basis (maximum of five railcars, fifteen trucks, or twenty containers per composite sample).

2. Inspection under the CuSum Loading Plan.

(a) Sublot Testing.

As shown in table 1.2 below, under the CuSum loading plan certain grains (marked with an "X") must be analyzed on a sublot basis first and then may be analyzed on a composite basis as an additional request.

Other grains (not marked) may be tested on either a subplot or composite basis per applicant request. Acceptable sublots must conform to contract specifications when “maximum” limits are specified (see table 1.2.)

Table 1.2. Grain(s) Tested on a Mandatory Sublot Basis

Grain	Aflatoxin	DON	Fumonisin	Zearalenone	Ochratoxin A
Corn	**X**	X	X	X	X
Sorghum	X				
Wheat		X			X
Barley		X			
<p>“X” denotes mandatory subplot basis - composite basis additionally No “X” denotes either subplot or composite basis ** Denotes mandatory inspection on all export lots.</p>					

When mycotoxin testing is required on unit trains inspected under the CuSum loading plan, obtain and test samples on either an individual carrier basis or a subplot basis. For mycotoxin testing, the maximum subplot size for unit trains consisting of less than 50 railcars is five railcars. For unit trains consisting of more than 50 railcars, the maximum subplot size is ten railcars.

Sublot testing frequency for shiplot grain will be the same as the sample for grade analysis unless the applicant specifically requests mycotoxin analysis on the basis of a component sample. For more details on the CuSum loading plan, refer to [Grain Inspection Handbook, Book III - Inspection Procedures](#).

(b) Additional Testing.

Upon request, perform additional testing as follows:

- (1) Composite samples may be analyzed in addition to official subplot testing for grains tested on subplot basis on shiplots and unit trains. Select a representative portion of each unground subplot sample totaling the required sample size, combine, and analyze at the end of the shiplot or unit train.

- (2) Composite testing certification must be reported on the same certificate as official subplot testing.

(c) Alternate Testing.

Upon request, an alternate testing basis may be used, provided that the minimum testing requirements are met. Examples of alternate testing are as follows:

- (1) Sublot testing may be used instead of composite sample analysis for grains routinely tested on a composite sample basis.
- (2) Grain shipments may be tested on a component sample basis in lieu of the subplot basis under the provisions of Grain Inspection Handbook, Book III.
- (3) Components are combined and averaged to determine the subplot result. Acceptable quality will be based on the subplot result as compared to the contracted “maximum” specification.

c. Warehouseman’s Sample-Lot Inspection Service.

Analysis is based on an official sample obtained by a licensed warehouse sampler and analyzed by official personnel. See FGIS Directive 9180.36 on the [FGIS Directives webpage](#) for more details.

1.6 REVIEW INSPECTIONS

7 CFR §§ 800.125 and 800.135 permit a review inspection on either official grade and factors or official criteria. An applicant may request a review inspection for official criteria separately from a review inspection for official grade and factors, even though both sets of results are reported on the same certificate.

Review inspection services for mycotoxins are provided on the basis of a new sample or on the basis of an official file sample in accordance with the regulations. The provisions of a new sample do not apply if obtaining a new sample involves a change in the method of sampling. In most cases, review inspections for mycotoxin analysis are performed on the basis on the file sample.

Board appeal inspection services are limited to the analysis of file samples.

Note: Do not consider any excess grain sample as a “new sample” for the basis of testing.

Levels of Review Inspection Service.

For submitted samples, lots that are certified on an individual carrier basis, and composite samples representing multiple carriers, a maximum of three review inspections (reinspection, appeal, Board appeal) may be performed on the original inspection service.

Only one field review (reinspection or appeal inspection) is permitted for shiplot, unit train, or lash barge material portions when testing is performed on a subplot basis under the CuSum loading plan. However, if the applicant requests a review of the entire lot, up to three review levels of service (reinspection, appeal, Board appeal) may be obtained for each subplot included in the lot. Inspection results for each review level shall replace the previous inspection result.

1. Reinspection Service.

The laboratory providing original testing services also provides reinspection services.

2. Appeal Inspection Service.

FGIS field offices can provide appeal testing services for mycotoxins. Field offices not equipped to provide testing should make arrangements with another FGIS testing location to provide the most timely and cost-effective service possible.

For all samples sent to the field office for analysis, write the words “**MYCOTOXIN APPEAL**” in the “Remarks” section of the grain sample ticket along with other pertinent information.

3. Board Appeal Inspection Services.

Board appeal inspection services are limited to the file samples and are provided by the Board of Appeals and Review (BAR) in Kansas City.

Rapid test kit method and the FGIS reference methods (UHPLC with fluorescence detection and UHPLC with mass spectroscopic detection, LC/MS/MS) are available for mycotoxins testing of Board appeal samples. The applicant must specify the FGIS reference method as the desired method for testing. Otherwise, the Board appeal inspection will be conducted using the rapid test kit method. When sending samples to the BAR, write the words “**MYCOTOXIN BOARD APPEAL**” in the “Remarks” section of the grain sample ticket.

1.7 LABORATORY SAFETY

During mycotoxin testing, official personnel may come into contact with potentially hazardous chemicals from the test kits. Refer to Chapter 2 of this handbook for further information on laboratory design and safety requirements.

1.8 HAZARDOUS WASTE MANAGEMENT

Mycotoxin testing can potentially result in hazardous waste generation. FGIS is committed to managing hazardous waste in a safe and environmentally sound manner that complies with all applicable federal, state, and local laws and regulations to promote employee safety and protect the environment.

FGIS laboratories and official service providers that generate hazardous waste are responsible to comply with all applicable laws in regard to waste management and disposal. Any violation of these laws may cause harm to a person or the environment and may result in a citation to the generator site or to the individual responsible for the violation. Minimum requirements for compliance and guidelines for the good laboratory practices are outlined in chapter 3 of this handbook.

1.9 DISCLAIMER

The mention of firm names or trade products does not imply that they are endorsed or recommended by the U.S. Department of Agriculture over other firms or similar products not mentioned.

CHAPTER 2

LABORATORY SAFETY

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2.1 GENERAL INFORMATION

Performing mycotoxin analysis on grains and commodities may expose official personnel to potentially harmful chemicals and situations. FGIS is committed to providing a safe work environment for its employees. To accomplish this goal, this chapter details laboratory requirements and safety procedures to limit exposure to dangerous situations.

Mycotoxin testing may require the use of flammable liquids and suspected carcinogens. The building owner (private or GSA) must permit the use of volatile solvents (e.g., methanol, ethanol, and acetonitrile) and potentially other hazardous materials in the space used by FGIS. FGIS will provide testing services on-site only in facilities that provide adequate protection to FGIS personnel. The following laboratory safety and work area requirements covered in this section apply to FGIS-occupied space; however, FGIS recommends the procedures stated within for use by delegated or designated official service providers.

2.2 APPROVED FGIS LABORATORY SPACE

If an applicant for service desires on-site testing, the applicant must provide space for personnel to perform mycotoxin testing. Whether the space is located in a building with other applicants, or is exclusively devoted to laboratory space, the plan for the intended laboratory space is subject to inspection and approval by FGIS prior to construction. The FGIS Safety and Health Office and Field Office Manager will review proposed plans and suggest ways to comply with the requirements described below. For more information pertaining to laboratory space requirements, refer to [FGIS Directive 9160.50](#).

The following are minimum requirements for laboratory space

a. Location.

Locate the laboratory at least 100 feet from the base of the elevator headhouse. This distance is subject to negotiation when:

1. The elevator uses exterior grain legs or inclined belts in lieu of interior grain legs.
2. The headhouse is equipped with blowout panels.
3. The headhouse consists of a lightly covered framework.

b. Laboratories must meet the following requirements when they are located in a building with other occupants.

1. Isolate the laboratory from non-laboratory occupants using a fire barrier having at least a 1-hour fire resistance.
2. Provide a fire barrier consisting of floors, ceilings, and interior walls.
3. Provide all passageways and other openings that lead to adjacent interior space with self-closing fire doors having a 1-hour fire resistance. Do not block these doors open.
4. Separate the space from central heating, ventilation, and air conditioning using automatic closing fire dampers in the heating, ventilation, and air conditioning ducts near the fire barrier or provide a separate heating, ventilation, and air conditioning system for the laboratory.

c. Size.

Dedicate the space strictly for laboratory (chemical) work. Supply adequate space for chemical analysis (minimum of 100 square feet) and a separate area for sample preparation and grinding purposes. Samples must be ground in a space separate from the analytical space.

d. Electrical System.

Provide the laboratory space with electrical power and lighting meeting the standards of the National Electrical Code. Wiring suitable for a Class I designation is not required. A three-wire system consisting of an energized wire, a neutral wire, and a grounding conductor is satisfactory.

Install overhead lighting fixtures through ceilings that serve as fire barriers. Fixtures suspended below such ceilings are acceptable.

e. Exhaust System.

The exhaust system must remove chemical (methanol, ethanol, and acetonitrile, and extraction buffer) vapors from the work area. Normal air conditioning and heating may provide adequate ventilation when performing testing procedures in a building devoted exclusively for laboratory space.

The local Collateral Duty Safety and Health Officer and the FGIS Safety and Health Office in Washington, D.C., shall assist in assessing on a case-by-case basis whether added ventilation such as a fume hood is necessary. If needed, situate the laboratory space so that the hood vents to the exterior of the building.

Fume hood ventilation will require a 6- or 8-inch diameter opening either vertically through the ceiling and roof or horizontally through an exterior wall. In some cases, a portable hood may be sufficient. Contact the FGIS Safety and Health Office for ventilation requirements.

f. Plumbing.

Provide the laboratory space with a basin having hot and cold potable water and sewer connection.

g. Eyewash and Safety Shower Station.

Provide the laboratory space with eyewash equipment (eyewash bottle or permanent faucet-mounted fixture). A permanent, faucet-mounted eyewash fixture is highly recommended. A safety shower station is recommended for laboratories where organic solvent-based extraction is used.

For further information about these requirements, contact the FGIS Safety and Health Office or the local Collateral Duty Safety and Health Officer.

2.3 WORK AREA REQUIREMENTS

a. Sample Grinding Area.

Samples must be ground in a space separate from the analytical space. The Field Office Manager and Collateral Duty Safety and Health Officer must determine whether added ventilation or a dust removal device is necessary in the grinding area to remove airborne dust particles. Refer to the FGIS Safety and Health Office in Washington, D.C., for assistance in determining whether added dust removal equipment (e.g., exhaust fan) is required.

b. Sample Testing Area.

Perform all tests with methods that involve the use of volatile chemicals (e.g., acetonitrile, methanol, and ethanol) in FGIS-approved laboratory space and in an adequately ventilated area. You may perform testing methods that are free from hazardous materials (water-based kits) in alternate locations per Field Office Manager approval.

The field office Manager and Collateral Duty Safety and Health Officer must evaluate the testing materials to determine if FGIS-approved laboratory space is required. For any testing performed in an alternate location (e.g., tabletop in inspection lab), consideration must be given to ensure proper lighting, plumbing, electrical, and ventilation requirements are met. Refer to the FGIS Safety and Health Office in Washington, D.C., for assistance.

2.4 FGIS LABORATORY PRACTICES

When working in a laboratory, FGIS employees must comply with the Chemical Hygiene Plan developed for the laboratory. To accomplish this, include the following as part of an overall FGIS laboratory “Standard Operating Procedure” (SOP). Maintain the SOP, this handbook, the current Safety Data Sheets (SDS), and Chemical Hygiene Plan at each laboratory or testing location.

During on-site supervision visits to official agency locations, FGIS employees must initially assess their personal safety requirements. If personal safety is questionable, FGIS employees must determine if wearing personal protective equipment can correct the safety deficiency in question at the testing location. If the employee cannot utilize personal protective equipment to provide for a safe work environment, then on-site mycotoxin testing shall occur only when the testing area is safe.

Unauthorized persons are restricted from entering the laboratory area during testing unless accompanied by official personnel. All visitors must observe the health and safety rules while in the area.

- a. Do not smoke, eat, drink, or chew gum or tobacco in the laboratory.
- b. Wash hands immediately before and after eating, drinking, and smoking outside of the laboratory area.
- c. Wear a disposable fire-retardant laboratory coat and disposable impermeable gloves when working.
- d. Clean all laboratory equipment and dispose of contaminated materials according to stated sanitation and waste disposal guidelines.
- e. Wear an approved disposable mask, such as a N-95, and hair protection when grinding samples or when otherwise exposed to airborne grain dust.
- f. If possible, avoid wearing contact lenses in the laboratory if the testing process involves hazardous chemicals. If you must wear contact lenses, make sure your supervisor is aware of this fact.
- g. Wear safety glasses or splash goggles when in the lab (also applies to visitors in the lab). Safety glasses must meet ANSI Z87.1 standards and must have non-detachable side splashguards.
- h. Do not store food or drink in the laboratory refrigerator. Store only the test kits and other items requiring refrigeration.
- i. Do not wear protective clothing outside the laboratory unless you are removing waste chemicals from the lab to outside storage facilities or carrying extra chemicals into the laboratory from an outside storage cabinet.

- j. Do not store masks and hair protectors in the grinding area where dust particles from the grinding operation may contaminate them.

2.5 CHEMICAL STORAGE

- a. Label all bottles and containers according to the most current OSHA Hazard Communication Standard (HCS 2012), incorporating the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). This applies to chemicals poured into a secondary container for use or storage in the lab. It also applies to mixtures or solutions of chemicals prepared in the lab. In addition to, or as part of the HCS labeling requirements, labels for mixtures or solutions prepared in the lab should include the name of the solution, preparation date, expiration date (if applicable), and preparer's initials written in permanent ink. For storing and handling the hazardous chemical in the laboratories, follow the local municipal, state government, and CFR 29, part number 1910 regulation.
- b. Store chemicals and equipment outside the fume hood.
- c. Store chemicals in places where they will not clutter bench tops or obstruct movements. Do not store solutions at a height exceeding eye level. Large bottles (i.e., over 4 L in size) shall be stored no more than two feet above ground level.
- d. Prepare all solutions and perform analyses under a working fume hood, if applicable.
- e. Maintain a current SDS for each chemical on site at the laboratory.
- f. Limit the total amount of flammable solvent in the laboratory to two gallons of undiluted solvent. Premixed extraction solvents purchased from test kit vendors are also limited to a two-gallon maximum.
- g. Store all flammable solvents in a flammable storage cabinet meeting OSHA and fire code requirements.

2.6 SANITATION PROCEDURES

- a. Sanitation.

The following sanitation requirements for spillage, labware, and equipment are applicable to mycotoxin (aflatoxin, DON, zearalenone, fumonisin, and ochratoxin A) testing performed in a FGIS approved laboratory or an alternate testing location depending on test method used.

Perform the following procedures only while wearing disposable, impermeable gloves, chemical splash goggles, and fire-retardant laboratory coat. If hands become contaminated, wash immediately with soap and water.

1. Spillage.

Clean all areas and materials contaminated by any testing or extraction solution spills. Wipe up the affected area using an absorbent cloth or paper towels, and then wash the area with a warm soap/water solution. Place contaminated cleaning materials in a plastic waste bag, close tightly, and discard with solid hazardous waste material.

2. Labware and Testing Equipment.

When performing test methods that use chemicals (methanol, ethanol, acetonitrile, etc.), prepare a solution consisting of dishwashing liquid and warm water. Completely submerge all used glassware (e.g., funnels, beakers, etc.) for 5 to 10 minutes, wash thoroughly, then rinse with clean warm water and allow to air dry before reusing. Ensure all testing equipment is free of all associated chemicals and residual sample dust prior to testing.

3. Disposable Materials.

(a) Non-Contaminated Disposables:

- (1) Empty the contents of all chemical solvents from used test kit components (e.g., micro-wells, test columns, test vials, disposable sample cups, and pipette tips) into a hazardous waste container.
- (2) Collect the completely emptied test kit components in a garbage bag for landfill disposal.

(b) Contaminated Disposables:

- (1) Collect contaminated disposable materials (e.g., contaminated gloves, paper towels) with other solid hazardous waste in an approved waste container for hazardous waste disposal according to EPA requirements.
- (2) Remove all contaminated materials from the laboratory on a daily basis as part of general laboratory/good housekeeping procedures.

(c) Excess Sample Extracts:

All sample extracts containing chemicals such as methanol, ethanol, or acetonitrile are hazardous waste and must be disposed of in an approved hazardous waste container.

Note: Refer to Chapter 3 of this handbook for more information pertaining to hazardous waste disposal procedures.

CHAPTER 3 HAZARDOUS WASTE MANAGEMENT

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3.1 GENERAL INFORMATION

This chapter will present information FGIS laboratories need to understand to develop a program for the proper disposal of hazardous waste generated from mycotoxin testing. Some mycotoxin test kit components used in the extraction process are considered hazardous under the U.S. Environmental Protection Agency (EPA) regulations. Depending on the location of the laboratory and the amount of waste generated, additional state specific environmental regulations may apply. Links to state environmental programs, which have their own regulations, are listed on the [EPA website](#). Official personnel must dispose of all materials in compliance with all EPA, state, and local regulations.

Because many states manage their own hazardous waste programs, this chapter is focused on outlining responsibilities of those involved in managing and participating in hazardous waste programs along with general guidelines.

It is not feasible to address all possible local, state, and federal regulations in this chapter. Instead, the information in this chapter is primarily based on the required federal hazardous waste regulations. Field staff must attend required training on hazardous waste under the Resource Conservation and Recovery Act (RCRA) and U.S. Department of Transportation (DOT) regulations to ensure that they meet all regulatory requirements during the collection, storage, and shipment of hazardous wastes. Regulatory requirements at the state and local levels may also apply. The field office manager is responsible for ensuring that all requirements are being met.

3.2 SCOPE

The following requirements apply to all FGIS field offices and field division facilities. FGIS recommends that all official service providers follow the instructions stated within and review their geographic service location(s) for any additional state and local regulations to ensure compliance, employee safety, and protection of the environment.

3.3 REGULATORY INFORMATION

A waste is any material that is discarded, abandoned, recycled, or considered inherently waste-like. The improper disposal of some wastes, such as acids, organic solvents, or metals like lead, can cause injuries to humans and damage the environment for long periods of time. To reduce the probability of human injury and damage to the environment, the EPA is responsible for regulating the disposal of hazardous wastes. Over the years, the EPA has created rules and regulations within RCRA that cover the disposal of these wastes. Most states have accepted the responsibility for the regulation of hazardous waste and created agencies to enforce their regulations. Their regulations are at least as stringent as the EPA.

The proper disposal of these hazardous wastes requires the materials be transported to treatment storage and disposal facilities (TSDFs). The DOT regulates the air, truck and rail transportation of these wastes.

Failure to follow these regulations could result in fines and citations for the agency. Individuals could also be charged in civil or criminal cases. The EPA and state regulatory agencies may make unannounced visits and inspections of all field laboratories to determine compliance and issue citations and fines for non-compliance.

The TSDFs may impose additional restrictions that, although not part of the EPA or state hazardous waste regulations, may affect acceptance of the waste due to concerns about safety issues, compatibility with the facility's treatment process, or other reasons. For this reason, consult with the disposal company well before any need for waste pickup and disposal.

3.4 RESPONSIBILITIES

a. FGIS Safety and Health Manager.

The FGIS Safety and Health Manager is responsible for:

1. Providing guidance to the field offices to better manage the hazardous waste program.
2. Assisting the Local Program Coordinators in assessing the needs of each laboratory.

b. Field Office Manager.

The field office manager is responsible for:

1. Designating one or more employees as Local Program Coordinators.
2. Ensuring that all employees who handle hazardous waste receive all proper training.

c. Local Program Coordinator.

The Local Program Coordinator is responsible for:

1. Assessing the waste output of each facility.
2. Understanding how state and local regulations differ from the national EPA regulations.
3. Keeping up to date with all EPA, DOT, state, and local training requirements.

4. Training employees who deal with hazardous waste on the proper storage and disposal procedures.
 5. Documenting all training of personnel.
 6. Coordinating hazardous waste removal with a licensed disposal company.
- d. Official Personnel.

Official Personnel are responsible for:

1. Participating in all required training before beginning any activities dealing with hazardous waste.
2. Following all requirements in this chapter and any procedures implemented by the Local Program Coordinator.

3.5 DETERMINATIONS IN SETTING UP HAZARDOUS WASTE PROGRAM

With the assistance of the FGIS Safety and Health Office, the Local Program Coordinator must make a hazardous waste assessment of each facility where waste is generated. This includes classifying the relevant waste streams and constituents and the generator status of the facility. The Local Program Coordinator must document and retain all determinations made concerning waste streams and generator status.

a. Waste Streams.

Typically, solvent-based mycotoxin analysis generates two separate waste streams, liquid and solid flammable waste. These must be stored separately from each other and from any other hazardous waste generated in the laboratory (including bleach used in inspection procedures).

(1) Liquid Waste

Liquid waste generated from organic solvent-based test kits is typically methanol, ethanol, or acetonitrile. These wastes are all classified as flammable and can be combined into one waste stream. Do not combine flammable waste with corrosive waste (i.e., bleach).

(2) Solid Waste

All testing materials that come into contact with flammable solvents are considered solid waste and must be disposed of in a flammable solid waste stream. This includes all disposable beakers, filters, and test tubes used in analyses.

b. Generator Status.

The Local Program Coordinator must evaluate the monthly quantity of waste generated at a facility in order to determine the facility generator status. The EPA classifies waste generators according to the following categories:

Note: State environmental agencies may impose stricter regulations:

- (1) Conditionally Exempt Small Quantity Generator (CESQG). A facility that generates less than 100 kg (220 lbs.) in every month is classified as a CESQC. A CESQG may not store more than 1,000 kg (2,200 lbs.) on site. This category of generator is exempt from some of the more stringent EPA guidelines.
- (2) Small Quantity Generator (SQG). A facility that generates more than 100 kg (220 lbs.) but less than 1,000 kg (2,200 lbs.) in any month is classified as an SQG.
- (3) Large Quantity Generator (LQG). A facility that generates more than 1,000 kg (2,200 lbs.) in any month is classified as an LQG. The EPA imposes the strictest set of rules on this category of generator.

EPA provides a [Hazardous Waste Generator Regulatory Summary](#) on their website.

The vast majority of FGIS laboratories should qualify as CESQG's according to the EPA definition. For assistance in determining the generator status of a facility, contact the FGIS Safety and Health Office.

Note: Make sure to check all state and local regulations for other possible classification issues.

3.6 LABORATORY PRACTICES

In order to best comply with hazardous waste regulations, the following laboratory practices should be followed. These procedures should be sufficient for the EPA regulations governing CESQG's. If a facility is classified as a SQG or above, make sure to check the pertinent regulations for compliance. As always, consult state and local regulations for additional requirements.

a. Satellite Waste Accumulation.

1. Designate an area under the fume hood as a hazardous waste satellite accumulation area.

2. Provide an appropriate container for each separate waste stream in the satellite accumulation area. The container must be capable of properly storing the waste without deterioration and must be kept closed at all times except when waste is being added. A container for liquid flammable waste may be a plastic, glass, or metal container with a self-closing lid or screw-off top. A container for solid flammable waste may be a plastic bucket with a lid. These are just a few examples.
3. Label the satellite waste container with the name of the waste stream, the constituent wastes, and the accumulation start date. The accumulation start date is the date on which waste was first added to the satellite container. This will reset whenever the container is emptied.
4. Affix labels to the satellite waste container identifying the hazards inherent to the waste (e.g., Flammable, Corrosive, etc.).
5. Pour liquid waste directly into the liquid waste container.
6. Enclose solid waste in plastic bags and place in the solid waste container.
7. Empty the container into the central waste accumulation site within 24 hours of being full.

b. Central Waste Accumulation Site.

1. Locate the central waste accumulation site at the same facility as the satellite accumulation area. Make sure the area is secure and free from environmental hazards that can cause problems. Consult with EPA, state, and local regulations for regulations concerning the central accumulation site.
2. Include a separate waste container for each waste stream. These will typically be 55-gallon drums.
3. Keep the container closed at all times except when adding waste.
4. Label the central waste containers with the name of the waste stream, the constituent wastes, and the accumulation start date.
5. Affix labels to the satellite waste container identifying the hazards inherent to the waste (Flammable, Corrosive, etc.).
6. Contract with a licensed disposal company to transport the waste when a container is full.

These practices are not necessarily exhaustive of all federal, state, and local regulations. The Local Program Coordinator should be equipped to institute a proper hazardous waste program after attending the required training.

3.7 SHIPPING HAZARDOUS WASTE

The Local Program Coordinator must contact a DOT licensed shipping company in order to transport the hazardous waste to a Treatment, Storage, and Disposal Facility (TSDF). According to EPA regulations, a CESQG must arrange to have hazardous waste removed before accumulating 1,000 kg (2,200 lbs.), while a SQG must arrange to have hazardous waste removed within 180 days of the date when accumulation started. More restrictive state and local regulations may apply.

Because different locations will have different requirements, the following steps are general procedures for shipping hazardous waste. The training that the Local Program Coordinator receives should cover the specifics. As always, state and local regulations may be more restrictive than the national regulations.

- a. The Local Program Coordinator should assure that all waste containers are properly labeled before shipping.
- b. The shipper may require a manifest. This is required for SQGs but not for CESQG, though it is often still used. The Local Program Coordinator should check the manifest for accuracy and sign it, if applicable. The DOT provides a list of [hazardous material codes](#) on their website.
- c. The shipper will return a completed copy of the manifest upon delivery to the TSDF.
- d. Maintain the shipping records for at least three years.

CHAPTER 4 SAMPLE PREPARATION PROCEDURES

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4.1 GENERAL INFORMATION

Proper mycotoxin testing is highly dependent on correct sampling and sample preparation. To ensure that the test results accurately reflect the mycotoxin concentration present in a lot, samples must be representative of the lot and of sufficient size to compensate for the uneven distribution of the contaminant. Samples must also not be too large so as to compromise the timeliness of the inspection process.

Technicians must make sure all sampling and grinding equipment is in good operating condition, clean, and properly checked before use.

When requesting mycotoxin testing on rice (milled, brown, or rough rice), the applicant must specify the basis of testing (milled or un-milled). If no basis is specified, official personnel must analyze the rice for the presence of mycotoxins according to the type of rice indicated on the official certificate. Official personnel must also determine whether the test kit in use is approved to provide the requested testing basis.

To ensure the accuracy of results reported, the technician must follow approved procedures when preparing extraction solutions or solvents to perform mycotoxin testing. In some cases, extraction procedures require the use of hazardous materials (e.g. methanol, ethanol, and acetonitrile) within testing instructions. Refer to Chapter 2 and Chapter 3 of this handbook for more information regarding laboratory safety and hazardous waste management guidelines.

4.2 WORK RECORDS

Each testing laboratory must maintain a work record for each test that includes the name of the applicant, date of service, sample or carrier identification, test results, initials of official personnel performing the test, and any other information deemed necessary to properly certificate the test results and bill the applicant. As practical, use existing forms, such as FGIS 992, "Services Performed Report;" FGIS 920, "Grain Sample Ticket;" FGIS 921, "Inspection Log," or work log to record laboratory results.

When sending a sample to the Technology and Science Division (including the Board of Appeals and Review) for mycotoxin testing or monitoring purposes, include all necessary information to facilitate sample processing and testing.

4.3 SAMPLE SIZE

Obtain samples according to the instructions in the Grain Inspection Handbook, Book I, "Grain Sampling."

For official analytical testing, the minimum sample size is based on the type of lot. Applicants may request a sample size larger than the minimum sample size.

For grains in which dockage is a factor (e.g., wheat, barley), remove the dockage before grinding the sample.

Table 4.1. Official Lot Type Minimum Sample Size

Mycotoxin	Trucks or Containers	Railcars	Barges, Sublots & Composite Samples	Submitted Samples
Aflatoxin	1,600 grams	1,600 grams	4,540 grams	4,540 grams (Recommended)
Deoxynivalenol (DON)	300 grams (1,000 grams corn only)	300 grams (1,000 grams corn only)	300 grams (1,000 grams corn only)	300 grams (1,000 grams corn only) (Recommended)
Zearalenone	1,100 grams	1,362 grams	4,540 grams	4,540 grams (Recommended)
Fumonisin	1,100 grams	1,362 grams	4,540 grams	4,540 grams (Recommended)
Ochratoxin A	1,100 grams	1,100grams (1,362 grams corn only)	1,100grams (4,540 grams corn only)	1,100 grams (4,540 grams corn only) (Recommended)

Notes:

- 1. Testing locations that receive submitted samples that are smaller than the minimum sample size, listed in Table 4.1, must grind the entire sample as submitted.**
- 2. When submitted samples are larger than the minimum sample size, listed in Table 4.1, split them down representatively using an FGIS-approved type divider to meet the recommended sample size before grinding and testing.**
- 3. Obtain composite samples from representative portions of the subplot samples after dockage has been removed.**

4.4 SAMPLE PORTIONS

- a. Sub-portions.

Grind the entire sample as required for official mycotoxin testing. Prepare sub-portions (work and file samples) from the ground sample using an FGIS-approved type divider

and scale to obtain sub-portion samples needed. Use table 4.2 as a guide to prepare the work sample for original testing services and a second portion (file sample) for review testing. For submitted samples, retain as large a sample as possible.

Table 4.2. Minimum Sub-portion Sizes

Sub-portion	Aflatoxin	DON	Zearalenone	Fumonisin	Ochratoxin A
Work	500 grams	100 grams (250 grams for corn)	500 grams	500 grams	500 grams
Test	50 grams	50 grams	50 grams	50 grams	50 grams
File sample	500 grams	200 grams (250 grams for corn)	500 grams	500 grams	500 grams

Note: For Aflatoxin testing save an additional 500-gram file sample (three 500-gram sub-portions in total) for Food and Drug Administration (FDA) analysis, when applicable, for “actionable lots”.

Note: The first 50 grams may be used to purge the grinder and prevent any cross-contamination of samples. For a DON testing work portion of 100 grams, a separate 50-gram portion of the same sample may be used for purging. Discard purging portion before proceeding.

Grind all samples for mycotoxin testing using a Romer Mill-Model 2a, Bunn Commercial Coffee Grinder, Udy Grinder, Perten Falling Number Mill, or an equivalent device that meets FGIS performance (particle size) requirements.

1. Ensure that the grinder is operating correctly.
2. Grind sample using a grinder that ensures delivery of the minimum particle size requirement.
3. Divide the sample using a riffle divider. The use of a riffle divider is highly recommended.

If using a Boerner divider and the sample is more than approximately 1,000 grams, divide the sample down to 1,000 grams.

Note: FGIS will continue to allow the use of a Boerner divider until phased out.

4. Collect the ground sample in a plastic bag that is large enough so that the entire ground sample does not fill more than 2/3 of the bag. Sufficient headspace is needed to allow adequate mixing.

5. Seal the bag so the ground sample is not lost while shaking to mix. Mix the ground sample thoroughly by shaking for at least 15 seconds. Do not reuse a bag for a different sample.
6. Remove the 50.0 ± 0.2 g test portion.
7. Seal the bag and retain the balance as a file sample. Shake the bag for 15 seconds prior to taking any subsequent test portions for reinspection, appeal, and Board appeal analyses.

b. Saving File Samples.

Maintain file samples (including the FDA file sample when applicable) for all lots/samples that:

1. Do not meet the contractual specification of the applicant for service.
2. Are required for the mycotoxin monitoring program.
3. Exceed the FDA action level of 20 ppb for aflatoxin only.

When applicable, maintain a representative file sample for each lot, subplot, composite, or submitted sample tested. For submitted samples that are less than the required file sample minimum, retain as large a sample as possible. For information concerning file sample retention periods, refer to [FGIS Directive 9170.13](#).

c. Storing File Samples.

Store file samples in a manner that will maintain the representativeness of the sample and prevent possible manipulation or substitution. Place the sample in paper bags, envelopes, or plastic or metal containers and label each file sample with the test date and identification. Ensure that file sample containers are strong enough to prevent loss of sample integrity when storing samples. Do not store samples near heat, windows, or in direct sunlight. Store samples in cold storage if available.

d. Disposition of File Samples.

At the end of the retention period, label the file samples “FOR LABORATORY USE ONLY - NOT FOR USE AS FOOD OR FEEDSTUFF” and discard the file samples in a dumpster or landfill disposal site.

e. Shipping Samples.

When it is necessary to send samples to other laboratory locations, take precautions to maintain sample integrity by securely packaging the samples. Label the shipping container “NOT FOR HUMAN CONSUMPTION”.

4.5 OPERATION OF GRINDERS

Note: Samples must be dockage and stone free before grinding.

Note: Do not grind samples that exceed 20 percent moisture content.

Samples must be ground to a particle size that is sufficiently fine enough to obtain a homogeneous blend.

Unless otherwise stated in the FGIS-issued mycotoxin test kit instructions, grind samples so that at least 60 percent of the ground sample passes a U.S. Standard No. 20 sieve.

FGIS employees must follow the manufacturer’s safety procedures for operating the grinder and must wear protective equipment (e.g., lab coat, mask, gloves, and hairnet) when grinding samples.

Official personnel must grind samples in an area separate from the testing area. Use the Romer Mill - Model 2A, Bunn Grinder, or equivalent to grind the sample. Samples that contain an excessive amount of moisture content (above 20 percent) are problematic to the mycotoxin grinding and testing procedures. High moisture grain does not grind to a suitable particle size which affects the accuracy of the test results. Therefore, official personnel must ensure that high moisture samples are allowed to naturally dry (open air container or pan) to a moisture level of 20 percent or less before grinding and testing.

Additionally, the oil content in soybean samples may prevent grinding to a suitable particle size for testing and can cause grinder overheating. When preparing soybeans for testing, grind the sample coarsely first and regrind as many times as needed, adjusting the setting until you obtain the correct particle size for testing.

a. Romer Mill.

1. General Operating Instructions.

The Romer Mill simultaneously grinds and sub-samples at the rate of approximately one pound per minute. An adjustable restrictor door located above the collection chute varies the amount of ground sample allowed into the collection chute. Official personnel must adjust the grinder to obtain the required testing and file portions from the sample.

Note: Do not dip out the sample portion used for work and file samples.

Adjust the grinder by locating the first line (far left) etched on the restrictor door. Position the door approximately 1/3 of the way between the first and second line. For a 10-pound sample, approximately 500 grams will be collected through the collection chute.

When testing for DON, collect all the ground sample from all three chutes or adjust the grinder for collection from only one chute.

Once the grinder is adjusted to obtain the 500-gram sample, mark the location of the setting. To increase the sample size, move the restrictor door to the left.

If a composite sample test is required in addition to the subplot-by-subplot analysis, obtain the composite sample sub-portion from the subplot samples after the removal of dockage.

2. Grinding the Sample.

Grind the entire sample with the grind lever set at the finest range.

If the grinder is experiencing difficulty (e.g., over-heating, bogging down) at the fine setting, change the grind lever to the coarsest setting. After grinding the remainder of the sample at the coarsest setting, switch the setting back to fine. Collect the entire sample portion and regrind at the fine setting.

Note: If the grinder motor overheats, the breaker switch will release and turn off the power to the grinder. If this occurs, allow the motor to cool and then set the grind lever to the coarse setting. Do not grind samples with moisture content above 20 percent.

b. Bunn Grinder.

1. General Operating Instructions.

The Bunn-O-Matic grinds at a rate of approximately 2 pounds per minute and has a holding capacity of approximately 3 to 4 pounds when fully closed. It is equipped with a cleaning lever that can be flipped to purge the grinding chamber of excess sample after operation. Official personnel must grind the entire mycotoxin sample and cut it down using an FGIS-approved divider to obtain the required work and file portions from the official or submitted sample.

Note: Do not dip out the sample portion used for work and file samples. If a composite sample test is required in addition to the subplot-by-subplot analysis, obtain the composite sample sub-portion from the whole kernel subplot samples only.

2. Grinding Samples.

Grind the entire sample with the grind lever set at the fine selection. Add 3 to 4 pounds at a time into the hopper when grinding 10 pounds or more. Official personnel must use an approved divider to reduce the size of the portions to the proper work, file, or composite samples.

If the grinder is experiencing difficulty (e.g., over-heating, bogging down) at the fine setting, change the grind lever to the coarse setting. After grinding the remainder of the sample at the coarse setting, switch the setting back to fine. Collect the entire sample portion and regrind at the fine setting.

Note: If the grinder motor overheats the breaker switch will release and turn off the power to the grinder. If this occurs, allow the motor to cool and then set the grind lever to the coarse setting. Do not grind samples with moisture content above 20 percent.

c. Other Equivalent Grinders.

When using other grinding equipment that meets FGIS performance standards, follow the procedure of the manufacturer and apply similar guidelines as those for the Romer and Bunn grinders.

4.6 CLEANING GRINDERS

A small amount of ground sample will remain in the grinder after the total sample has been ground. To prevent the contamination of subsequent samples, clean the grinder using one of the following cleaning procedures:

a. If a Vacuum Cleaner is Available.

After a sample has been ground and collected, with the unit turned on, use a vacuum cleaner with an attachment that will fit over the mouth of the chute. Place the hose attachment at the bottom of each chute for about 30 seconds. After all the chutes have been cleaned, turn the power off and prepare for the next sample.

b. If a Vacuum Cleaner is Not Available.

Clear the grinder by purging by discarding a small portion of the first 15 to 50 grams of the sample to be tested.

1. Pour the sample into the grinder and turn it on long enough to collect the first 15 to 50 grams.
2. Turn the power off and discard the grounded purge sample portion.

3. Turn the power back on and finish grinding the sample to collect the remaining subsample for analysis.

4.7 CHECKING PARTICLE SIZE

a. Particle Size.

Unless otherwise stated in the FGIS-issued mycotoxin test kit instructions, the minimum quantity of ground grain (coarse and small grains) that should pass through a No. 20 sieve is 60 percent. Whenever the ground particles appear to be too coarse, or the results of a grinder check indicate that less than 60 percent of the ground portion passes through the No. 20 sieve, adjust the grinder to meet the minimum requirement.

Check grinding apparatuses periodically to determine whether they are producing a final product that meets the particle size requirement as listed above. Official personnel shall determine the frequency of the checks based on a number of items that include:

1. Visual observation of the ground product.
2. Number of samples ground since last check.
3. Number of days since the last check was performed.

Note: Record all particle check results in a convenient location for future reference purposes.

b. Procedures for Checking the Performance of the Grinder.

Equipment

Balance, weighing pan, U.S. Standard No. 20 testing sieve including lid and collection pan (meeting ASTM E-11 specifications, 8-inch diameter, 850- μ m mesh, stainless steel or brass), and cleaning brush.

Test Procedure

Sieve Analysis:

1. Grind approximately 100 g of the grain of interest and collect in a plastic bag that is large enough, so the entire ground sample fills no more than 2/3 of the bag. Sufficient headspace is needed to allow adequate mixing. Alternatively, a sample that was recently ground for an inspection service using the grinder can be used for the sieve test. Again, the ground sample must be in a plastic bag filled no more than 2/3 full.
2. Place a pan on the balance and tare the balance. Shake the ground sample

in the bag for at least 15 seconds. Transfer 10 - 11 grams to the tared pan and record the original mass (M_i) to two decimal points (i.e., 10.02 g) (see figure 4.1.)

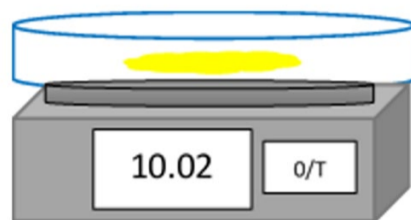


Figure 4.1. Balance Example – Original Mass

3. Remove this pan from the balance and place the sieve collection pan on the balance. After placing the sieve collection pan on the balance, tare the balance (see figure 4.2.)

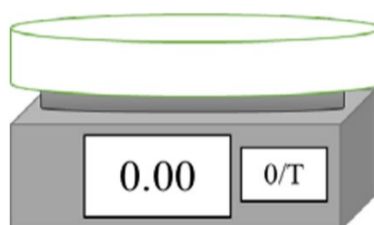


Figure 4.2. Balance Example - Tared

4. Remove the sieve collection pan from the balance. Place the sieve mesh pan on the sieve collection pan. Transfer the weighed sample onto the sieve and place the lid on the sieve mesh pan.

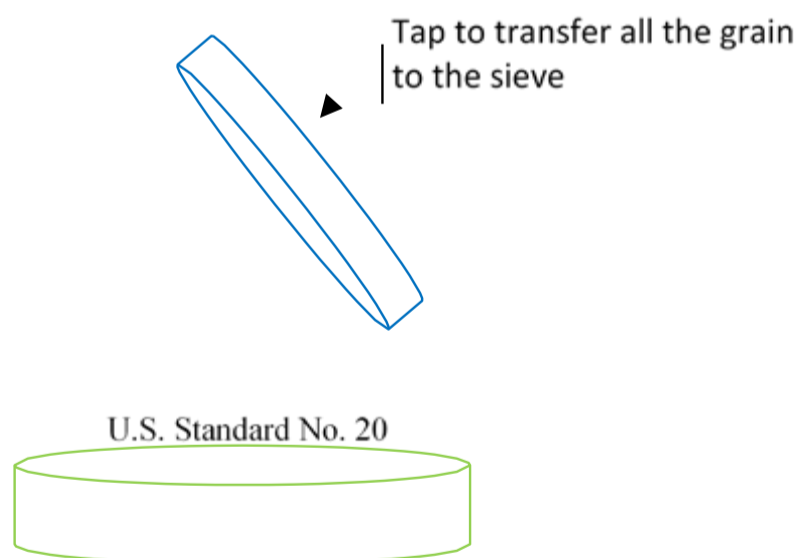


Figure 4.3. Transfer of Grain to Sieve

5. Shake the sieve using a side-to-side action (see figure 4.4 below), while occasionally tapping the edges of the pan 2-4 times on the bench top. This helps the fine particles pass through the mesh.

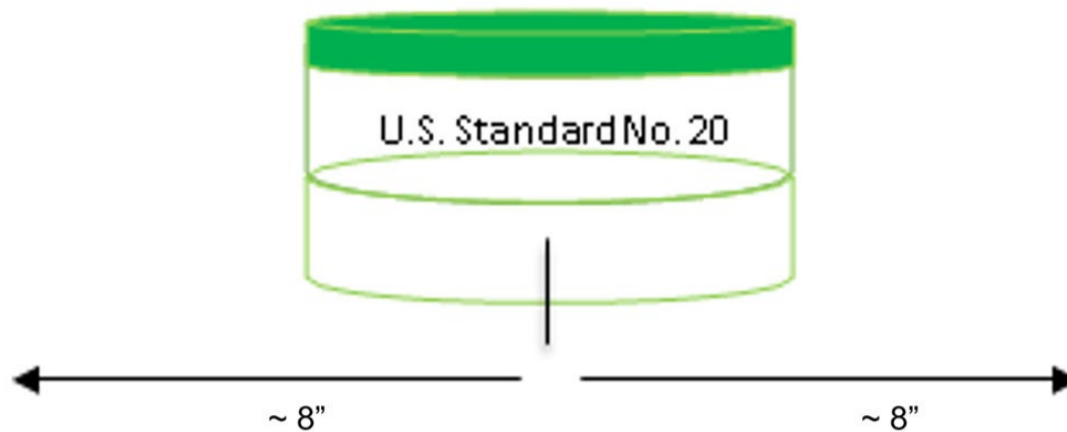


Figure 4.4. Sieve Shaking Motion

6. Remove the lid and sieve mesh pan. Place the sieve collection pan on the previously tared balance from Step 2. Observe the mass. This mass represents the mass passing through the No. 20 sieve (M_p).

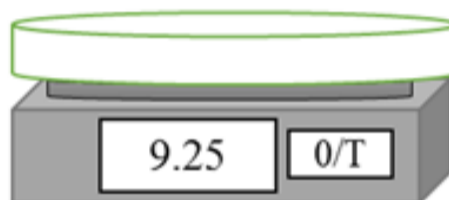


Figure 4.5. Balance Example - Mass Passing Through Sieve

7. Remove the sieve collection pan from the balance and place the sieve pan over the sieve collection pan. Cover the sieve pan with the lid. Repeat steps 6 and 7 until the mass passing through the sieve remains close to constant (± 0.02 g) between weight measurements. Record this mass as M_p .

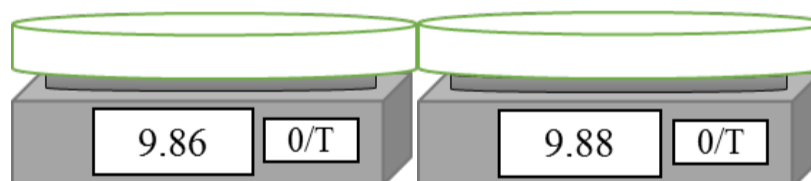


Figure 4.6. Balance Example – Constant Measurements

8. Remove the ground material from the sieve mesh pan and the sieve collection pan. Clean each pan with a brush as necessary.

Sieve Data Analysis

Calculate the percentage sample passing a U.S. Standard No. 20 sieve using the following equation:

$$\text{Percent Passing} = (M_p / M_i) \times 100\%$$

Where, M_p is the mass passing through 20-mesh sieve and M_i is the original mass of the sample.

For example:

Mass passing = 9.87 g

Mass initial = 10.02 g

$$\begin{aligned}\text{Percent Passing} &= (M_p / M_i) \times 100\% \\ &= (9.87/10.02) \times 100\% \\ &= 98.5 \%\end{aligned}$$

4.8 PREPARATION OF EXTRACTION SOLVENTS

Several approved test methods for mycotoxin testing may require different combinations of chemicals (e.g., methanol, ethanol, and acetonitrile) and distilled or deionized water to prepare extraction solvents. Some test methods require different percentages for various approved commodities and, in some cases, specific chemical quality (Reagent or HPLC grade) for preparation. Below are the standard procedures for preparing extraction solvents for testing percentages that are common to FGIS-approved test methods (see table 4.3.)

Note: Refer to the specific test kit instructions issued by FGIS for the procedure for preparation of the extraction solvent.

Table 4.3. General Preparation Procedures for Extraction Solvent

Extraction Solvent	Preparation Procedures
60% Methanol (60/40) v:v	Combine 600 milliliters (mL) methanol with 400 mL distilled or deionized water. Mix well
70% Methanol (70/30) v:v	Combine 700 mL methanol with 300 mL distilled or deionized water. Mix well.
80% Methanol (80/20) v:v	Combine 800 mL methanol with 200 mL distilled or deionized water. Mix well.
50% Ethanol (50/50) v:v	Combine 500 mL ethanol with 500 mL distilled or deionized water. Mix well.
65% Ethanol (65/35) v:v	Combine 650 mL ethanol with 350 mL distilled or deionized water. Mix well.
86% Acetonitrile (86/14) v:v	Combine 860 mL acetonitrile with 140 mL distilled or deionized water. Mix well.

- a. Label the container, showing date of preparation and the preparer's initials. If the amount (more or less) of extraction solvent being prepared needs adjusting based on the workload at individual locations, make sure that the percentage ratio is maintained.
- b. Thoroughly mix the prepared solvent before use.
- c. To prepare smaller or larger amounts of extraction solvent the ratio of chemical to distilled or deionized water must be maintained.

4.9 TEST KIT PROCEDURES

Follow the FGIS-issued test kit instructions for the specific test kit being used.

The FGIS-issued test kit instructions can be found on the AMS website on the FGIS Mycotoxin Test Kit Evaluation [page](#) under FGIS Performance Verified Mycotoxin Test Kits.

CHAPTER 5 CERTIFICATION

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5.1 GENERAL INFORMATION

Mycotoxin results are recorded on a pan ticket, worksheet, or loading log, and in the “Results” section of the official certificate.

Certify mycotoxin test results on grain in accordance with 7 CFR §§ 800.160-166 under the USGSA. Certify test results on processed grain products and other commodities in accordance with sections 7 CFR §§ 868.70-75 under the AMA.

Applicants may request that separate certificates be issued for grade and for mycotoxin service when both are determined on the same lot. Each certificate will show the actual date that the results are received.

7 CFR §§ 800.125 and 800.135 of the regulations under the USGSA permit a review inspection on either official grade and factors or official criteria. Applicants may request that a review inspection for official grade or official factors and official criteria be handled separately, even though both sets of results are reported on the same certificate.

When reporting official grade or official factors and official criteria on the same certificate, show a statement on the review inspection certificate indicating that the review results are for official grade, official factors, or official criteria, and that all other results are those of the original, reinspection, or appeal inspection results, whichever is applicable.

5.2 GENERAL PROCEDURES

Although only quantitative testing is available, applicants for service can request results certified on quantitative or qualitative basis.

Record the test results on the work records without rounding.

Certify results according to section 5.3.a, unless the applicant requested qualitative certification, then follow section 5.3.b to certify results.

- a. Certifying Test Results of Single and Combined Lots, Unit Trains, and Shiplots
 1. Single Lot Inspection Basis for Trucks and Railcars. Certify each test result on a separate certificate.
 2. Combined Land Carrier Basis for Trucks, and Railcars. If an applicant requests mycotoxin testing on a composite basis (i.e., up to 5 railcars, 15 trucks, or 20 containers) and the inspection for grade on the basis of individual carriers, factor only certificates are issued for the mycotoxin testing and separate grade certificates are issued for each carrier.
 3. Composite Sample Testing for Shiplots. Certify the composite results using the appropriate statement.

4. Submitted Sample Testing. Certify the results using the appropriate statement.
5. Unit Train and Shiplot Inspection under the CuSum Loading Plan.
 - (a) Sublot Size for Unit Trains.
 - (1) The maximum size subplot for mycotoxin testing is 5 railcars for unit trains consisting of fewer than 50 cars. For unit trains consisting of 50 railcars or more, the maximum subplot size is 10 railcars.
 - (2) For unit trains, the subplot size for mycotoxin testing and for grade analysis may be different. For example, an applicant may request grade analysis on the basis of a subplot containing 2 cars and request mycotoxin analysis on the basis of 5 cars.
 - (b) Sublot Size for Shiplots. The testing frequency for shiplot grain will be the same as the sample for grade analysis unless the applicant specifically requests mycotoxin analysis on the basis of a component sample.
 - (c) Recording Test Results. Mycotoxin test results of subplot samples taken throughout loading are recorded on the loading log. A material portion occurs if the subplot result exceeds the limit as specified in the load order.
 - (d) Certifying Test Results. Certify the lot based on the mathematical/weighted average (as applicable) of the accepted subplot results.
 - (e) Material Portions. Certify material portions separately.
 - (1) If a material portion occurs, the applicant has the option of requesting a review inspection. Review inspection results replace previous results when determining if a material portion exists.
 - (2) If a material portion designation due to mycotoxin is not removed by the review inspection process, the applicant may leave the material portion on board and receive a separate certificate; return the grain to the elevator; or discharge the material portion along with additional grain in common stowage equivalent to one half the material portion quantity.

5.3 STANDARD CERTIFICATION STATEMENTS

a. Quantitative Certification

Follow this section for quantitative certification.

Table 5.1 STANDARD QUANTITATIVE CERTIFICATION

Mycotoxin	Test Kit Range	Test Result	Certify as:	Test Result	Certify as:	Test Result	Certify as:
Aflatoxin	5-300 ppb	Less than 5.5 ppb	Aflatoxin does not exceed 5 ppb.	5.5 - 300 ppb	Nearest whole ppb.	301 ppb or greater	Aflatoxin exceeds 300 ppb.
DON	0.50 - 30 ppm	Less than 0.55 ppm	DON does not exceed 0.5 ppm.	0.55 – 30.49 ppm	Nearest whole ppm.	30.50 ppm or greater	DON exceeds 30 ppm.
Fumonisin	0.50 - 30 ppm	Less than 0.55 ppm	Fumonisin does not exceed 0.5 ppm.	0.55 – 30.49 ppm	Nearest whole ppm.	30.50 ppm or greater	Fumonisin exceeds 30 ppm.
Zearalenone	100 - 1000 ppb	Less than 101 ppb	Zearalenone does not exceed 100 ppb.	101 - 1000 ppb	Nearest whole ppb.	1001 ppb or greater	Zearalenone exceeds 1000 ppb.
Ochratoxin A	5 - 100 ppb	Less than 5.5 ppb	Ochratoxin A does not exceed 5 ppb.	5.5 - 100 ppb	Nearest whole ppb.	101 ppb or greater	Ochratoxin A exceeds 100 ppb

1. When mycotoxin results are less than the test kit range lower limit, use the following statement:

“(Mycotoxin) does not exceed (test kit range lower testing limit) (ppb or ppm).”

2. When mycotoxin results are within the test kit range limits, use the following statement:

“(Mycotoxin) (result rounded as required) (ppb or ppm).”

(a) Certify to the nearest whole number.

(b) Upon request of applicant, results for DON and fumonisin may be rounded to nearest tenth and reported in the “Remarks” section of the official certificate, and on the same certificate with the applicable standard certification.

3. When mycotoxin test results exceed the upper limit of the test kit range,

use the following statement to certify results:

“(Mycotoxin) exceeds (test kit range upper limit) (ppb or ppm).”

4. When testing rice (e.g., rough, brown, or milled rice) certify sample results according to the type of rice on the official certificate. If the requested basis (e.g., milled rice) is different than the type on the grade line (e.g., rough rice) of the certificate, use the following statement to certify results:

“(Mycotoxin) (test result) (ppb or ppm). Test performed on a (milled or unmilled) sample basis.”

Note: Test rice samples on the specified basis according to the test procedures for the test kit in use.

b. Qualitative Certification.

Follow this section for qualitative certification. Refer to table 5.2 below for more information.

Note: When averaging subplot results, no individual subplot result can exceed the requested threshold.

Table 5.2. STANDARD QUALITATIVE CERTIFICATION.

Mycotoxin	Test Result	Certify as:	Test Result	Certify as:
Aflatoxin	≤ 20 ppb	Aflatoxin equal to or less than 20 ppb.	> 20 ppb	Aflatoxin exceeds 20 ppb.
DON	≤ (specified threshold)	DON equal to or less than (specified threshold).	> (specified threshold)	DON exceeds (specified threshold).
Fumonisin	≤ (specified threshold)	Fumonisin equal to or less than (specified threshold).	> (specified threshold)	Fumonisin exceeds (specified threshold).
Zearalenone	≤ (specified threshold)	Zearalenone equal to or less than (specified threshold).	> (specified threshold)	Zearalenone exceeds (specified threshold).
Ochratoxin A	≤ (specified threshold)	Ochratoxin A equal to or less than (specified threshold).	> (specified threshold)	Ochratoxin A exceeds (specified threshold).

1. When mycotoxin results are equal to or less than a specific threshold, either by applicant request or below the test kit range lower limit:

“(Mycotoxin) equal to or less than (specified threshold or test kit lower limit).”

2. When mycotoxin results are greater than the requested threshold or test kit

range upper limit:

“(Mycotoxin) exceeds (specified threshold or test kit upper limit).”

5.4 OPTIONAL STATEMENTS

Certification statements may be modified to report true and factual events. Before modifying a certification remark, consult with the Policies, Procedures, and Market Analysis Branch. Report all optional statements in the “Remarks” section of the official certificate, and on the same certificate with the applicable standard certification.

a. Reporting Results to the Tenth.

At the request of the applicant certify mycotoxin (DON and fumonisin) test results above 0.5 ppm and below 5.5 ppm to the tenth ppm.

TABLE 5.3 OPTIONAL REPORTING FOR DON AND FUMONISIN QUANTITATIVE TESTING

Mycotoxin	Test Kit Range	Test Result	Certify as:	Test Result	Certify as:	Test Result	Certify as:
DON	0.5 - 30 ppm	Less than 0.55 ppm	DON does not exceed 0.5 ppm.	0.55 – 30.44 ppm	Nearest tenth ppm.	30.45 ppm or greater	DON exceeds 30 ppm.
Fumonisin	0.5 - 30 ppm	Less than 0.55 ppm	Fumonisin does not exceed 0.5 ppm	0.55 – 30.44 ppm	Nearest tenth ppm.	30.45 ppm or greater	Fumonisin exceeds 30 ppm.

“(Mycotoxin name) (results rounded to the nearest tenth) ppm”

Take care to interpret load orders correctly. If the applicant wishes to have the mycotoxin certified on the alternate basis, the load order should be written to include a limit such as 1.0 ppm or 2.0 ppm as opposed to 1 ppm or 2 ppm.

b. Mycotoxin not Detected.

At the request of the applicant, use the following statement when mycotoxin is not detected.

“(Mycotoxin) not detected.”

NOTE: If any individual subplot result exceeds 0 ppb or 0.0 ppm, this statement cannot be used for certification.

c. Converting Parts per Billion (ppb) to Parts per Million (ppm)

At the request of the applicant, certify the result in ppb or ppm using an approved statement.

1. To convert **ppb** to **ppm**, divide the ppb result by 1,000. Report and certify the converted ppm result to the nearest hundredth ppm.
2. To convert to **ppm** to **ppb**, multiply the ppm result by 1,000. Report and certify the converted ppb result to the nearest whole ppb.

Upon request, provide the following statement:

“(Actual ppb or ppm result) is equivalent to (converted ppb or ppm results)”

d. Converting to Milligrams (mg) per Kilogram (kg), or Micrograms (µg) per Kilogram (kg)

At the request of the applicant, convert and certify results in milligrams per kilogram (mg/kg) or micrograms per kilogram (µg/kg). Use the following equivalents to determine mg/kg or µg/kg:

ppm = mg/kg

ppb = µg/kg

“(Actual result ppb or ppm) is equivalent to (converted mg/kg or µg/kg result).”

e. Multiple Results on the Same Certificate

When certifying multiple mycotoxin results on the same certificate and the results are based on different sample types, the certificate must reflect the difference. As a guideline, the multiple results are shown as follows:

“Sublot sample results: (Mycotoxin) equal to or less than (specified threshold).” “Composite sample result: (Mycotoxin) (results) (ppb or ppm).”

f. Negative Result Statement

At the request of the applicant, one of the following statements may precede the applicable standard statements when test results are less than the specified threshold (e.g., 20 ppb for aflatoxin).

“The (mycotoxin) result is negative.” OR “Negative (mycotoxin).”

g. Type of Test Statement

Use this statement when the applicant requests the type of mycotoxin test used shown on the certificate.

“Results based on (indicate type of test used) method.”

- h. HPLC Reference Method Testing. TSD offers HPLC reference method testing for mycotoxins for Board appeal samples under the authority of USGSA. In addition, certain commodities can be submitted for analysis under the authority of AMA. Contact TSD for more information on acceptable samples and reference method testing.

1. Aflatoxins

“Total Aflatoxins (result) ppb. Results based on HPLC reference method.”

Individual aflatoxin B1, B2, G1, and G2 results can be provided upon applicant request.

2. Deoxynivalenol

“Deoxynivalenol (result) ppm. Results based on HPLC reference method.”

3. Fumonisin

“Total Fumonisin (result) ppm. Results based on HPLC reference method.”

Individual fumonisin B1, B2, and B3 results can be provided upon applicant request.

4. Ochratoxin A

“Ochratoxin A (result) ppb. Results based on HPLC reference method.”

5. Zearalenone

“Zearalenone (result) ppb. Results based on HPLC reference method.”

5.5 REVIEW INSPECTION STATEMENTS

Use the appropriate statements listed below for reinspection, appeal, and Board appeal inspections.

- a. Results are reported on the same kind of certificate issued for the original service and supersede the previously issued inspection certificate.

“This certificate supersedes Certificate No. (number) dated (date).”

- b. The superseded certificate is null and void as of the date of the

subsequent (reinspection/appeal/Board appeal) certificate.

“The superseded certificate has not been surrendered.”

- c. When a file sample is used, enter the following statement on the reinspection, appeal, or Board appeal certificate:

“Results based on file sample.”

- d. When reporting more than one official result on the same certificate but at different levels of inspection, explain this condition using one of the following applicable statements:

“(Grade, factor, or official criteria) results based on reinspection. All other results are those of the original inspection service.”

“(Grade, factor, or official criteria) results based on the appeal inspection. All other results are those of the (original inspection/reinspection) service.”

“(Grade, factor, or official criteria) results based on the Board appeal inspection. All other results are those of the (original inspection/reinspection/appeal inspection) service.”

CHAPTER 6 FDA CONTAMINATION LEVELS

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6.1 GENERAL INFORMATION

The Food and Drug Administration (FDA) is responsible for protecting public health by ensuring the safety and security of our nation's domestic food supply. FDA has established regulatory limits concerning mycotoxins present in food, grain, or animal feed for both domestic and export shipments. These limits provide an adequate margin of safety to protect human and animal health. FDA states these limits in the form of acceptable levels, action levels, and advisory levels for different mycotoxins that may be consumed by humans and different species of animals.

6.2 FDA ACTION LEVELS

Action Levels: Action levels are established based on the unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable. The blending of a food or feed containing a substance in excess of an action level with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of the contaminant.

Action levels represent limits at or above which FDA will take legal action to remove products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant.

The action levels are established and revised according to criteria specified in 21 CFR §§ 109 and 509 and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective. Table 6.1 provides information pertaining to the FDA limits for aflatoxin applicable to human food and animal feed products.

Table 6.1. FDA AFLATOXIN LIMITS ACCORDING TO INTENDED USE

Level	Intended Use
20 ppb	Corn, peanut products, cottonseed meal and other animal feeds and feed ingredients intended for dairy animals; for animal species or uses not specified below, or when the intended use is not known.
20 ppb	Corn, peanut products and other animal feeds and feed ingredients, but excluding cottonseed meal, intended for immature animals.
100 ppb	Corn and peanut products intended for breeding beef cattle, breeding swine or mature poultry.
200 ppb	Corn or peanut products intended for finishing swine of 100 pounds or greater.
300 ppb	Corn and peanut products intended for finishing (i.e., feedlot) beef cattle.

Additionally, FDA has advisory levels for DON and fumonisin considered adequate to protect human and animal health. These advisory levels are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. Visit www.fda.gov for more information on specific and recommended levels for mycotoxins in food, grain, and feed.

6.3 MEMORANDUM OF UNDERSTANDING

FGIS and FDA, having certain related objectives in carrying out their respective regulatory and service functions, have agreed upon a Memorandum of Understanding (MOU) ([FGIS Directive 9060.2](#)) to ensure the most effective possible system for identifying lots of grain, rice, pulses, and food products which exceed the FDA action level of aflatoxin contamination.

Under the provisions of the MOU, FGIS and officially delegated or designated agencies must report to FDA each lot (grain, rice, and processed products) that, during the course of an official sample-lot inspection, exceeds the 20 ppb FDA action level for aflatoxin.

According to the United States Grain Standards Act, all corn exported from the United States must be tested for aflatoxin contamination unless the buyer and seller agree not to have the corn tested.

FGIS or a designated or delegated official service provider shall perform the aflatoxin testing service unless the buyer and seller agree to have the corn tested by another entity. Aflatoxin results that exceed the actionable level of 20 ppb must be reported to FDA.

6.4 RECONDITIONING PROCEDURES

FDA will permit reconditioning of aflatoxin-contaminated corn lots at export locations by mechanical cleaning. Actionable lots can be reconditioned on either the entire subplot basis or, in the case of multiple bins per subplot, on a bin-by-bin basis.

The following conditions apply to reconditioning actionable lots.

- a. Applicants may request multiple passes across mechanical cleaners to recondition actionable corn lots or bins.
- b. Only one analytical test of a reconditioned lot or bin is allowed. The analytical results from the reconditioned lot or bin will be the final determination for disposition.
 1. In the case of sublots separated and reconditioned on an individual bin basis, the subplot (all bins) must be reconditioned in its entirety before analytical testing.

2. If the grain company elects to proceed with multiple attempts to recondition an actionable lot or bin, the attempts must proceed in a continuous manner, with screenings being directed into a designated or empty bin, to obtain a representative sample.
- c. To assure proper reconditioning, the grain company must mechanically clean the lot at a rate not to exceed 50 percent of the rated cleaner capacity.
- d. FGIS or the official agency must oversee the cleaning process, sample the reconditioned lot (cleaned corn) using a diverter-type mechanical sampler, and analyze the samples for aflatoxin.
- e. FGIS or the official agency must sample the screenings using the most practical procedures available and test the screenings for aflatoxin contamination.

Note: Local or regional FDA offices reserve the right to modify the reconditioning procedures.

6.5 FGIS RESPONSIBILITIES

When positive lots are identified at export locations, field office managers (FOM) should work with the grain facility representatives and develop a standard operating procedure (SOP) for reconditioning aflatoxin-contaminated corn.

FOMs should review the SOP with local FDA officials before implementing the reconditioning process, unless instructed otherwise by FDA.

a. Export Locations.

At export locations, FGIS or official delegated state agency personnel, as applicable, are responsible for:

1. Reporting actionable lots to the local FDA field office.
2. Preserving the identity of actionable lots prior to reconditioning.
3. Monitoring the reconditioning process at the grain facility.
4. Sampling and testing reconditioned lots and screenings for aflatoxin. When sampling screenings, use the most practical method available to obtain a representative sample.
5. Preserving the identity of reconditioned lots and screenings. Screenings are not considered a reconditioned lot.

6. Documenting and reporting aflatoxin results of reconditioned lots and screenings to FDA.
7. Completing a report of the reconditioning process. Include in the report the following information:
 - (a) Date reconditioned.
 - (b) Grain elevator and location.
 - (c) Type of sample and carrier.
 - (d) Original results.
 - (e) Reconditioned whole grain aflatoxin results.
 - (f) Screenings aflatoxin results.
 - (g) Size of cleaner screens used to recondition the lot.
 - (h) Elevator set-up information.

b. Domestic Locations.

FOMs servicing interior locations should contact the local FDA office servicing the area where the contaminated lot is located to discuss and determine responsibilities for managing the reconditioning process. Official agencies and affected grain companies are encouraged to participate in these discussions to facilitate the development of an SOP.

6.6 SAMPLE SIZE AND PREPARATION

Obtain the minimum sample size as directed in Chapter 4 of this handbook. If requested by the applicant, a larger sample size may be obtained.

Grind the entire corn sample obtained for aflatoxin testing and prepare three 500-gram subportions from the ground sample. See Table 6.2 for the type and use of each 500-gram sample portion.

Table 6.2. Sample Portions by Type and Use.

Sample Portion	Use
Test Portion	Original inspection service
File Portion	Review inspection service
FDA Portion	Retain for FDA analysis if results exceed 20 ppb.

When reconditioned lots are re-sampled in accordance with the FDA guidelines, a file portion is not required.

If FGIS original results for a reconditioned lot of corn or screenings exceed 20 ppb, FDA will use its sample portion for any subsequent verification of results.

6.7 DISPOSITION POLICY

The grain industry must comply with FDA policy regarding the disposition of corn and screenings resulting from the reconditioning process. In general, disposition will occur as follows:

- a. Screenings may be used for animal feed if the aflatoxin content meets FDA feed guidelines. The screenings may not re-enter human food channels in any fashion.
- b. Reconditioned (cleaned) corn with less than 20 ppb aflatoxin may be handled without restrictions. When the reconditioning process fails and the corn continues to exceed the 20-ppb level, disposition is based on current FDA policy.

Note: Contact the local FDA office regarding other questions concerning specific disposition action.

CHAPTER 7

REVISION HISTORY

Contents

Change No. 2	January 6, 2023	7-2
Change No. 1	June 28, 2016	7-2

Change No: 2 January 6, 2023

This update superseded the FGIS Mycotoxin Handbook dated June 28,2016. This handbook has been updated to incorporate FGIS's agency move to AMS, the inclusion of Policy Bulletin Board #275 Mycotoxin Testing in Grain: Sample Preparation Guidance, as well as general revisions and formatting. In addition, definitions, tables, and processes were updated to the current standards. The specific technical updates are listed below.

All Chapters have multiple non-technical revisions that are not listed below.

Chapter 1 – 1.5, Test kit ranges were revised to current performance criteria.

Chapter 4 – 4.3, Table 4.1 updated minimal sample sizes to account mycotoxin-specific requirements, additional, testing and purging grinders. In addition, measurements in pounds (lbs.) were removed for simplicity and uniformity.

4.7 – The section was reorganized and a new procedure for checking particle size was added (inclusion of FGIS Policy Bulletin Board #275.)

4.9 – Removed all standard supplies and equipment. Each test kit provides a list of supplies and equipment, which is on the FGIS website. A hyperlink is provided to the test kit instructions is included in this section.

4.10 – Removed disclaimer.

Chapter 5 – Tables 5.1 & 5.3 were updated to include the changes to the test kit ranges.

Change No: 1 June 28, 2016

Chapter 4 was updated to revise instructions concerning the particle size for grinders.