Directive

FGIS 9180.88

June 12, 2023

DETECTION OF FECAL MATTER

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1. PURPOSE

This directive provides instructions for obtaining qualitative determination for the presence of fecal matter in grain under the U.S. Grain Standards Act (USGSA).

2. BACKGROUND

Large Animal Excreta (LGANX) (e.g., deer, elk, cattle) when found in a grain sample, is considered Distinctly Low Quality (DLQ) and graded as Sample Grade. Further, LGANX is typically in pellet form and is actionable on officially sampled lots under the Memorandum of Understanding between FGIS and the Food and Drug Administration (see FGIS Program Directive 9060.2 Implementation of the FGIS-FDA Memorandum of Understanding located on the link below).

https://www.ams.usda.gov/sites/default/files/media/FGIS9060_2.pdf

LGANX is visually determined and is considered separately from the factor animal filth. LGANX are distinctly larger than rodent pellets or bird droppings, and accordingly one or more would make the sample distinctly low quality. Stakeholders in the grain export sector requested a more objective determination than the visual method.

Upon request, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS) Federal Grain Inspection Service (FGIS) will provide testing service to confirm whether a suspected sample is LGANX and is provided through the review/appeal process. The fecal matter detection method is only available at the Board appeal level and is the default determination method.

The fecal matter detection method service will be provided by FGIS' Technology and Science Division (TSD) in Kansas City, Missouri.

3. **REPLACEMENT HIGHLIGHTS**

This directive supersedes FGIS Program Directive 9180.88 Detection of Fecal Matter, dated December 13, 2022. This directive updates responsibilities for Applicants for Service, Official Agencies and Field Offices, and the Technology and Science Division; updates the Sample Forwarding instructions; adds instructions for requesting service; and updates Certification instructions.

4. **RESPONSIBILITIES**

a. <u>Applicant for Service</u>. For an officially sampled lot at the Board appeal level, the applicant must complete a Fecal Matter Testing Transmittal Sheet (Attachment 1). The applicant may request service through the MyFGIS Service Request Portal and attach the transmittal sheet. If the applicant does not have access to the MyFGIS Service Request Portal the FGIS Field office (FO) may enter the request on their behalf, upon receipt of the Fecal Matter Transmittal Sheet (Attachment 1). Instructions for the MyFGIS Service Request Portal are given in Section 7.

The applicant for service must provide payment in advance through Pay.gov unless they have a current USDA revolving credit account.

The applicant must provide the FO with their own shipping account information. The applicant pays for the shipping.

For more information about MyFGIS, please see the customer guide found at <u>https://fgisonline.ams.usda.gov.</u>

b. <u>Official Agencies and Field Offices</u>. Federal appeals are conducted by the supervising Field Office and Board appeals are conducted by TSD. The OA/FO must include the original sample, the LGANX separation, and the Fecal Matter Testing Transmittal Sheet (Attachment 1) filled out by the applicant, with shipments of Federal and Board appeals.

<u>Official agencies</u>: The applicant will make the Federal appeal request to their supervising Field Office. The supervising FO reviews the sample, issues the Federal appeal certificate, then forwards the Board appeal sample, if requested, to TSD.

The applicant is responsible for all shipping expenses. The OA/FO must maintain custody of the sample(s) until delivery to the courier.

On the shipping label, include instructions stating that after-hour deliveries are to be deposited in the black drop box located at the south entrance to the building near the flagpole.

Upon shipping the sample, the official agency must transfer the request for service from the applicant to their supervising field office in MyFGIS.

Upon shipping the sample, the field office must transfer the request for service from the applicant to TSD in MyFGIS.

c. <u>Technology Science Division (TSD)</u>. For official sample service TSD is responsible for performing the requested test, maintaining a file sample, and issuing the board appeal certificate to the applicant and OA/FO as soon as practicable after completing the test. TSD will bill the applicant for the testing services and other applicable hourly fees.

5. PREPARING AND FORWARDING SAMPLES

<u>Sample Preparation</u>. Provide all suspected LGANX. To prevent comingling of pellets, place only one pellet in a plastic bag or glass vial and label appropriately. Place the plastic bag(s) in a sturdy cardboard box or padded envelope for shipping.

For samples containing LGANX:

- (1) If LGANX was determined on the basis of the lot as a whole during time of sampling (barge, truck, railcar, container), send only the LGANX.
- (2) If LGANX was determined on the basis of a component sample, send only the LGANX.
- (3) If LGANX was determined on the basis of an officially graded sample, send the LGANX and the official file sample (packaged separately).

b. <u>Sample Forwarding</u>.

- 1. For an official agency: send the sample by overnight transport to your supervising field office using the information below. Include the Fecal Matter Testing Transmittal Sheet (Attachment 1). Immediately following shipment, document the shipping method and tracking number on the MyFGIS service request and transfer it to the supervising field office in the system.
- 2. For a field office: Send the sample by overnight transport to TSD using the information below. Include the Fecal Matter Testing Transmittal Sheet (Attachment 1). Immediately following shipment, document the shipping method and tracking number on the MyFGIS service request and transfer it to TSD in the system.

Note: All sample submissions received after 2 pm CST Friday will be considered weekend testing and will be billed according to Program Directive 9180.74 provided on the link below:

https://www.ams.usda.gov/sites/default/files/media/FGISDirective9180_74.pdf

Send samples to:

USDA, AMS, FGIS ATTN.: Biotechnology Lab/ FMA Technology and Science Division 10383 North Ambassador Drive Kansas City, Missouri 64153-1394

On the shipping label, include instructions stating that after-hour deliveries are to be deposited in the black drop box located at the south entrance to the building near the flagpole.

6. INSTRUCTIONS FOR REQUESTING SERVICE

a. For Applicant entering a request directly:

After logging into MyFGIS:

- 1. Open 'New Service Request'
 - Organization Requesting Service: MyFGIS profile of the requesting party
 - Service Request Name: Include 'FMA', along with other sample identification.
 - Service Date: Date requested

- Service Time: Time requested
- Provider: [OSP with the current samples]
- Type of Account: Select the FMMI revolving account or COD account as applicable.

o For COD accounts, FGIS staff will complete billing documents for your review in MyFGIS and payment through Pay.Gov

- Service Category: Other Services
- Contact: Identify whom has requested the service
- Click 'Next'
- 2. Identify the location where the commodity was sampled:
 - Select the location from the dropdown
 - If not present, add the location (this will become part of the MyFGIS profile of the applicant)
 - click Next
- 3. Review the cart
 - Review name / location / contact / accounting
 - Attach the fecal matter transmittal sheet (Attachment 1) using 'Add Document.'
 - Submit Service Request.
- 4. The request will now appear here: Service Requests Submitted
- 5. All contacts noted in step 1 will be notified when the service is scheduled.
- b. For OSP working on behalf of the applicant to enter the request:
 - 1. Open 'New Service Request'
 - o Organization Requesting Service: Use the MyFGIS # provided to select the requesting party.
 - o Service Request Name: Include 'FMA', along with other sample identification.
 - o Service Date: Date requested.
 - o Service Time: Time requested.
 - o Provider: [OSP entering request]
 - o Type of Account: Select the active FMMI or COD account according to the instructions of the applicant.
 - o Service Category: Other Services
 - o Purchase Order / Contract Number: Optional.
 - Contact:
 Click the box to select whom has requested the service If not found, add the person.
 - o Click 'Next'

- 2. Identify the location where the commodity was sampled:
 - o Select the location from the dropdown.
 - o If not present, add the location (this will become part of the MyFGIS profile of the applicant)
 - o click 'Next'
- 3. Review the cart:
 - o Review name / location / contact / account number.
 - o Attach the fecal matter transmittal sheet (Attachment 1) using 'Add Document.'
- 4. Submit Service Request.
- 5. The request will now appear here: Service Requests Received
- c. For Official Agency holding an official sample to be sent for analysis:
 - 1. Staff holding the "Assigner" role will receive an email that the request was submitted.
 - 2. Log into MyFGIS and open: "Service Requests Received"
 - 3. Open the request by clicking on the request number to review.
 - a. Prepare the samples for shipment and ship
 - b. Enter a comment identifying the shipping method and tracking number
 - 4. Return to the list
 - a. Select the checkbox next to the entered request
 - i. If you need to establish a billing document for your OSP (e.g. sampling, shipping),
 - 1. Select the 'Action:' of "Create Bill."
 - a. Note the created Billing Document (BD) number.
 - b. Navigate to the Billing Dashboard/GBA to perform billing.
 - ii. Select the 'Assign To:' action and choose "Other OSP."
 - iii. Choose your supervising field office from the dropdown and Assign.
 - b. The request will be moved from the 'Open' source to the 'Transferred' source.
 - 5. Once transferred, you can access the request in the 'Transferred' source.
- d. For Field Office holding the official sample to be sent for analysis:
 - 1. Staff holding the "Assigner" role will receive an email that the request was submitted
 - 2. Log into MyFGIS and open: "Service Requests Received"

- 3. Open the request by clicking on the request number to review.
 - a. Prepare the samples for shipment and ship
 - b. Enter a comment identifying the shipping method and tracking number
- 4. Return to the list
 - a. Select the checkbox next to the entered request
 - i. If you need to establish a billing document for your OSP (e.g. sampling, shipping),
 - (1) Select the 'Action:' of "Create Bill."
 - (a) Note the created Billing Document (BD) number.
 - (b) Navigate to the Billing Dashboard/GBA to perform billing.
 - ii. Select the 'Assign To:' action, and choose "Other OSP."
 - iii. Choose "FGIS Technology and Science Division" from the dropdown and Assign.
 - b. The request will be moved from the 'Open' source to the 'Transferred' source.
- 5. Once transferred, you can access the request in the 'Transferred' source.
- e. For FGIS Technology and Science Division:
 - 1. Staff holding the "Assigner" role will receive an email that the request was transferred or submitted.
 - 2. Log into MyFGIS and open: "Service Requests Received."
 - 3. Open the request by clicking on the request number to review a. Review request for completeness.
 - 4. Create a billing document by selecting the checkbox by the service request and selecting the 'Action:' of "Create Bill."
 - a. Note the created Billing Document (BD) number.
 - b. Open the Billing Dashboard and then open this new BD.
 - c. Add the appropriate billing lines to the billing document.
 - i. Use G2FMA for the test.
 - d. If the account Type is COD:
 - i. Notify the applicant that the estimate is available in MyFGIS.
 - ii. They need to pay via Pay.Gov and provide the amount paid and tracking number.
 - iii. After payment is received, record the Pay.Gov tracking number and amount in the bill comments.
 - e. Submit the bill.
 - f. Return to MyFGIS: "Service Requests Received"
 - 5. Upon receipt of the sample:
 - a. Schedule the test by entering the date/time for the request on the grid.
 - b. Accept the service request document by selecting the checkbox by the service request and selecting the 'Action:' of 'Accept.'
 - i. The contacts identified in the service request will be notified that the request was received and scheduled.
 - c. Conduct the tests.
 - 6. After testing is completed:
 - a. If additional costs are incurred

- i. Create an additional billing document by selecting the checkbox by the service request and selecting the 'Action:' of "Create Bill."
- ii. Add the appropriate billing lines to the billing document.
- iii. If the account type is COD, the additional amount must be collected and the subsequent Pay.Gov tracking number and amount documented in bill comments before releasing results.
- iv. Submit the bill.
- b. Issue the certificates.
 - i. Supersede the appeal certificate.
 - ii. Ensure that the MyFGIS number and Applicant Name match the service request.
 - iii. The certificates are available to the applicant in CRT.
- c. Complete the service request document by selecting the checkbox by the service request and selecting the action 'Complete.'
- d. The request will be moved from the 'Open' source to the 'History' source, and no further actions are available.

7. CERTIFICATION

- a. If LGANX was determined on the basis of the lot as a whole (barge, truck, railcar, container), the identification on the certificate must represent the entire lot (e.g. carrier id).
 - 1. The original provider shall issue an original official sample-lot inspection certificate or commodity inspection certificate with the count of "Large Animal Excreta" and "Distinctly Low Quality: Fecal Matter" shown in the Results section of the certificate.
 - 2. If an appeal is requested, after inspection, an appeal certificate shall be issued by the field office with the count of "Large Animal Excreta" and if confirmed, "Distinctly Low Quality: Fecal Matter" in the Results section of the certificate.
 - 3. If a board appeal is requested, a board appeal certificate shall be issued by TSD that supersedes the appeal certificate.
 - a. If visual determination is requested, a board appeal certificate shall be issued with the count of "Large Animal Excreta" and if confirmed, "Distinctly Low Quality: Fecal Matter" in the Results section of the certificate.
 - b. If fecal matter determination test is requested
 - i. If fecal matter is confirmed, show "Fecal Matter" as 'Detected', along with the count of "Large Animal Excreta" and "Distinctly Low Quality: Fecal Matter" in the Results section of the certificate.
 - ii. If fecal matter is not found, show "Fecal Matter" as 'Not Detected' and set the count of "Large Animal Excreta" as 0 in the Results section of the certificate. Do not show the factor 'Distinctly Low Quality' in results.

- b. If LGANX was determined on the basis of a component sample that has not been composited and has become a material portion, the material portion must be marked on the inspection log as transferred out of the lot to a new lot. This component may not be rejoined to the initial lot. The identification of the component on the certificate must be noted as follows:
 - Name of Material Portion at the time of inspection (MP-1, MP-4, etc)
 - Load Start DateTime of the material portion 01/26/2023 1530
 - Bin(s) / Rail Car(s) / Location of Commodity after elevation and sampling.
 - Example: "MP-4 Start: 01/26/2023 1530 Bin 63,79"
 - 1. The original provider shall issue an original official sample-lot inspection certificate or commodity inspection certificate with local movement and with the count of "Large Animal Excreta" and "Distinctly Low Quality: Fecal Matter" shown in the Results section of the certificate.
 - 2. If an appeal is requested, after inspection, an appeal certificate shall be issued by the field office with the count of "Large Animal Excreta" and if confirmed, "Distinctly Low Quality: Fecal Matter" in the Results section of the certificate.
 - 3. If a board appeal is requested, a board appeal certificate shall be issued by TSD that supersedes the appeal certificate.
 - a. If visual determination is requested, show the count of "Large Animal Excreta" and if confirmed, "Distinctly Low Quality: Fecal Matter" in the results section of the certificate.
 - b. If fecal matter determination test is requested
 - i. If fecal matter is confirmed, show "Fecal Matter" as 'Detected', along with the count of "Large Animal Excreta" and "Distinctly Low Quality: Fecal Matter" in the results section of the certificate.
 - ii. If fecal matter is not found, show "Fecal Matter" as 'Not Detected', and set the count of "Large Animal Excreta" as 0 in the results section of the certificate. Do not show the factor 'Distinctly Low Quality' in results.
- c. If LGANX was determined on the basis of an officially graded sublot that has become a material portion. The identification of the sublot on the certificate must be noted as follows:
 - Name of Material Portion at the time of inspection (MP-1, MP-4, etc)
 - Load Start DateTime of the material portion 01/26/2023 1530
 - Bin(s) / Rail Car(s) / Location of Commodity after elevation and sampling.
 - Example: "MP-4 Start: 01/26/2023 1530 Bin 63,79"

- 1. The original provider shall issue an original official sample-lot inspection certificate or commodity inspection certificate with local movement and with the count of "Large Animal Excreta" and "Distinctly Low Quality: Fecal Matter" shown in the Results section of the certificate.
- 2. If an appeal is requested, after inspection, an appeal certificate shall be issued by the field office with the count of "Large Animal Excreta" and if confirmed, "Distinctly Low Quality: Fecal Matter" in the Results section of the certificate.
 - i. The inspection log shall be updated to include an appeal sublot result of the count of LGANX shown on the appeal certificate.
- 3. If a board appeal is requested, a board appeal certificate shall be issued by TSD that supersedes the appeal certificate.
 - If visual determination is requested, a board appeal certificate shall be issued with the count of "Large Animal Excreta" and if confirmed, "Distinctly Low Quality: Fecal Matter" in the Results section of the certificate.
 - b. If fecal matter determination test is requested
 - i. If fecal matter is confirmed, show "Fecal Matter" as 'Detected', along with the count of "Large Animal Excreta" and "Distinctly Low Quality: Fecal Matter" in the Results section of the certificate.
 - ii. If fecal matter is not found, show "Fecal Matter" as 'Not Detected' and set the count of "Large Animal Excreta" as 0 in the Results section of the certificate. Do not show the factor 'Distinctly Low Quality' in results.
 - c. The inspection log shall be updated to include a board appeal sublot result of the count of LGANX shown on the board appeal certificate. If fecal matter was not detected and the material portion was eliminated, the inspection log sublot name shall be updated accordingly.

Note: Because LGANX is actionable on officially sampled lots under the Memorandum of Understanding between FGIS and the Food and Drug Administration, FGIS Program Directive 9060.2 Implementation of the FGIS-FDA Memorandum of Understanding is incorporated by reference. A final determination that a suspected sample is confirmed fecal matter (LGANX) requires notification to FDA according to the directive.

8. FEES

FGIS will use the billing code G2FMA (Fecal Matter Assay) to bill for the Board Appeal fecal matter determination service, as stated in FGIS Program Directive 9180.74 found on the AMS FGIS website at

https://www.ams.usda.gov/about-ams/fgis-program-directives.

9. ATTACHMENT

Attachment 1 – Fecal Matter Testing Transmittal Sheet

Attachment 1

Fecal Matter Testing Transmittal Sheet		
Applicant's Name		
MyFGIS Number		
Carrier ID		
Date Sampled		
Sampling Location		
Sample Identification		
(e.g. MP-4 Start: 01/20/2023 1530 Bin 63,79)		
Original Certificate Number		
Appeal Certificate Number		
Point of Contact Name		
Point of Contact Email		