

6.4 RECONDITIONING PROCEDURES

FDA will permit the reconditioning of the following types of actionable lots of grain at domestic or export locations by mechanical cleaning/screening:

- 1) Animal filth in Wheat, Rye, Rice, and Pulses
- 2) Insect Damaged Kernels in Wheat
- 3) Aflatoxin: more than 20 ppb
- 4) Deleterious Foreign Matter in Grain (NOTE: for removal of metal fragments, grain should be passed over/through a magnet)
- 5) Distinctly Low Quality (DLQ) in Grain and Rice, on account of large animal excreta

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.

For wheat found to be actionable due to insect damaged kernels, the affected grain company may elect to divert the affected lot(s) of wheat directly into animal feed without reconditioning. This may be done by the FOM or affected grain company notifying FDA of the diversion, without any further approval.

The following conditions apply to reconditioning actionable lots.

- 1) Applicants may make multiple passes across mechanical cleaners to recondition actionable grain, rice, or pulse lots or bins.
- 2) The reconditioned lot or bin of grain will be eligible for one original inspection and a full set of review inspections. In accordance with FGIS policy, review inspection results supersede the results of all previous levels of inspection. The final inspection/analytical result, once any applicable review inspections are complete, from the reconditioned lot or bin will be the final determination for disposition.
 - a) 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.
 - b) 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.
- 3) To assure proper reconditioning, the grain company must mechanically clean the lot at an appropriate rate to achieve the desired outcome.
- 4) FGIS or the official agency must oversee the cleaning process, sample the reconditioned lot using an approved sampling device and procedures (e.g., a diverter-type mechanical sampler), and inspect/analyze the samples for actionable conditions.
 - a) For aflatoxin contamination, FGIS or the official agency must sample the screenings using the most practical procedures available and test the screenings.

At interior locations, the local FDA office may modify the reconditioning procedures to provide for a cost-effective process.

6.5 FGIS RESPONSIBILITIES

When actionable 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 the actionable lot(s).

FOMs do not need to review the SOP with local FDA officials before implementing the reconditioning process, unless it deviates from the pre-approved process for reconditioning by passing the actionable lot(s) over a cleaner/screener (or magnet in the case of metal fragments).

- 1) Export Locations. At export locations, FGIS or official delegated state agency personnel, as applicable, are responsible for:
 - a) Reporting actionable lots to the local FDA field office.
 - b) Preserving the identity of actionable lots prior to reconditioning.
 - c) Monitoring the reconditioning process at the grain facility.
 - d) Sampling and testing reconditioned lots.
 - i) When sampling screenings for aflatoxin, use the most practical method available to obtain a representative sample.
 - e) Preserving the identity of reconditioned lots and screenings (Screenings are not considered a reconditioned lot).
 - f) Documenting and reporting results of reconditioned lots to FDA.
 - g) Completing a report of the reconditioning process. Include in the report the following information:
 - i) Date reconditioned.
 - ii) Grain elevator and location.
 - iii) Type of sample and carrier.
 - iv) Original results.
 - v) Reconditioned whole grain results.
 - (1) When cleaning for aflatoxin, Screenings aflatoxin results.
 - vi) Size of cleaner screens used to recondition the lot.
 - vii) Elevator set-up information.

2) Domestic Locations.

FOMs/Official Agencies servicing interior locations should follow the same procedures as above. FOMs servicing interior locations should only contact the local FDA office servicing the area where the contaminated lot is located to discuss any deviations from the pre-approved process for reconditioning by passing the actionable lot(s) over a cleaner/screener (or magnet in the case of metal fragments) 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

For all lots of actionable grain, except aflatoxin, obtain the minimum sample size as directed in Chapter 1 of Grain Inspection Handbook Book 1 – Sampling. For lots of grain actionable on account of aflatoxin, obtain the minimum sample size as directed in Chapter 4 of the FGIS Mycotoxin handbook. If requested by the applicant, a larger sample size may be obtained.

For all lots of actionable grain, except aflatoxin, inspect the sample per the appropriate FGIS Grading Procedure found in Grain Inspection Handbook Book 2 – Grain Procedures. In addition to retaining a file sample per FGIS file sample retention rules, retain an additional portion for FDA if the results show the lot is still actionable.

NOTE: When testing for aflatoxin grind the entire sample obtained and prepare three 500-gram subportions from the ground sample.

Sample Portion	Use
Test Portion	Original inspection service
File Portion	Review inspection service
FDA Portion	Retain for FDA analysis if results are still actionable

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 grain are still considered actionable, 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 actionable lots of grain resulting from the reconditioning process. In general, disposition will occur as follows:

- 1) The screenings may not re-enter human food channels in any fashion. In the case of screenings containing aflatoxin, screenings may be used for animal feed if the aflatoxin content meets FDA feed guidelines.
- 2) Reconditioned (cleaned) grain that no longer exceeds FDA action limits may be handled without restrictions. When the reconditioning process fails and the grain continues to exceed FDA action limits, disposition is based on current FDA policy.

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