

SEPARATION PROTOCOLS

The following information, excerpted from “Small Entities Compliance Guide for Renderers,” FDA Guidance for Industry 67, Center for Veterinary Medicine, Food and Drug Administration, U.S. Department of Health and Human Services, February 1998, pages 7-11, describes the acceptable methods to be used by facilities seeking approval under 1774 to separate prohibited Category 1 and Category 2 materials from permitted materials. **These protocols are not acceptable for facilities, who are not permitted to handle any prohibited materials in the same building.**

HOW CAN I PROVIDE FOR MEASURES TO AVOID COMMINGLING OR CROSS-CONTAMINATION?

1. Separation

- You could have separate equipment or facilities for the manufacture, processing, blending, or storage of prohibited and non-prohibited materials. This could be entirely separate buildings, rooms, or other locations, or separate storage containers for incoming material and finished product, and separate manufacturing lines.
- Separate equipment for prohibited material should be clearly identified to help ensure that prohibited material is not mistakenly added to product intended to contain non-prohibited material only.

OR

2. Clean-out

- Clean-out could be physical cleaning, flushing, sequencing, or other means, either alone or in combination with separation measures that are adequate to prevent carryover of prohibited material into non-prohibited material. Clean-out procedures should be used on all equipment and conveyances that handle both prohibited and non-prohibited material.
- Documentation for clean-out should include a description of how clean-out is implemented – who is responsible; how clean-out is monitored and verified; how volume of clean-out flush material was determined; and a description of how clean-out flush material is handled.

OR

3. Combination of separation and clean-out

- An example would be use of some separate and some common equipment (clean-out would be required for the latter).

You need written procedures, whether you use separation, clean-out, or a combination:

- Written procedures should include the procedures followed from the time of receipt of incoming material until the time of shipment of finished products. They should reflect what actually happens in your operation.
- Written procedures should have enough detail to provide a clear understanding of your actual procedures. An investigator should be able to easily identify operations that are described in the written procedures.

WHAT ARE SOME EXAMPLES OF MEASURES THAT I COULD FOLLOW TO PREVENT COMMINGLING AND CROSS CONTAMINATION?

1. PROCESSING OPTION ONE

This example is a single plant with two or more totally segregated processing lines. This includes all process functions from raw material receiving through and including finished product load-out.

Suggested Procedures for Processing Option One

No clean-out procedures are necessary for this processing situation, because the lines are completely separate. This type of plant should have the ability to process prohibited and non-prohibited products from the same plant so long as procedures are in place to assure total segregation. These procedures should be part of the plant's written procedures specifying measures the firm is taking to prevent commingling and cross contamination and should be available for inspection and FDA review for compliance purposes.

2. PROCESSING OPTION TWO

This example is a single plant which has two or more segregated raw material receiving, grinding, cooking, and pressing lines but shares finished product conveying, grinding, and load-out systems.

Suggested Procedures for Processing Option Two

The suggested procedures to prevent commingling and cross contamination for this type of plant deal specifically with the meal grinding (and screening), storage, and load-out systems. It is assumed that this type of plant would have separate storage facilities for prohibited versus non-prohibited product. It may have separate or common load-out facilities.

STEP #1 - The first step in the clean-out and flushing procedure should be to empty all transport and processing equipment from the first point of commonality of products to the final load-out device.

STEP #2 - The system should then be flushed with a sufficient volume of non-prohibited product to accomplish one complete change of operating volume of the entire system

(exclusive of separate meal storage facilities). The flush material should be considered prohibited product and treated as such.

STEP #3 - Once the system has been flushed, all subsequent material processed would be non-prohibited material. Specific operating procedures should be part of the plant's written procedures specifying the procedures to prevent commingling and cross contamination and available for inspection and FDA review for compliance purposes.

3. PROCESSING OPTION THREE

This example is a single plant with separate raw material receiving and grinding, common cooking and pressing, and common or separate finished product handling.

Suggested Procedures for Processing Option Three

The procedures to prevent commingling and cross contamination for this type of plant deal specifically with the cooking and pressing systems. The meal grinding, storage, and load-out systems should be cleaned and flushed according to the guidance in processing option two above. It is also assumed that this type of plant would have separate storage facilities for prohibited versus non-prohibited finished meal. It may have separate or common load-out facilities.

STEP # 1- The first step should be to empty all transport and process equipment (including the cooker) from the first point of commonality of raw material to the meal grinding system.

STEP # 2- The system should then be cleaned and/or flushed with sufficient non-prohibited raw material to accomplish the following changes of the operating volume of the cooker:

- In the case of a continuous cooker with a bottom discharge (to provide positive cooker clean-out), raw material equal to at least one half the operating volume of the cooker;
- In the case of a continuous cooker without a bottom discharge,, raw material equal to at least the operating volume of the cooker; or
- In the case of a batch cooker system, raw material equal to at least one half the operating volume of the cooker for each batch cooker.

In general, the volume of material required to flush the cooking system should provide an adequate flush of the meal grinding, storage, and load-out system, as well. The flush material should be considered prohibited product and treated as such. All subsequent material processed should be considered non-prohibited product. Specific operating procedures should be documented and verified, should be part of the plant's written procedures specifying the procedures utilized to prevent commingling and cross contamination, and should be available for inspection and FDA review for compliance purposes.

4. PROCESSING OPTION FOUR

This example is for a single plant with one processing line handling both prohibited and non-prohibited material. This includes all process functions from raw material receiving through and including product load-out.

Suggested Procedures for Processing Option Four

The procedures to prevent commingling and cross contamination for this type of plant deal with the complete plant process. It is assumed that this type of plant would have adequate storage facilities to separate prohibited from non-prohibited finished product. It may have separate or common load-out facilities.

The procedures should include measures to empty and clean and/or flush all transport and process equipment including the raw material receiving hoppers, conveyors, grinders, and cooker from the first point of commonality of raw material through the load-out system. As a guideline, the volume of flushing material should be equal to the operating volume of the process and transport equipment, including the cookers.

The flush material should be considered prohibited product and treated as such. All subsequent material processed should be considered non-prohibited product. Specific operating procedures should be documented and verified, should be part of the plant's written procedures specifying the procedures utilized to prevent commingling and cross contamination and should be available for inspection and FDA review for compliance purposes.

Due to the degree of variability among rendering systems, a Hazard Analysis and Critical Control Points (HACCP)-based approach of process controls would be helpful in implementing any of the above procedures. This will enable differences to be addressed on a site-specific basis. Renderers could follow the above clean-out procedures by determining their plant's individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. Individual clean-out procedure, including time and volume calculations, should be part of the plant's written procedures specifying the procedures utilized to prevent commingling and cross-contamination and should be available for inspection and FDA review for compliance purposes.