

U.S. Exporter of Animal By-Products for the Manufacture of Pet Food Pre-Inspection Package

*****This pre-inspection package is for facilities exporting animal origin pet food ingredients directly to the EU for production of pet food, or for intermediate suppliers of ingredients supplied to U.S. producers of products to be exported to the EU for animal consumption. This package is not to be used for materials covered by any other pre-inspection package, such as meals, digests, or spray dried products.**

I. BACKGROUND

REGULATION (EC) No 1774/2002 published October 3, 2002 (effective December 31, 2003) establishes the requirements for importing animal by-products not intended for human consumption into the European Union (EU).

The EU requires that U.S. facilities exporting animal by-products to the EU for the production of pet food to be inspected and approved. Facilities exporting products produced under the inspection of the Food Safety and Inspection Service (FSIS) should have FSIS certify the materials for export. If the facility only exports products produced under FSIS inspection (which FSIS is willing to certify) then no APHIS approval is required.

The EU requires that U.S. facilities exporting animal feed be inspected and approved by the Animal and Plant Health Inspection Service (APHIS) prior to export. In addition, **all facilities that provide ingredients of animal origin (e.g., blenders, digest manufacturers, spray dry manufacturers, and renderers) to approved facilities must be inspected and approved.** Some facilities may be supplying unprocessed materials to these domestic producers of pet food for export to the EU. If these facilities require APHIS approval (are not already under FSIS, FDA, or other authority, or are at risk of having SRMs included in the products), then this is the inspection package to use for those facilities. **However, this is not the proper checklist for materials covered by other pre-inspection packages, e.g., meals, digests, or spray dried products.**

The former EU categorization of materials into “high-risk” and “low-risk” categories has been replaced by a categorization of material into the numbered categories: one, two, and three. While at one time, some European Union countries would accept Specified Risk Materials (SRMs), now all SRMs must be removed from raw materials.

Facilities may continue to handle SRMs and Category 1 and 2 materials. However, these prohibited materials must be kept separate from the material to be shipped to the EU, or from materials to be included in product to be shipped to the EU. Material to be exported to the EU must be kept separate at all times. The only acceptable methods for separation are those listed in Appendix One, Separation Protocols, of this document. This appendix is excerpted from “Small Entities Compliance Guide for Renderers, FDA Guidance for Industry 67.”

Some materials that previously could be exported to the EU or included in pet food to be exported to the EU are now prohibited. These materials include those materials derived from animals that died in transit and were therefore not presented for ante-mortem examination. With few exceptions (detailed in the Category 3 Material Notarized Form) materials derived from animals that did not pass post mortem inspection are also ineligible.

II. DEFINITION

Approved facility: In this memo, this term will apply to facilities approved either to export to the EU or to provide to domestic U.S. producers unprocessed animal by-products for pet food production.

III. PRE-INSPECTION PROCEDURES

Prior to the scheduling of the inspection, the following documents should be forwarded to the area office:

1. A cover letter stating what materials (including species of origin) the plant wishes to be approved to export to the EU or to supply domestic producers, and specifying contact information for the plant contact individual;
2. Category Three Material Notarized Form;
3. Notarized Specified Risk Material Form.

The above noted documents should meet the following specifications:

All forms must be the specific versions included in this document. All forms should be notarized. The title should indicate that the individual could be expected to have knowledge of the information included in the notarized form. For example, the Category 3 Material Notarized Form should not be endorsed by the labeling officer.

A. Category 3 Material Notarized Form

The document verifies that only Category 3 Materials are included in materials destined for export to the EU and specify the suppliers of these materials. The approving authority and any applicable approval numbers should be included for each supplier.

An exception to this requirement is ocean caught fish or other sea animals (except mammals) where no approval number or authority name is required. Rather than the approval numbers, a statement should be included that these materials only include fresh caught fish or other sea mammals (except mammals).

The notarized form must certify that the Category 3 Materials are kept separate from any Category 1 or Category 2 materials, and specify the method of separation.

B. Notarized Specified Risk Material Form

Effective October 1, 2003 the EU has expanded the materials considered to be SRMS to include the tonsils of bovine animals of all ages and the ileum of sheep and goats of all ages.

IV. INSPECTION

A plant management official with knowledge of plant operation and all issues addressed in the attached checklist should accompany the inspector during the inspection. This plant official should review this entire checklist prior to the inspection, and be prepared to provide evidence that the facility is adequately addressing each item.

The inspection will begin with a meeting in the plant management office, at which time the plant official should be prepared to review, with the inspector, the documents listed below.

1. A completed notarized "Category 3 Material Notarized Form" declaring that the facility only uses Category 3 Materials in products produced for inclusion in products produced for export to the EU.
2. A completed "Notarized Specified Risk Materials Statement Form," declaring that the facility does not include Specified Risk Materials in product produced for export to the EU or for inclusion on product to be exported to the EU, and that the plant has in place a procedure to prevent the commingling or cross-contamination of Specified Risk Materials with product destined for the EU.
3. If the facility receives Category 1 or Category 2 materials, a written procedure for the prevention of commingling or cross-contamination. This procedure must be consistent with the methods described in Appendix One, Separation Protocols, excerpted from "Small Entities Compliance Guide for Renderers, FDA Guidance for Industry 67."

If the facility is exporting material to the EU for the production of pet food, the facility must mark the product for export as detailed here (check appropriate selections):

- a. In the case of frozen material: Marked by a cross of liquefied charcoal or activated carbon, on each outer side of each frozen block, in such a way that the markings cover at least 70% of the diagonal length of the frozen block and is at least 10 cm in width; and/or
- b. In the case of unfrozen material: Marked by spraying with liquefied charcoal or by applying charcoal powder in such a way that the charcoal is clearly visible on the material.

V. REINSPECTION

Facilities must be inspected annually and are responsible for contacting the area office to arrange for the inspection. Once more than 12 months have passed since the previous

inspection, the area office will not endorse export certificates based upon the previous inspection.

Prior to the annual inspection, all documents should be updated, notarized with the current date, and forwarded to the area office.

U.S. Supplier of Animal By-Products for Pet Food Production Inspection Checklist

*****This checklist is not for suppliers of any processed materials covered by any other pre-inspection package, e.g., meals, digests, or spray dried materials.**

1. Animal and Plant Health Inspection Service (APHIS) Approval Number (This blank should be left uncompleted for newly inspected facilities): _____.

2. Facility/company name: _____.

3. Address of location being inspected:

_____.

4. Address of headquarters if different from plant:

_____.

5. Contact person at plant: Name _____, Telephone _____, Facsimile _____.

6. ____ yes ____ no Has the plant provided you with a current notarized "Notarized Category 3 Material Form"? Please attach to this checklist and forward to NCIE.

7. ____ yes ____ no Have you reviewed the plant records verifying that their suppliers of all animal origin fats and proteins are from approved sources listed on their "Notarized Category 3 Material Form"?

8. ____ yes ____ no Has the plant provided you with a current "Notarized Specified Risk Material Form"? Please attach to this checklist and forward to NCIE.

9. ____ yes ____ no ____ N/A Did the plant present you with a written plan for the prevention of commingling or cross-contamination of Category 1 or 2 Materials with the Category 3 Materials approved for export to the EU? (The answer is N/A if the plant verifies on its "Category 3 Material Notarized Form" that it does not receive, store, or process Category 1 or Category 2 materials.)

10. ___ yes ___ no ___ N/A If the facility is exporting material to the EU for the production of pet food, does the facility mark the product for export as detailed here (check appropriate selections):

- ___ a. In the case of frozen material: Marked by a cross of liquefied charcoal or activated carbon, on each outer side of each frozen block, in such a way that the markings cover at least 70% of the diagonal length of the frozen block and is at least 10 cm in width; and/or
- ___ b. In the case of unfrozen material: Marked by spraying with liquefied charcoal or by applying charcoal powder in such a way that the charcoal is clearly visible on the material.

11. ___yes ___ no Are the materials shipped from the plant either deep frozen, or preserved in a way to prevent spoilage?

12. ___yes ___ no Did you tour the facility's storage facilities and find that they appear adequate (covered, dry where appropriate, etc)?

13. ___yes ___no Did you observe any obviously unhygienic activities (such as loose animals on the production floor) during your inspection?

14. ___ yes ___ no ___ N/A If the facility exports any materials to be used as feed for farm animals (review invoices/labels to determine intended use of product), does the facility only include animal origin ingredients that are parts of slaughtered animals that have passed post mortem inspection (or poultry heads, feet, or intestines that have not passed post mortem inspection)?

15. Please list the materials produced by the facility for direct export to the EU (marked products) (**Please include species of origin of materials**):

16. Please list any other materials produced by the facility to supply domestic pet food producers (but which is not marked for export to the EU) (**Please include species of origin of materials**):

Category 3 Material Notarized Form

This serves to inform officials of the United States Department of Agriculture's Animal and Plant Health Inspection Service that _____
(Plant's name), located at _____

(Plant's street address, including City, State, and Zip Code) only produces materials destined for export to the European Union, from animal origin materials included on the following list. (*Check all those that apply*):

___ Parts of slaughtered animals that have passed post mortem inspection (or poultry heads, feet, or intestines that have not passed post mortem inspection) at the following Food Safety and Inspection Service (FSIS)-approved or State-approved slaughter plants: (*attach list*). **[If materials are exported to the EU that are intended to be used as feed for fur animals, only materials meeting this definition are utilized for that purpose.]**

___ Hides, skins, hooves, horns, pig bristles, or feathers from animals that have passed ante-mortem inspection at the following Food Safety and Inspection Service (FSIS)-approved or State-approved slaughter plants: (*attach list*).

___ Blood from (*insert non-ruminant species of origin, such as porcine or poultry*) animals that have passed ante-mortem inspection at the following Food Safety and Inspection Service (FSIS)-approved or State-approved slaughter plants: (*attach list*).

___ Blood from ruminant species (*insert ruminant species such as bovine, ovine, or caprine*) that have passed post-mortem inspection at the following Food Safety and Inspection Service (FSIS)-approved or State-approved slaughter plants: (*attach list*).

___ Animal by-products derived from the production of products fit for human consumption including (*attach list*)

___ Raw milk from (*list regulatory agency approving source facilities and approval numbers*)

___ Fresh caught fish or other sea animals (except mammals)

___ Fishmeal from (*list facilities and National Marine Fisheries Service Approval Numbers*)

___ Eggs and egg-byproducts from (*list facilities, pertinent regulatory agency such as APHIS, AMS, FSIS, or other State agency, and approval numbers*)

___ Only meals (other than fish meal) from rendering facilities approved by APHIS to export meals to the European Union (*list suppliers and APHIS approval numbers*)

This notarized form further certifies that these Category 3 Materials are not commingled with any Category 1 or 2 Materials. To ensure that product produced for inclusion in products for export to the EU has not been commingled with any Category 1 or Category 2 materials, this facility (check one of the below options):

- ___ Does not receive, store, or process any Category 1 or 2 Materials; OR
- ___ Utilizes a **Separation Protocol** as described in the "Small Entities Compliance Guide for Renderers, FDA Guidance to Industry 67"; OR
- ___ Utilizes a **Clean-out Protocol** as described in the "Small Entities Compliance Guide for Renderers, FDA Guidance to Industry 67"; OR
- ___ Utilizes a **Separation and Clean-out Protocol** as described in the "Small Entities Compliance Guide for Renderers, FDA Guidance to Industry 67."

This facility does not produce material destined for export to the European Union containing any of the following: products derived from mammals or poultry (except for poultry heads, feet, and intestines) that did not pass post mortem veterinary inspection, products derived from animals that died in transit, or any materials that fall under the definition of Category 1 material as defined in EC Reg 1774/2002.

I certify that the statements listed above are true to the best of my knowledge and belief.

Signed by: _____ Date: _____

Printed name of signing official: _____

Position of signing official: _____--

Company name: _____

Company phone number: _____

Notary signature: _____

Notarized Specified Risk Materials Statement Form

This serves to inform officials of the United States Department of Agriculture's Animal and Plant Health Inspection Service that _____ (Plant's name), located at

(Plant's street address, including City, State, and Zip Code) does NOT include any of the following materials in items destined for export to the European Union:

- Skull, brain, eyes, vertebral column excluding the vertebrae of the tail and the transverse processes of the lumbar vertebrae, but including dorsal root ganglia and spinal cord of bovine animals over 12 months;
- Tonsils and intestines from the duodenum to the rectum of bovine animals of all ages;
- Skull, brain, eyes, tonsils, and spinal cord of sheep or goats that were over 12 months or which have a permanent incisor erupted through the gum, and the ileum and spleen of sheep and goats of all ages;
- Mechanically recovered meat produced after 03/31/01 from the bones of bovine, caprine, or ovine animals;
- Material from animals that were slaughtered by means of gas injection into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous system by means of elongated rod-shaped instrument introduced into the cranial cavity.

Furthermore, this notarized form certifies that materials produced at this facility destined for export to the EU will not be commingled or cross-contaminated with any of the above Specified Risk Materials. To ensure that product produced for export to the EU has not been commingled with any Specified Risk Materials, this facility (check one of the below options):

- ___ Does not receive, store, or process any Category 1 or 2 Materials; OR
- ___ Utilizes a **Separation Protocol** as described in the "Small Entities Compliance Guide for Renderers, FDA Guidance to Industry 67"; OR
- ___ Utilizes a **Clean-out Protocol** as described in the "Small Entities Compliance Guide for Renderers, FDA Guidance to Industry 67"; OR
- ___ Utilizes a **Separation and Clean-out Protocol** as described in the "Small Entities Compliance Guide for Renderers, FDA Guidance to Industry 67."

I certify that the statements listed above are true to the best of my knowledge and belief.

Signed by: _____ Date: _____

Printed name of signing official: _____

Position of signing official: _____ --

Company name: _____

Company phone number: _____

Notary signature: _____

APPENDIX ONE 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 pet food, spray dry, blender, and digest facilities to separate prohibited Category 1 and Category 2 materials from permitted materials.

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 incoming material is received until the time finished products are shipped. 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 ensure 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 that 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 should be 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.