

U.S. Category 3 Material Rendering Facility Pre-Inspection Package

I. BACKGROUND

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

The former EU categorization of materials into “high-risk” and “low-risk” categories has been replaced by a categorization of material into the numbered categories: 1, 2, and 3. While at one time, some European Union countries would accept Specified Risk Materials (SRMs), now all SRMs must be removed from raw materials.

While the former regulations allowed the handling of “banned” material in approved facilities, as long as the material was not commingled with material to be exported, Regulation 1774/2002 specifies that rendering facilities producing processed animal protein or animal fats for animal consumption must be dedicated to Category 3 materials. ***However, the EU has agreed to temporarily allow (until October 31, 2005) rendering and processing facilities to handle Category 1 and 2 materials as long as these materials are kept separate from materials destined for export to the EU with no chance of commingling.*** Approvals granted to facilities which handle Category 1 or 2 materials will no longer be valid after October 31, 2005.

If facilities are handling SRMs and Category 1 or 2 materials, these prohibited materials must be kept separate from the materials destined for export to the EU. Materials destined 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.”

The new requirements apply to animal origin fats as well as animal origin proteins.

The EU requires rendering facilities to have a written self-inspection program in place which has critical control points (CCPs) established for each of the critical limits (reduction, time, temperature, pressure) applicable to their processing method and for microbiological test results. Rendering facilities must have a “process flow diagram” that shows the flow of material through their system. This diagram must identify the location of each CCP. The written plan must also include a procedure to be followed if one of the critical limits is not achieved. Records of these CCPs must be kept for 2 years.

With very few exceptions, only mammalian (other than dairy) and avian materials derived from carcasses approved for human consumption may be included in product produced for export to the EU. Some exceptions include hides and skins, hooves and horns, pig bristles, poultry heads, poultry feet, poultry intestines, and feathers from animals that passed ante-mortem inspection.

Rendering facilities must have in place a written plan for testing for physiochemical residues.

The new regulation also requires facilities to meet certain minimum requirements for sanitation and hygiene.

Laboratories conducting required laboratory testing must be approved by the Animal and Plant Health Inspection Service (APHIS). In-house laboratory facilities will be inspected by APHIS during the facility inspection. Off-site facilities, if not already approved by APHIS for this testing, will need to schedule separate inspections.

Facilities approved by other entities may present a letter from that authority describing in detail the approval process utilized by that entity. If the approval process addresses all APHIS criteria addressed in the U.S. Laboratory Inspection Checklist, APHIS may determine to consider that approval equivalent.

II. PRE-INSPECTION PROCEDURES

Prior to the scheduling of the inspection, the following documents should be forwarded to the area office with a cover letter stating the desire of the plant to be approved to export what products to the EU, and specifying contact information for a plant official who will serve as the contact with Veterinary Services:

1. Category 3 Material Notarized Form
2. Notarized Specified Risk Material Form
3. Notarized Approved Laboratory Form
4. Written Self-inspection Program
5. Process flow diagram
6. "Notarized Processing Method Form," or "Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form," or multiple forms if more than one processing method is utilized at the plant. If multiple processing methods are utilized, the forms should indicate what product is produced with each method.
7. If alternative heat treatment Method 7 is utilized by the plant, **copies of the laboratory results** summarized on the "Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form" must be included.
8. Purification Form (required for producers of rendered fats)

The above noted documents should meet the following specifications:

All forms must be the specific versions included in this document. All forms listed above should be notarized. The notarized forms should also list the position that the signatory holds in the company. The position 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 Form should not be endorsed by the labeling officer.

Below is more detail concerning the requirements of the above forms.

A. Category 3 Material Notarized Form

The document must verify that only Category 3 Materials are included in materials destined for export to the EU, and specify the suppliers of these Category 3 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 animals (except mammals).

B. Notarized Specified Risk Material Form

This form must be the exact “Notarized Specified Risk Materials Statement Form” included in this document.

Effective October 1, 2003 the EU is expanding 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.

C. Notarized Approved Laboratory Form

This form must specify details of any laboratory conducting the required testing.

D. Self-Inspection Program

This program must have all of the following elements in writing:

- Procedures to follow if a critical limit is not met: If product is produced without meeting a critical limit, the plan must state that the area office will be notified that the material is: a) destroyed, b) reprocessed, or c) sold domestically.
- Specific critical control points (CCPs) and critical limits are listed below:
- Particle size: The critical limit listed in the plan must be the same as the critical limit listed in the Processing Method Table for the processing method utilized in the “Notarized Processing Method Form” (p 17) or the “Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form” (p 19). For example, if Processing Method 1 is utilized by the facility, the critical limit for the particle size is a maximum size of 50 mm.

- Processing time: The critical limit listed in the plan must be the same as the critical limit listed in the Processing Method Table for the processing method utilized in the “Notarized Processing Method Form” or the “Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results.”
- Processing temperature: The critical limit listed in the plan must be the same as the critical limit listed in the Processing Method Table for the processing method utilized in the “Notarized Processing Method Form” or the “Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form.”
- Processing pressure: This requirement is for those renderers using Processing Method 1, and possibly for those renderers using Processing Method 7. Facilities using Processing Method 1 must have a critical limit minimum of 3 bars. For renderers using Alternative Heat Treatment, Method 7, the area office should review the “Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form.” If this summary indicates that pressure treatment is utilized in the process, the appropriate CCP and critical limit should be noted in the plan.
- Salmonella: The plan must indicate a critical limit for each batch of product. The critical limit must be an absence of Salmonella in 25 g of product ($n = 5$, $c = 0$, $m = 0$, $M = 0$).
- Enterobacteriaceae: The plan must indicate a critical limit for each batch of product. The critical limit should be a maximum of an “m” value of 10 for the number of bacteria in all samples ($n = 5$, $c = 2$, $m = 10$, $M = 300$ in 1 g).
 - ❖ N = number of samples to be tested;
 - ❖ m = threshold value for the number of bacteria: the result is considered satisfactory if the number of bacteria in all samples does not exceed m ;
 - ❖ M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
 - ❖ c = number of samples the bacterial count of which may be between m and M , the sample still being considered acceptable if the bacterial count of the other samples is m or less.

E. Process Flow Diagram

The written process flow diagram must demonstrate where each of the CCPs is located in the process. For any required critical limit (see above), a CCP location must be noted.

F. Processing Method Forms

All renderers must supply either a “Notarized Processing Method Form” (if they are using processing Methods 1,2,3,4,5, or 6) or a “Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form” (if they are using alternative heat treatment method 7).

Notarized Processing Method Form (p 19): The Processing Method Table must list which method is being utilized. Method 6 may not be utilized if any material other than fishmeal is processed. The critical limits listed in the Processing Method Table must meet the requirements noted in the Processing Methods Table for the method selected.

“Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form” (p 21): The “Details of Alternative Method Tested” Form must establish critical limits and CCPs for at least particle size and temperature. Critical limits must be included for the following parameters if they are part of the method utilized: absolute time, pressure, raw material feed-rate, and fat recycling rate. The three microbiological test result charts on the form should also be reviewed. The 30 *Clostridium perfringens* results should all show an absence of the bacteria. The 30 Salmonella test results should all show an absence of Salmonella. The 30 Enterobacteriaceae results should all show an “m” value less than or equal to 10.

If a previously approved facility is using the same (exact) processing method, and any of the above tests were completed for 30 consecutive days previously, then these prior laboratory tests may be utilized to fulfill part of this requirement.

G. Purification Form

The facility must present you with this form describing their purification process with laboratory results attached method has been tested and found to not have greater than 0.15 % total insoluble impurities. Laboratory results must be attached. These laboratory tests do not need to be conducted at an APHIS approved laboratory, but MUST state that the tested material does not contain total insoluble impurities exceeding 0.15 % in weight. Alternatively, the report may state what the level of total insoluble impurities by weight is, and that level must be 0.15 or less. The description of the purification process, should for example, state that the product is filtered through a filter with a specific pore size.

III. INSPECTION

A plant management official with knowledge of the plant’s operations and all issues addressed in the attached checklist should accompany the inspector during the inspection. The plant official should review the inspection checklist before the inspection and be prepared to provide evidence that the facility is adequately addressing each item. Also note that the facility must be producing product during the inspection, and the facility should be prepared to demonstrate all required sample collections.

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 “process flow diagram” showing the flow of material through their system. This diagram must identify the location of each CCP.
2. A written “self-inspection” program that has critical control points established for each of the critical limits (reduction, time, temperature, pressure) applicable to their processing method and for microbiological test results. This written plan must also include a procedure to be followed if one of the critical limits is not achieved.
3. Records of CCP monitoring should be available for at least 2 years, or since the program was implemented if less than 2 years.
4. A completed “Notarized Category 3 Material Notarized Form for Renderers,” declaring that the facility only handles Category 3 Material.
5. A completed “Notarized Specified Risk Materials Statement Form” declaring that the facility does not handle SRMs.
6. A completed “Notarized Approved Laboratory Form,” detailing the specifics of the laboratory conducting laboratory tests.
7. A written pest control program.
8. If the facility uses processing method 1, 2, 3, 4, 5, or 6, a completed “Notarized Processing Method Form.”
9. If the facility uses alternative processing Method 7, a completed “Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form,” including copies of the required laboratory test results.
10. A completed “Notarized Approved Laboratory Form.” If the laboratory is off-site, and the laboratory has not yet been approved by APHIS for this purpose, the plant official should have confirmed with the laboratory that they are willing to undergo the process to become APHIS approved.
- 11. *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.”***
12. Calibration records for gauges and measuring equipment.
13. A written plan for testing representative samples for physicochemical residues.
14. Records of regular cleaning of processing equipment and storage facilities.
15. Purification Form

16. A list of all types of the product categories produced at this plant. This list should include which of the following products are produced:

- | | |
|---|--|
| <input type="checkbox"/> bovine meat-and-bone meals | <input type="checkbox"/> bovine blood meal |
| <input type="checkbox"/> ovine (lamb and sheep) meat-and-bone meals | <input type="checkbox"/> ovine blood meals |
| <input type="checkbox"/> caprine (goat) meat-and-bone meals | <input type="checkbox"/> caprine blood meals |
| <input type="checkbox"/> porcine meat-and-bone meals | <input type="checkbox"/> porcine blood meals |
| <input type="checkbox"/> chicken meat-and-bone meals | <input type="checkbox"/> feather meals |
| <input type="checkbox"/> turkey meat-and-bone meals | <input type="checkbox"/> poultry blood meals |
| <input type="checkbox"/> fish meals | <input type="checkbox"/> other including mixed |
| <input type="checkbox"/> tallow | species product specified |
| <input type="checkbox"/> lard | here: _____ |
| <input type="checkbox"/> rendered poultry fat. | _____ |
| <input type="checkbox"/> catering waist | _____ |
| | _____ |

The inspector may then wish to go over the checklist with their plant tour guide to establish that all questions should be addressed during the tour. The guide should then guide the inspector through the facility, addressing each item on the checklist. At the end of the tour, the inspector should ask the guide to return to any areas necessary, or to show the evidence for any unanswered question.

During the inspection, the inspector should keep in mind the information he or she has reviewed in the supplied notarized forms and diligently observe for any indications of inaccuracies.

The inspector should look especially closely at the receiving area in the plant. If any intact feathered or haired carcasses are present, there is a high likelihood that the plant is processing “died in transits” or other carcasses that have not received post mortem inspection, and therefore should have a separation protocol in place.

The plant should be able to demonstrate records for any lot of finished product eligible for export to the EU. These records should include records of critical control points and raw materials of animal origin.

If the facility utilizes an “in-house” laboratory, then the laboratory director must be available in person for interview during the inspection.

IV. ANNUAL INSPECTION

Facilities must be inspected annually and are responsible for contacting the area office to arrange for the annual inspection. If more than 12 months have passed since the last inspection, the area office will not endorse export certificates.

Prior to the annual inspection, all documents (except for the test results) should be updated, notarized with the current date, and forwarded to the area office.

• **U.S. Rendering Facility Inspection Checklist**

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

2. Rendering facility/company name: _____.

3. Address of facility being inspected:

_____.

4. Address of headquarters if different from facility address:

_____.

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

6. ___Yes ___No Has the plant provided you with a current notarized "Category Three Material Notarized Form for Renderers"? Please attach to this checklist and forward to NCIE.

7. ___Yes ___No Has the plant provided you with a current Notarized Specified Risk Materials Statement Form? Please attach to this checklist and forward to NCIE.

8. ___ Yes ___ No Has the plant provided you with either a current "Notarized Processing Method Form" or a current "Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form?" Please attach to this checklist and forward to NCIE. Please note specifics if multiple processing methods are utilized to produce product for export to the EU: _____

9. _____ Which processing method(s) is (are) utilized by the plant? (Please place appropriate Method Number from the "Processing Method Table" (p 9 below) in the blank.)

10. ___ Yes ___ No ___ N/A If processing method 7 is utilized, does the area office have on file laboratory reports supporting the summaries included in the “Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form?”

Processing Methods Table

Method	Particle size	Time	Temperature	Pressure	Notes
1	< or =50 mm	20 min	133 C	3 bars	Batch or continuous.
2	<or =150 mm	125 min	100 C	Not required	Batch only.
		120 min	>110 C		
		50 min	>120 C		
3	< or = 30 mm	95 min	>100 C	Not required	Batch or continuous
		55 min	>110 C		
		13 min	>120 C		
4	< = 30mm in vessel with added fat:	16 min	>100 C	Not required	Batch or continuous
		13 min	>110 C		
		8 min	>120 C		
		3 min	>130 C		
5	< = 20 mm; heated until fat & water coagulate and can be removed	Proteinaceous Material then heated:		Not required	Batch or continuous
		120 min	>80 C		
		60 min	>100 C		
6= By-products reduced to ... in size, mixed with formic acid to reduce pH to ..., then store mixture for ... hours. Then introduced into a heat converter, heated to a core temperature of Then product must be separated into liquid, fat, and greaves. To obtain protein concentrate, the liquid phase must be pumped into two heat exchangers which are steam-heated and equipped with vacuum chambers. The greaves portion must then be reincorporated prior to storage.					Fishmeal only
7					Explained below

Method 7: Any method approved by the competent authority where it has been demonstrated that the final product has been sampled on a daily basis for a month in compliance with the following microbiological standards:

(a) Samples taken directly after heat treatment: *Clostridium perfringens* absent in 1 g.

(b) Sample taken during or upon withdrawal from storage at the processing plant:

Salmonella: absence in 25 g: n = 5, c = 0, m = 0, M = 0 and

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 g

- Where: N = number of samples to be tested;
- m = threshold value for the number of bacteria: the result is considered satisfactory if the number of bacteria in all samples does not exceed m;
- M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
- c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less

(c) Facility must submit a completed “Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form” Form with acceptable laboratory results attached, unless a completed form is already on file at the area office.

11. ___ Yes ___ No Did the plant show you a written “Self Inspection” program meeting the requirements outlined in section II. D. (p 3-4) of the **U.S. Rendering Facility Pre-Inspection Package**?

12. ___ Yes ___ No Did the plant provide you a “process flow diagram” that follows the material through the system and that identifies the location of each CCP? Please attach to this checklist and forward to NCIE.

13. ___ Yes ___ No Has the facility established Critical Control Points (CCPs) for the heat treatment including raw material particle size, temperature achieved during the heat treatment, pressure applied to the raw material (where applicable – method one), and duration of the heat treatment process or feed rate to a continuous system?

14. ___ Yes ___ No Has the facility established minimum standards for each CCP noted in question 13?

15. ___ Yes ___ No Is the plant maintaining CCP records for 2 years (or since the beginning of the CCP implementation if less than 2 years)?

16. ___ Yes ___ No Did the facility show you written records of calibrations from gauges and other measuring equipment such as thermometers done within a year, and are these records maintained for at least 2 years? (These records should show the method of calibration.)

17. ___ Yes ___ No Was the management able to show you the monitoring (measuring) equipment for each of their critical control points (minimally time, temperature, and where applicable pressure as noted in the above “Processing Methods Table”)?

18. ___ Yes ___ No Was the management able to show you the recording devices that continuously record the results of the measurements noted in question 17?

19. ___ Yes ___ No Did you view the plant collecting five samples of a batch in storage, and verify that their collection process appears to be random and to lead to collection of adequate amounts of sample (five at least 25 gram samples)?

20. ___ Yes ___ No Has the facility completed a “Notarized Approved Laboratory Form”? (Please attach a copy of the notarized form to this checklist.)

21. ___ 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.)*

22. ___ Yes ___ No Does the facility have separate “clean” and “unclean” areas, with a clear distinction between areas for the unloading of incoming by-products and areas for processing and storage?
23. ___ Yes ___ No Does the facility have a covered area for receiving raw materials? If the answer is “no”, but the facility is saying that they will have a covered area by a certain date, please place that date here: _____.
24. ___ Yes ___ No Is the receiving area easily cleaned (no dirt or gravel floors)?
25. ___ Yes ___ No Are floors constructed to facilitate draining (no large areas of standing water)?
26. ___ Yes ___ No Are there restrooms including facilities for personnel to change clothes and wash hands, accessible to all employees?
27. ___ Yes ___ No Is there hot water available?
28. ___ Yes ___ No Is there a designated area for cleaning containers and receptacles used for transporting the unprocessed (raw) materials?
29. ___ Yes ___ No Does the plant have in place a system where personnel working in the unclean sector of the plant must change clothes and change or disinfect footwear prior to moving from the unclean to the clean areas of the plant?
30. ___ Yes ___ No Does the plant have in place a system where equipment and utensils are cleaned and disinfected prior to moving from the unclean to the clean sector of the facility?
31. ___ Yes ___ No Did the plant show you a written “pest control program” that addressed rodent and insect control at the plant?
32. ___ Yes ___ No Did you observe any obviously unhygienic conditions (such as loose animals on the production floor) during your inspection? (Attach explanation if answering “yes.”)
33. ___ Yes ___ No Did the facility and equipment appear to be in good repair (e.g., no large holes in walls or roof)? (Attach explanation if answering “no.”)
34. ___ Yes ___ No Does the facility either have adequate facilities for disinfecting the wheels of vehicles delivering by-products, or a protocol in place to prevent these vehicles from entering “clean” areas of plant premises?
35. ___ Yes ___ No Does the facility have an area to check incoming material for the presence of extraneous matter (such as packaging, metal, etc.) and for the removal of such matter from material prior to processing?

36. ___ Yes ___ No Does the plant have measures to prevent condensation inside bins, conveyors, or elevators (is there liquid dripping from above without some equipment to catch the liquid before it comes into contact with material processed)?

37. ___ Yes ___ No Does the facility have records of regular cleaning of processing equipment and storage facilities?

38. ___ Yes ___ No ___ N/A If the facility uses a "batch system," does the facility monitor temperature with a permanent thermocouple and plot temperature against real time?

39. ___ Yes ___ No ___ N/A If the facility uses a "batch system," and if pressure is a CCP, does the plant monitor pressure with a permanent pressure gauge, and plot pressure against real time?

40. ___ Yes ___ No ___ N/A If the facility uses a "batch system," does the facility have both time/temperature and time/pressure diagrams?

41. ___ Yes ___ No ___ N/A If the facility uses a "continuous system," are temperature and pressure monitored with either thermocouples or an infrared gun, and are temperature and pressure plotted against real time?

42. ___ Yes ___ No ___ N/A If the facility uses a "continuous system," are there defined positions in the processing system where pressure gauges are present?

43. ___ Yes ___ No ___ N/A If the facility uses a "continuous system," has the facility measured minimum transit time inside the entire relevant part of the system, using insoluble markers, or another method offering equivalent guarantees?

44. ___ Yes ___ No Does the plant have in place a written plan of action to implement if one of the critical limits is not reached during the processing of product, and does this plan specify that APHIS will be contacted if product is produced without meeting the critical limit?

45. ___ Yes ___ No Does the plant have in place a written plan for a residue testing program for physiochemical residues?

46. ___ Yes ___ No ___ N/A If the facility utilizes an off-site laboratory for microbiology, is that laboratory approved by APHIS to conduct microbiological testing for exporters? (Please insert APHIS approval code here: _____.)

47. ___ Yes ___ No ___ N/A If the facility utilizes an in-house laboratory, did you inspect the laboratory and complete the "US Laboratory Inspection Checklist"? Please attach to this checklist and forward to NCIE.

48. Please check all of the species of the product categories produced *for export to the EU* at this plant:

- | | |
|---|--|
| <input type="checkbox"/> bovine meat-and-bone meals | <input type="checkbox"/> bovine blood meal |
| <input type="checkbox"/> ovine (lamb and sheep) meat-and-bone meals | <input type="checkbox"/> ovine blood meals |
| <input type="checkbox"/> caprine (goat) meat-and-bone meals | <input type="checkbox"/> caprine blood meals |
| <input type="checkbox"/> porcine meat-and-bone meals | <input type="checkbox"/> porcine blood meals |
| <input type="checkbox"/> chicken meat-and-bone meals | <input type="checkbox"/> feather meals |
| <input type="checkbox"/> turkey meat-and-bone meals | <input type="checkbox"/> poultry blood meals |
| <input type="checkbox"/> fish meals | <input type="checkbox"/> other including mixed |
| <input type="checkbox"/> tallow | species product specified |
| <input type="checkbox"/> lard | below: _____ |
| <input type="checkbox"/> rendered poultry fat | _____ |
| <input type="checkbox"/> catering waist | _____ |
| | _____ |

Please list all types of materials, if any, produced at this plant for export to the EU not listed above:

49. Yes No N/A If the facility produces rendered fats either for export to the EU, or for inclusion in animal food for export to the EU, has the plant provided you with a current notarized "Purification Form", with laboratory results attached showing that product produced using the plant's processing method does not exceed a level of .15 % by weight of total insoluble impurities, and have you verified that the plant uses the purification process described on the form? Please attach to this checklist and forward to NCIE.

50. Yes No N/A Does the facility produce any materials not eligible for export to the EU? If so, please list these materials here (using category descriptions as listed in question 48 above):

51. Comments:

52. Recommendation for approval to export:

Approve

Disapprove

Printed name of inspector

Signature of Inspector

Inspection Date

Signature of Veterinarian in Charge concurring
With recommendation in number 52.

Date

Please forward a copy of the completed form and all required notarized forms to the National Center for Import and Export, Animal and Plant Health Inspection Service, 4700 River Rd., Unit 40, Riverdale, MD 20737-1231 (telephone: 301-734-3277; fax: 301-734-8226).

NOTE: To maintain approval, facilities must be inspected at least once every 12 months.

US LABORATORY INSPECTION CHECKLIST

This checklist is available separately.

Category 3 Material Notarized Form for Renderers

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*).

___ 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 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 materials 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 for Renderers

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 materials 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 spleen and the ileum of sheep and goats of all ages;
- Mechanically recovered meat produced after 03/31/01 from the bones of cows, sheep, or goats;
- 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 processed 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: _____

Notarized Processing Method Form
(for facilities using processing methods 1, 2,3,4,5, or 6)

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), processes animal origin material using the below noted parameters: *(The notarized form should include the method used and the established critical limits. For the facility to be approved, one of the methods specified in the below Processing Methods Table, including the specified critical limit, must be utilized by the facility. If multiple processing methods are used, a separate form should be completed for each method. Each form should specify which products are produced utilizing this method.)*

Processing Methods Utilized Table

EU Approved Method	Particle size critical limit	Time critical limit	Temperature Critical limit	Pressure Critical limit *	Batch or continuous

* "Not Required" is acceptable for Methods 2,3,4,5, and 6, for "Pressure Critical limit."

Processing Methods Table

EU Approved Method	Particle size critical limit	Time critical limit	Temperature critical limit	Pressure critical limit	Notes critical limit
1	< or =50 mm	20 min	133 C	3 bars	Batch or continuous.
2	<or =150 mm	125 min	100 C	Not required	Batch only.
		120 min	>110 C		
		50 min	>120 C		
3	< or = 30 mm	95 min	>100 C	Not required	Batch or continuous
		55 min	>110 C		
		13 min	>120 C		
4	<= 30mm in vessel with added fat:	16 min	>100 C	Not required	Batch or continuous
		13 min	>110 C		
		8 min	>120 C		
		3 min	>130 C		
5	<= 20 mm; heated until fat & water coagulate and can be removed	Proteinaceous Material then heated:		Not required	Batch or continuous
		120 min	>80 C		
		60 min	>100 C		
6= By-products reduced to ... in size, mixed with formic acid to reduce pH to ..., then store mixture for ... hours. Then introduced into a heat converter, heated to a core temperature of Then product must be separated into liquid, fat, and greaves. To obtain protein concentrate, the liquid phase must be pumped into two heat exchangers which are steam-heated and equipped with vacuum chambers. The greaves portion must then be reincorporated prior to storage.					Fishmeal only

Signed by: _____ Date: _____

Printed name of signing official: _____

Position of signing official: _____

Company name: _____

Company phone number: _____

Notary signature: _____

Notarized Summary of Alternative Heat Treatment, Method 7, and Test Results Form

Please attach to this schedule a copy of test results from 30 days of consecutive testing. Laboratory results must indicate no detection of *Clostridium perfringens* during the testing period.

Name and full address of plant seeking certification:

Plant/company name:

Street address:

Mailing address:

City, State, Zip Code:

If multiple processing methods are used, a separate form should be completed for each method. Each form should specify which products are produced utilizing this method

Details of alternative method tested		
Processing parameter	Critical limit (for example maximum particle size)	Critical Control Point (where the measurement is taken)
Particle size (Mandatory)		
Temperature (Mandatory)		
Absolute time (as appropriate)		
Pressure (as appropriate)		
Raw material feed-rate (as appropriate)		
Fat recycling rate (as appropriate)		

Notarized Purification 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) utilizes a purification process in the production of rendered fats for export to the EU which produces a product that does not exceed 0.15 % total insoluble impurities in weight. This purification process involves (describe in general terms):

Attached are laboratory results for product produced using this purification system which show that the final product does not exceed 0.15 % total insoluble impurities in weight.

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: _____

Details of the Laboratory Conducting the Microbiological Testing

Laboratory name:

Street address:

Mailing address:

City, State, Zip Code:

Name of laboratory contact:

Telephone number of laboratory contact:

Facsimile number of laboratory contact:

Summary of Laboratory Results

Clostridium perfringens

Please fill in the table below with the results of laboratory tests for 30 consecutive days of microbiological testing for *Clostridium perfringens*. Please note, for APHIS to approve this facility for export of product to the EU, results must show no detections of *Clostridium perfringens*, in 1 gram samples, for 30 consecutive operating days. Samples must be taken directly after heat treatment.

Day	Date	Result	Day	Date	Result	Day	Date	Result
1			11			21		
2			12			22		
3			13			23		
4			14			24		
5			15			25		
6			16			26		
7			17			27		
8			18			28		
9			19			29		
10			20			30		

Salmonella Testing

Please fill in the table below with the results of laboratory tests for 30 consecutive days of microbiological testing for Salmonella. Please note, for APHIS to approve this facility for export of product to the EU, results must show the absence of Salmonella in 25 g (where: n = 5, c = 0, m = 0, M = 0)* for 30 consecutive operating days. Samples must be taken during or upon withdrawal from storage at the processing plant.

Day	Date	Result	Day	Date	Result	Day	Date	Result
1			11			21		
2			12			22		
3			13			23		
4			14			24		
5			15			25		
6			16			26		
7			17			27		
8			18			28		
9			19			29		
10			20			30		

Enterobactereaceae Testing

Please fill in the table below with the results of laboratory tests for 30 consecutive days of microbiological testing for Enterobactereaceae. Please note, for APHIS to approve this facility for export of product to the EU, results must show Enterobactereaceae results meeting the following parameters: n = 5, c = 2, m = 10, M = 300 in 1 gram*, for 30 consecutive operating days. Samples must be taken during or upon withdrawal from storage at the processing plant.

Day	Date	Result	Day	Date	Result	Day	Date	Result
1			11			21		
2			12			22		
3			13			23		
4			14			24		
5			15			25		
6			16			26		
7			17			27		
8			18			28		
9			19			29		
10			20			30		

* m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m ;
 M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more;
and
 c = number of samples the bacterial count of which may be between m and M , the sample still being considered acceptable if the bacterial count of the other samples is m or less

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 Approved Laboratory 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) has microbiological testing performed on product being exported to the European Union at the following laboratory:

Laboratory name:

Street address:

Mailing address:

City, State, Zip Code:

Approving/accrediting agency: _____ Number _____

Name of laboratory contact:

Telephone number of laboratory contact:

Facsimile number of laboratory contact:

Name of Laboratory Director:

Degrees and/or other qualifications of individual:

If laboratory is located off-site, please circle: This laboratory is a (circle type of laboratory) "commercial," "private," "federal," "state," or "university") laboratory.

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 for facilities to separate prohibited Category 1 and Category 2 materials from permitted materials. **Separation protocols will only be acceptable for renderers, for the time period that the EU grants derogation from the requirement that facilities be dedicated to Category 3 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 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 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 to 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.