Approval of Facilities to Process Animal Proteins Not Intended for Human Consumption for Export to the European Union

TAHD-DSAT-IE 2010-4-1

1. Purpose

The purpose of this document is as follows:

- to explain the European Union (EU) import requirements for processed animal proteins of Canadian origin not for human consumption; and
- to standardize Canadian Food Inspection Agency (CFIA) field inspections of processing facilities for these products.

This document does not cover the following:

- blood products (except blood meal), milk, milk-based products, colostrum, gelatine, hydrolyzed proteins, dicalcium phosphate, eggs and egg by-products, tricalcium phosphate and collagen; and
- pet foods prepared from these proteins.

2. Background

Regulation (EC) No. 1774/2002 establishes the requirements for the importation of animal by-products not intended for human consumption into the EU.

Chapter 1 of Annex VII to Regulation (EC) No. 1774/2002 mentions the general requirements, while Chapter II of Annex VII sets out the specific requirements for processed animal proteins.

Member states (MSs) must authorize imports of processed animal proteins if the following is true:

a) they originate from third countries that appear in the list of the following document: *List of third countries from which Member States may authorise imports of processed animal proteins (excluding fishmeal) (health certificate Chapter 1)*, or in the case of fish meals, in the list of this document: *List of third countries from which Member States may authorise imports of fishmeal and fish oil (health certificate Chapters 1 and 9)*;

Canada

b) they come from a processing plant approved by the;
c) they have been processed according to Regulation (EC) No. 1774/2002; and
d) they are accompanied by a health certificate that conforms to the model set out in Chapter I of Annex X to Regulation (EC) No. 1774/2002.

After they have been imported into the EU and before consignments are released for free circulation with the EU, the competent authority of the importing MS must sample imports of processed animal protein at the border inspection post to ensure compliance with the requirements of Chapter 1 (paragraph 10) of Annex VII to Regulation (EC) No. 1774/2002.

1. The competent authority of the MS must act as follows:

    a) sample each consignment of products carried in bulk; and
    b) carry out random sampling of consignments of products packaged in the manufacturing plant of origin.

2. However, when six consecutive tests on bulk consignments, originating in a given third country, prove negative, the competent authority may carry out random sampling of subsequent bulk consignments from that third country. If one of these random samples proves positive, the competent authority carrying out the sampling must inform the CFIA so that it can take the appropriate measures to remedy the situation. The CFIA must bring these measures to the attention of the competent authority carrying out the sampling. If a further positive result from the same source occurs, the competent authority of the MS must sample each consignment from the same source until six consecutive tests again prove negative.

3. Competent authorities of the MS must keep for at least two years a record of the results of sampling carried out on all consignments that have undergone sampling.

4. Where a consignment proves to be positive for salmonella, either of the following must occur:

    a) It must be dealt with in accordance with the procedure laid down by Article 17(2)(a) of Directive 97/78/EC(1); or
    b) It must be reprocessed in a processing plant that was approved pursuant to this regulation or decontaminated by a treatment authorized by the competent authority of the MS. A list of permitted treatments may be established in accordance with the procedure referred to in Article 32(2). The consignment must not be released until it has been treated, tested for salmonella by the competent authority in accordance with item 4.A.3 of the current directive, and a negative result obtained.

The regulation requires that the CFIA approve facilities exporting to or for transit through the EU the processed animal proteins not intended for human consumption. To grant this approval, the CFIA must consider such factors as the nature and origin of the raw material, the processing methods, the existence of self-inspection programs, the materials processed, the conditions of hygiene and storage, and the intended end use.

Prior to the CFIA's inspection of facilities, owners are required to submit to the CFIA for review specific forms attesting that the plant meets the minimum requirements. Following the pre-inspection review of these forms by the district office, an inspection of the facilities is scheduled.

3. Definitions

Approved processed animal proteins facility: those facilities approved by the CFIA to process animal proteins not intended for human consumption for export to the EU.

Blood meal: meal products derived from the heat treatment of blood or fractions of blood in accordance with Chapter II of Annex VII, and intended for animal consumption or organic fertilizers.

Fish meal: processed animal protein derived from sea animals, except sea mammals.

Processed animal proteins: animal proteins derived entirely from Category 3 material, which have been treated in accordance with Chapter II of Annex VII to render them suitable for direct use as feed material or for any other use in feeding stuffs, including pet food, or in organic fertilizers or soil improvers. However, these do not include blood products, milk, milk-based products, colostrum, gelatine, hydrolyzed proteins and dicalcium phosphate, eggs and egg-products, tricalcium phosphate and collagen.

4. Import Requirements

A. Processed Animal Proteins Not Intended for Human Consumption, Including Mixture and Products, Other Than Pet Food Containing Such Proteins

Import conditions are set out in Chapter I of Annex X to Regulation (EC) No. 1774/2002.

1. The following is true of the processed animal proteins, or product that contains these proteins:
   i. they have been produced exclusively from Category 3 material according to the EU definition (see Definition of Categories 1, 2, and 3 Animal Products and By-Products According to the European Legislation 1774-2002, or directive APHD-DSAE-IE-2009-9-1); and

ii. they have been subjected to the following processing standard:

a) heating to a core temperature of more that 133°C for at least 20 minutes without interruption at a pressure (Absolute) of at least 3 bars produced by saturated steam, with a particle size prior to processing of not more than 50 millimetres;

OR

b) for non-mammalian protein, other than fish meal, one of processing methods 1 to 5 or 7, as set out in Appendix D;

OR

c) for fish meal, processing method 6, as set out in Appendix D;

OR

d) for porcine blood, one of processing methods 1 to 5, as set out in Appendix D, and in the case of recourse to method 7, a heat treatment of at least 80°C.

2. The competent authority examined a random sample immediately prior to dispatch and found compliance with the following standards:

- Salmonella: Absence in 25 g: n = 5, c = 0, m = 0, M = 0
- Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1g

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.)
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).

The district office must ensure that all suppliers, other than federally inspected slaughter plants, are CFIA-approved (with a Traceability Certificate for processed animal proteins).

B. Processed Animal Proteins Intended for Pet Food

Import conditions are set out in Chapter (3B) of Annex X to Regulation (EC) No. 1774/2002.

1. The following is true of the processed animal proteins or product that contains these proteins:
   i. They were produced exclusively from Category 3 material according to the EU definition (see directive APHD-DSAE-IE-2009-9-1).
   ii. They were subjected to the following processing standard:

      a) for blood products – processed according to methods 1 to 5 or 7, as set out in Appendix D (For porcine blood and method 7, a heat treatment of at least 80°C has been applied.)

      b) for processed animal protein (other than fish meal) – processed according to methods 1 to 5 or 7, as set out in Appendix D (For method 7, a heat treatment of at least 80°C has been applied.)

      c) for fish meal – submitted to any of the processing methods or to a method and parameters to ensure that the product complies with the microbiological standards, as set out in item 4.A.3 of the current directive.

   iii. They were analyzed by random sampling of at least 5 samples from each processed batch taken during or after the storage in the processing plant, and in compliance with the following standards:

      - Salmonella: Absence in 25 g: n = 5, c = 0, m = 0, M = 0
      - Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1g

      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.)
      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).

The district office must ensure that all suppliers, other than federally inspected slaughter plants, are CFIA approved (with a Traceability Certificate for processed animal proteins).

5. Export Certification of Processed Animal Proteins Not Intended for Human Consumption to the EU

Prior to endorsing export certificates to the EU, district offices should ensure that the processing facilities have been granted final approval by the CFIA, and that they are included in the list of facilities approved for export to the EU.

6. Plant Approval for Export to the EU

See Approval of Facilities to Export Animal By-Products Not Intended for Human Consumption to the European Union (EU) (directive AHPD-DSAE-IE-2009-8-1).

a) Hygiene Requirements for Category 3 Intermediate Plants

See section IV.a of directive APHD-DSAE-IE-2009-8-1.

b) Hygiene Requirements for Category 3 Storage Plants

See section IV.b of directive APHD-DSAE-IE-2009-8-1.

c) Hygiene Requirements for Category 3 Processing Plants

See section IV.c of directive APHD-DSAE-IE-2009-8-1.

d) Supervision of Production

See section IV.d of directive APHD-DSAE-IE-2009-8-1.

e) Validation Procedures

See section IV.e of directive APHD-DSAE-IE-2009-8-1.

f) Plant's Own Checks – Hazard Analysis and Critical Control Points Type

For processing plants, the EU legislation requires that a self-inspection program, similar to the Hazard Analysis and Critical Control Point (HACCP), be in place. Table 1, below, shows the processing methods, critical control points, and critical limits for plants that process animal proteins.

See section IV.f of directive APHD-DSAE-IE-2009-8-1.

Table 1 – Processing methods, required critical control points and critical limits

Processing Method	CCPs: Particle Size (mm)[a]	CCPs: Temperature (°C)[a]	CCPs: Time (min) and Absolute Pressure (bars)[a]	System
1	- 50mm	133°C	20 min, 3 bars	Batch or continuous
2[b]	- 150mm - 150mm - 150mm	100°C 110°C 120°C	125 min 120 min 50 min	Batch
3[b]	- 30mm - 30mm - 30mm	100°C 110°C 120°C	95 min 55 min 13 min	Batch or continuous
4[b]	- 30mm - 30mm - 30mm - 30mm	100°C 110°C 120°C 130°C	16 min 13 min 8 min 3 min	Batch or continuous
5[b]	- 20mm - 20mm	80°C 100°C	120 min 60 min	Batch or continuous
6[c]	- 50mm - 30mm	90°C 70°C	60 min 60 min	Batch or continuous
7	see note [d]	see note [d]	see note [d]	

(a) This approach is mandatory to process animal protein of all mammalians that is intended for livestock feed.

(b) The animal by-products may be cooked in such a manner that the time temperature requirements are achieved at the same time.

(c) For Category 3 animal by-products of fish origin only.

(d) Any processing method approved by the CFIA where it has been demonstrated to that authority that the final product has been sampled on a daily basis over a period of 30 working days in compliance with the following microbiological standards:

1. Samples of material taken directly after heat treatment: Clostridium perfringens absent in 1 g of the products.
2. Samples of material taken during or upon withdrawal from storage at the processing plant:
   - Salmonella: Absence in 25 g: n = 5, c = 0, m = 0, M = 0
   - 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.)
   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).

7. Official Control and List of Approved Plants

See section V of directive APHD-DSAE-IE-2009-8-1.

8. Hygiene Requirements for the Collection and Transport of Animal By-Products and Processed Products

See section VI of directive APHD-DSAE-IE-2009-8-1.

9. Pre-Inspection Procedures

Prior to scheduling the facility's inspection, the district office must forward the following documents to plant management:

1. Notarized Approved Supplier Form (Appendix A)
2. Notarized Processing Method Form Used for Animal Proteins at Processing Facilities (Appendix B)

Prior to CFIA inspection of the plant, the plant management must complete and forward these documents to the district office.

Prior to plant inspection, the district office should confirm that the required forms have been provided and that they meet all requirements. All forms should be notarized and should list the position of the signatory in the company. The title indicates that the individual could be expected to have knowledge of the information included in the notarized form. These notarized documents should be updated (signed and provided to the district office) yearly.

10. Notarized Approved Supplier Form

The facility must provide a Notarized Approved Supplier Form (Appendix A), declaring that it only receives materials of Category 3, from either federally inspected slaughter facilities, or provincially inspected slaughter facilities with a veterinary inspector on site full time. The forms must identify the supplying facilities.

11. Notarized Processing Method Form for Animal Proteins Used at Processing Facilities

The form (Appendix B) also requires the facility to certify that it has in place a self-inspection program with the required critical limits.

12. Inspection Procedures

Prior to arriving at the plant for an inspection, the inspector should review the forms already sent to the district office, as well as the inspection checklist.

The inspection should begin in the plant management office. The required forms and the plant self-inspection program should be reviewed with plant management at this time.

The inspector may then wish to review the checklist – CFIA Plant Inspection Checklist for Approval of Facilities to Export Processed Animal Protein Not Intended for Human Consumption to the European Community *(*(Appendix C) – with a plant guide to establish the questions that should be addressed during the tour. The guide should then take 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 deemed necessary to revisit or to provide evidence for any unanswered questions.

During inspections, inspectors should keep in mind the information reviewed in the supplied notarized forms and the self-inspection plan, and diligently observe for any indication of inaccuracies.

13. Billing for Inspections

See section IX of directive APHD-DSAE-IE-2009-8-1.

14. Inspection Reports

See section X of directive APHD-DSAE-IE-2009-8-1.

15. Approval Numbers

See section XI of directive APHD-DSAE-IE-2009-8-1.

16. Facility Name or Address Changes

See section XII of directive APHD-DSAE-IE-2009-8-1.

Appendices

- *Appendix A: Notarized Approved Supplier Form*
- *Appendix B: Notarized Processing Method Form for Facilities Processing Animal Proteins*
- *Appendix C: CFIA Plant Inspection Checklist for Approval of Facilities*
- *Appendix D: List of Processing Methods Approved by the European Union*

Appendix A: Notarized Approved Supplier Form

This serves to inform Canadian Food Inspection Agency (CFIA) officials that

_____

located at _____

_____
(Plant's street address, including city, province, and postal code)

only receives raw animal by-products of Category 3, according to the European Union (EU) definition, to be processed for eventual export to the EU as processed animal proteins not intended for human consumption from the following facilities:

Facility Name	City (Country)	CFIA Facility Approval #

I certify that I fully understand the EU definition of "Category 3 material" and that the statements listed above are true to the best of my knowledge and belief.

Signed by: _____ Date: _____

Position: _____

Company name: _____

Notary signature: _____

Appendix B: Notarized Processing Method Form for Facilities Processing Animal Proteins

This serves to inform Canadian Food Inspection Agency (CFIA) officials that

_____

located at _____

_____

(Plant's street address, including city, province, and postal code)

processes animal proteins from _____ (species), using the processed method below (check appropriate selection), and has in place a self-inspection program with the critical limits referenced:

Table 2 – Checklist - Processing methods, required critical control points and critical limits

Check ✓	Processing method	CCPs: Particle Size (mm)[a]	CCPs: Temperature (ºC)[a]	CCPs: Time (min) and Absolute Pressure (bars)[a]	System
	1	- 50mm	133°C	20 min, 3 bars	Batch or continuous
	2[b]	- 150mm - 150mm - 150mm	100°C 110°C 120°C	125 min 120 min 50 min	Batch
	3[b]	- 30mm - 30mm - 30mm	100°C 110°C 120°C	95 min 55 min 13 min	Batch or continuous
	4[b]	- 30mm - 30mm - 30mm - 30mm	100°C 110°C 120°C 130°C	16 min 13 min 8 min 3 min	Batch or continuous
	5[b]	- 20mm - 20mm	80°C 100°C	120 min 60 min	Batch or continuous
	6[c]	- 50mm - 30mm	90°C 70°C	60 min 60 min	Batch or continuous
	7	see note [d]	see note [d]	see note [d]	

(a) This approach is mandatory to process animal protein of all mammalians that is intended for livestock feed.

(b) The animal by-products may be cooked in such a manner that the time temperature requirements are achieved at the same time.

(c) For Category 3 animal by-products of fish origin only.

(d) Any processing method approved by the CFIA where it has been demonstrated to that authority that the final product has been sampled on a daily basis over a period of 30 working days in compliance with the following microbiological standards:

1. Samples of material taken directly after heat treatment: Clostridium perfringens absent in 1 g of the products.
2. Samples of material taken during or upon withdrawal from storage at the processing plant:
   - Salmonella: Absence in 25 g: n = 5, c = 0, m = 0, M = 0
   - 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.)
   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).

Comments:

_____

_____

_____

I certify that I fully understand the EU definition of "Category 3 material" and that the statements listed above are true to the best of my knowledge and belief.

Signed by: _____ Date: _____

Position: _____

Company name: _____

Notary signature: _____

Appendix C: CFIA Plant Inspection Checklist for Approval of Facilities

1. Canadian Food Inspection Agency (CFIA) Approval Number: _____

2. Plant/Company name: _____

3. Address of location being inspected: _____

_____

4. Address of headquarters if different: _____

_____

5. Contact person at plant: _____

Telephone: _____ Facsimile: _____

6. Processed animal proteins produced at this plant for export to the EU:

☐ Porcine meat and bone meal

☐ Poultry meat and bone meal

☐ Feather meal

☐ Blood meal

☐ Porcine

☐ Fish meal

☐ Other

7. Observations: _____

_____

_____

8. Recommendation for approval to export to the EU (Check all that apply):

a.	Porcine meat and bone meal	☐ Yes	☐ No
	Poultry meat and bone meal	☐ Yes	☐ No
	i. for pet food and fur animals	☐ Yes	☐ No
	ii. for fertilizer	☐ Yes	☐ No
b.	Non-ruminant blood meal	☐ Yes	☐ No
	Fish meal	☐ Yes	☐ No
	i. for feed for non-ruminants	☐ Yes	☐ No
	ii. for pet food and fur animals	☐ Yes	☐ No
	iii. for fertilizer	☐ Yes	☐ No

_____ _____
Approved Disapproved

_____
Name of inspector (printed)

_____ _____
Signature of inspector Inspection date

_____ _____
Signature of area network export specialist concurring with the recommendation in number 8 Date

Approval valid until (date): _____

Please forward a copy of the completed form and all notarized forms to the CFIA area network export specialist.

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

Checklist

1. ☐ Yes ☐ No Has the plant provided you with a **current notarized approved supplier form?** (Please attach to this checklist, and forward to area network export specialist.)
2. ☐ Yes ☐ No Has the plant provided you with a current **notarized processing method form for animal proteins used at processing facilities?** (Please attach to this checklist, and forward to area network export specialist.)

Checklist for Intermediate Plants

3. ☐ Yes ☐ No The premises are adequately separated from other premises such as slaughterhouses.
4. ☐ Yes ☐ No The layout of plants ensures the total separation of Category 1 and Category 2 material from Category 3 material, from reception until dispatch.
5. ☐ Yes ☐ No The plant has a covered space to receive animal by-products.
6. ☐ Yes ☐ No The plant is constructed in a way that eases cleaning and disinfection. Floors are laid down in a way that facilitates the draining of liquids.
7. ☐ Yes ☐ No The plant has adequate lavatories, change rooms, and wash basins for staff.
8. ☐ Yes ☐ No The plant has appropriate arrangements for protection against pests such as insects, rodents, and birds.
9. ☐ Yes ☐ No The plant has a waste water disposal system that meets hygiene requirements.
10. ☐ Yes ☐ No The plant has suitable temperature-controlled storage facilities of sufficient capacity for maintaining animal by-products at appropriate temperatures, and is designed to allow the monitoring and recording of those temperatures.
11. ☐ Yes ☐ No The plant has adequate facilities for cleaning and disinfecting the containers or receptacles in which Category 3 material is received, as well as the vehicles in which they are transported. Adequate facilities are provided for disinfecting vehicle wheels.
12. ☐ Yes ☐ No The sorting of Category 3 material is carried out in a way that avoids any risk of the propagation of animal diseases.
13. ☐ Yes ☐ No During sorting or storage, Category 3 material is handled and stored separately from goods besides other Category 3 material, and in a way that prevents any propagation of pathogens.

14. ☐ Yes ☐ No Category 3 material is stored properly, and, where appropriate, chilled or frozen, until re-dispatched.

Checklist for Storage Plants

15. ☐ Yes ☐ No Premises that store processed products derived from Category 3 material must not be at the same site as premises storing processed products derived from Category 1 or Category 2 material, unless in a completely separate building.

16. ☐ Yes ☐ No The plant has a covered space to receive and store animal by-products.

17. ☐ Yes ☐ No The plant is constructed in a way that eases cleaning and disinfection. Floors are laid down in a way that facilitates the draining of liquids.

18. ☐ Yes ☐ No The plant has adequate lavatories, change rooms, and wash basins for staff.

19. ☐ Yes ☐ No The plant has appropriate arrangements for protection against pests such as insects, rodents, and birds.

20. ☐ Yes ☐ No The plant has adequate facilities for cleaning and disinfecting the containers or receptacles in which the products are received, as well as the vehicles, other than ships, in which they are transported. Adequate facilities are provided for disinfecting vehicle wheels.

21. ☐ Yes ☐ No Products are stored properly until re-dispatched.

Checklist for Processing Plants

22. ☐ Yes ☐ No Premises for the processing of animal by-products are not at the same site as slaughterhouses, unless located in a completely separate building. However, a conveyer system may link an individual processing plant to a slaughterhouse on the same site, provided that the following conditions are met:

   i. there are separate entrances, reception bays, equipment, exits, and personnel for the processing plant and the slaughterhouse;
   ii. the animal by-products to be processed originate on the same premises; and
   iii. unauthorized persons and animals do not have access to the processing plant.

23. ☐ Yes ☐ No The processing plant has clean and unclean sectors, adequately separated. The unclean sector has a covered place to receive animal by-products and is constructed in a way that eases cleaning and disinfection. Floors are laid in a way that facilitates the draining of liquids. The processing plant has adequate lavatories, change rooms, and wash basins for staff.

24. ☐ Yes ☐ No To prevent recontamination of the finished product by incoming animal by-products, a clear separation exists between the area of the plant that unloads incoming material for processing and those areas set aside for the processing of that product and the storage of the processed product.

25. ☐ Yes ☐ No The processing plant has adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received, as well as the vehicles (other than ships), in which they are transported.

26. ☐ Yes ☐ No Adequate facilities are provided for disinfecting wheels when vehicles are departing the unclean sector of the processing plant.

27. ☐ Yes ☐ No The processing plant has a waste water disposal system that meets the competent authority's requirements.

28. ☐ Yes ☐ No Animal by-products are processed as soon as possible upon arrival, and are stored properly until processed.

29. ☐ Yes ☐ No Containers, receptacles, and vehicles used for transporting unprocessed material are cleaned in a designated area, and that area is situated or designed to prevent the risk of contamination of processed products.

30. ☐ Yes ☐ No Persons who work in the unclean sector do not enter the clean sector without changing their work clothes and footwear, or without disinfecting the latter. Equipment and utensils are not taken from the unclean sector into the clean sector, unless first cleaned and disinfected. Personnel movement procedures are established to control the movement of personnel between areas and to prescribe the proper use of footbaths and wheel baths.

31. ☐ Yes ☐ No Preventative measures against birds, rodents, insects, and other vermin are taken systematically, and a documented pest control program is in place.

32. ☐ Yes ☐ No Cleaning procedures are established and documented for all parts of the premises. Suitable equipment and cleaning agents are provided.

33. ☐ Yes ☐ No Hygiene control includes regular inspection of the environment and equipment. Inspection schedules and results are documented and kept for at least two years.

34. ☐ Yes ☐ No Installations and equipment are kept in a good state of repair, and measuring equipment is calibrated at regular intervals.

35. ☐ Yes ☐ No Processed products are handled and stored at the processing plant in a way that precludes recontamination.

Checklist for Collection and Transport of Category 3 Material

Identification

36. ☐ Yes ☐ No Category 3 material is identified and kept separate from any other animal by-product and is identifiable during collection and transportation.

37. ☐ Yes ☐ No Processed products are identified and kept separate and are identifiable during transportation.

38. ☐ Yes ☐ No A marking substance for the identification of animal by-products or processed products of a specific category is used only for the category for which its use is required.

39. ☐ Yes ☐ No Animal by-products and processed products are dispatched from one location to another in packaging, containers, or vehicles that are prominently and, at least for the period of transport, indelibly colour-coded or well identified.

40. ☐ Yes ☐ No During transport, a label attached to the packaging, container, or vehicle must clearly indicate the category of the animal by-products or, for processed products, the category of animal by-products from which the processed products were derived.

Vehicles and Containers

41. ☐ Yes ☐ No Animal by-products and processed products are collected and transported in sealed new packaging or covered leak-proof containers or vehicles.

42. ☐ Yes ☐ No Vehicles and reusable containers, and all reusable items of equipment or appliances that come into contact with animal by-products or processed products, are handled as follows:
   i. cleaned, washed, and disinfected after each use; and
   ii. maintained in a clean condition.

43. ☐ Yes ☐ No Reusable containers are dedicated to the carriage of Category 3 material to the extent that is necessary to avoid cross-contamination.

Temperature Conditions

44. ☐ Yes ☐ No The transport of animal by-products takes place at an appropriate temperature to avoid any risk to animal or public health.

45. ☐ Yes ☐ No The design of vehicles used for refrigerated transport ensures the maintenance of an appropriate temperature throughout transport.

Checklist for Self-Inspection Plan

46. ☐ Yes ☐ No A written self-inspection program that meets the requirements outlined in section VII of this document is in place in the plant.

47. ☐ Yes ☐ No Critical Control Points (CCPs) for each of the critical limits noted in section VII of this document (for the appropriate processing method) have been established in the plant.

48. ☐ Yes ☐ No The records are maintained for two years (or since the beginning of the CCP implementation if less than two years) in the plant.

49. ☐ Yes ☐ No An effectiveness check is performed after the processing of the raw material.

50. ☐ Yes ☐ No The plant has in place a written plan of action to implement if one of the critical limits is not reached during the processing of the product, and this plan specifies that the CFIA will be contacted if the product is produced without meeting the critical limit.

_____

Name of inspector (printed)

_____ _____

Signature of inspector Inspection date

Appendix D: List of Processing Methods Approved by the European Union

Method 1

Reduction

1. If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature, and pressure

2. After reduction, the animal by-products must be heated to a core temperature of more than 133°C for at least 20 minutes without interruption at a pressure (Absolute) of at least 3 bars produced by saturated steam.[1] The heat treatment may be applied as the sole process or as a pre- or post-process sterilization phase.

3. The processing may be carried out in batch or continuous systems.

[1] All the air is evacuated and replaced by steam in the whole sterilization chamber.

Method 2

Reduction

1. If the particle size of the animal by-products for processing is more that 150 millimetres, the animal by-products must be reduced in size, using appropriate equipment, and set so that the particle size after reduction is not greater than 150 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 150 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature, and pressure

2. After reduction, the animal by-products must be heated to a core temperature greater than 100°C for at least 125 minutes, a core temperature greater than 110°C for at least 120 minutes, and a core temperature greater than 120°C for at least 50 minutes.

3. The processing must be carried out in a batch system.

4. The animal by-products may be cooked in such a manner that the time temperature requirements are achieved at the same time.

Method 3

Reduction

1. If the particle size of the animal by-products for processing is more than 30 millimetres, the animal by-products must be reduced in size, using appropriate equipment, and set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature, and pressure

2. After reduction, the animal by-products must be heated to a core temperature greater than 100°C for at least 95 minutes, a core temperature greater than 110°C for at least 55 minutes, and a core temperature greater than 120°C for at least 13 minutes.

3. The processing may be carried out in batch or continuous systems.

4. The animal by-products may be cooked in such a manner that the time temperature requirements are achieved at the same time.

Method 4

Reduction

1. If the particle size of the animal by-products for processing is more than 30 millimetres, the animal by-products must be reduced in size, using appropriate equipment, and set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature, and pressure

2. After reduction, the animal by-products must be placed in a vessel with added fat and heated to a core temperature greater than 100°C for at least 16 minutes, a core temperature greater than 110°C for at least 13 minutes, a core temperature greater than 120°C for at least eight minutes, and a core temperature greater than 130°C for at least three minutes.

3. The processing may be carried out in batch or continuous systems.

4. The animal by-products may be cooked in such a manner that the time temperature requirements are achieved at the same time.

Method 5

Reduction

1. If the particle size of the animal by-products for processing is more than 20 millimetres, the animal by-products must be reduced in size, using appropriate equipment, and set so that the particle size after reduction is no greater than 20 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 20 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature, and pressure

2. After reduction, the animal by-products must be heated until they coagulate, and then pressed so that fat and water are removed from the proteinaceous material. The proteinaceous material must then be heated to a core temperature greater than 80°C for at least 120 minutes and a core temperature greater than 100°C for at least 60 minutes.

3. The processing may be carried out in batch or continuous systems.

4. The animal by-products may be cooked in such a manner that the time temperature requirements are achieved at the same time.

Method 6

Reduction

1. The animal by-products must be reduced to at least the following:

   a) 50 mm in case of heat treatment in accordance with paragraph 2(a); or
   b) 30 mm in case of heat treatment in accordance with paragraph 2(b).

   They must then be mixed with formic acid to reduce and maintain the pH to 4.0 or lower. The mixture must be kept for at least 24 hours, pending further treatment.

Time, temperature, and pressure

2. Following reduction, the mixture must be heated to the following:

a) a core temperature of at least 90°C for at least 60 minutes; or
b) a core temperature of at least 70°C for at least 60 minutes.

When using a continuous flow system, the progression of the product through the heat converter must be controlled by means of mechanical commands, limiting its displacement in such a way that, at the end of the heat treatment operation, the product has undergone a cycle which is sufficient in both time and temperature.

Method 7

1. Any processing method approved by the competent authority where it has been demonstrated to that authority that the final product has been sampled on a daily basis over a period of one month in compliance with the following microbiological standards:

   a) For samples of material taken directly after heat treatment: Clostridium perfringens absent in 1 g of the products.

   b) For samples of material taken during or upon withdrawal from storage at the processing plant:
      - Salmonella: absence in 25 g: n = 5, c = 0, m = 0, M = 0
      - 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.)
      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).

2. Details of the critical control points under which each processing plant satisfactorily complies with the microbiological standards must be recorded and maintained so that the owner, operator, or their representative and the competent authority can monitor the operation of the processing plant. The information to be recorded and monitored must include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed rate, and fat recycling rate.

3. This information must be made available to the EU upon request.