

DOG AND CAT FOOD* CONTAINING NON-EXEMPT ANIMAL ORIGIN INGREDIENTS

***These requirements also pertain to dog/cat food vitamin and mineral supplements, e.g., chewable tablets.**

General Information

Taiwan prohibits the importation of dog and cat food from the United States with some exceptions as noted below.

- Dog and cat foods containing NO animal origin ingredients are permitted entry. [See entry on “Dog and cat food containing NO animal origin ingredients” for export certification requirements.]
- Dog and cat foods containing no animal origin ingredients except those derived from dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen are permitted entry. Dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and collagen are considered exempt or non-regulated ingredients. [See entry on “Dog and/or cat food containing NO animal origin ingredients except those derived from dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen” for export certification requirements.]
- Dog and/or cat chews containing no animal-origin ingredients other than hides (which includes poultry skins) plus or minus exempt animal origin ingredients (i.e., dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen) are permitted entry. [See entry on “Dog/cat chews containing hides but NO other animal-origin ingredients except dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen” for export certification requirements.]
- Dog and/or cat foods produced by manufacturing facilities inspected and approved by a competent government authority in the United States* for the production of dog or cat food. This document provides guidance on this category of dog and cat foods.

***Facility Approval by Competent Authority in the United States**

Currently, the only dog and cat food manufacturers eligible to export products to Taiwan with non-exempt animal origin ingredients are those that have been approved by the Taiwanese government’s Bureau of Animal and Plant Health Inspection Quarantine (BAPHIQ). Under Taiwan’s new requirements for dog and cat food and chews, which become effective October 1, 2014, the USDA’s Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) will be able to inspect and approve these facilities on behalf of Taiwan in accordance with the terms of a bilateral agreement. This agreement is currently being negotiated. Both APHIS/VS and the Taiwanese authorities (both animal and public health) must agree on a comprehensive inspection package, and the overall process that will enable APHIS/VS to assume this role.

In anticipation of the October 1, 2014 implementation date of the new requirements, and prior to a bilateral agreement on the approval process for new facilities, APHIS has proposed that Taiwan allow APHIS to re-inspect the facilities already approved by Taiwan to permit these facilities to use the newly allowed bovine* ingredients (e.g., U.S. origin protein free tallow; deboned skeletal muscle meat free of specified risk materials [SRMs], as defined by Taiwan), as well as either a dedicated line or approved cleanout/separation protocol in lieu of facility dedication. Until Taiwan agrees to this proposal, approved facilities will not be able to exercise these options. Although Taiwan's new requirements impose no restrictions on ovine or caprine ingredients (with the exception of ruminant meat-and-bone meal), and facilities should be able to use U.S. origin ovine meat and offal ingredients, these are not considered non-regulated (exempt) ingredients. We therefore advise facilities to not add any new ingredients (including ovine ingredients) to their products until the details are fully negotiated between APHIS/VS and BAPHIQ.

*Taiwan has agreed to accept bison ingredients in U.S. origin dog and cat foods from approved facilities, subject to the same requirements and restrictions as bovine ingredients. Bison ingredients may not be added to products for export to Taiwan, however, until we have a bilateral agreement on a re-approval process.

Until APHIS/VS reaches a bilateral agreement with Taiwan on the inspection criteria and processes required for approval of new facilities, dog and cat food manufacturers that wish to be approved for Taiwan may be able to request approval from Taiwan. As in the past, APHIS/VS will not be involved in arranging for these inspections. The Pet Food Institute (PFI) has volunteered to coordinate applications for inspections through the USDA representatives with the American Institute of Taiwan in Taipei, Taiwan.

For further information on the Taiwanese application and approval process, interested manufacturers should contact:

Pet Food Institute (PFI)
Phone: 202-367-1120
Fax: 202-367-2120
info@petfoodinstitute.org

APHIS/VS involvement in the overall approval process* has been limited to completion of a "Plant Certification for Manufacturers of Pet Food to be Exported to Taiwan." Manufacturers should contact their local VS Office for instructions on how to obtain this form after consulting with PFI. The VS Office must inspect the manufacturing facility before endorsing the form, and the manufacturer must also provide a notarized affidavit to the VS Office attesting to compliance with the required statements.

*As noted above, APHIS/VS is currently negotiating with Taiwan on inspection criteria and processes whereby APHIS/VS will inspect and approve manufacturing facilities for export of dog and cat food with non-exempt ingredients to Taiwan.

Once a facility is approved by Taiwan (and in the future, APHIS/VS), only products manufactured on or after the facility's approval date may be certified for export. Taiwan will not allow entry of products manufactured prior to the approval date.

Certification of Products for Export

APHIS/VS will only endorse export certificates for shipments of dog and cat food containing non-exempt ingredients to Taiwan from facilities currently approved by Taiwan. As noted above, APHIS/VS will begin approving U.S. dog and cat food manufacturers on behalf of Taiwan as soon as a bilateral agreement is reached on inspection criteria and processes.

Although the implementation date for Taiwan's new requirements for dog and cat food is officially October 1, 2014*, it will not be permissible for facilities currently approved by Taiwan to include the additional bovine ingredients allowed under the new requirements, nor will these facilities be able to exercise the options of using either a dedicated line or a cleanout/separation protocol in lieu of facility dedication until there is a bilateral agreement between APHIS/VS and Taiwan on a re-approval process.

***All shipments of non-exempt dog and cat food to Taiwan that are loaded on-board vessel on or after October 1, 2014, must be certified using the new certificates.**

The endorsing VS Office will review the VS internal database to be sure that the manufacturing/exporting facility(ies) is/are approved to export dog and cat food to Taiwan.

The VS 16-4 may NOT be used for these shipments. The certificates required for these exports, which have been bilaterally agreed to by APHIS/VS and Taiwan, are described below. The appropriate document(s) to use depends on whether the shipment includes products manufactured by ONE approved manufacturing facility OR the shipment includes products manufactured by two or more approved manufacturing facilities.

The certificates are as follows:

- “DOG/CAT FOOD CONTAINING ANIMAL ORIGIN INGREDIENTS (OTHER THAN DAIRY, FISH, GELATIN, DICALCIUM PHOSPHATE, CHONDROITIN, GLUCOSAMINE AND/OR COLLAGEN) EXPORTED TO TAIWAN (Short Form A).” This certificate is to be used for shipments containing products from a SINGLE approved manufacturing facility.*
- “DOG/CAT FOOD CONTAINING ANIMAL ORIGIN INGREDIENTS (OTHER THAN DAIRY, FISH, GELATIN, DICALCIUM PHOSPHATE, CHONDROITIN, GLUCOSAMINE, AND/OR COLLAGEN) EXPORTED TO TAIWAN (Long Form B).” This certificate is to be used for shipments containing products from TWO OR MORE approved manufacturing facilities. The detailed information on each manufacturing facility must be provided using the “Manufacturing Facility Addendum. “ An Addendum is needed for EACH manufacturing facility.

*A certificate continuation page (“Certificate Continuation Page”) may also be needed to provide the additional attestation(s) required if the consignment contains packages with labels that do NOT show the exact company name and address of the approved manufacturing facility identified on the certificate. This continuation page may be used for this purpose with both the Short Form A or the Long Form B.

To access the above referenced certificates in fillable adobe format, please close this document. That should return you to the page that includes this link (on general information) plus links for all the referenced documents.

[For more information on how to complete the referenced certificates, please see the following pages.](#)

DOG/CAT FOOD CONTAINING ANIMAL ORIGIN INGREDIENTS (OTHER THAN DAIRY, FISH, GELATIN, DICALCIUM PHOSPHATE, HONDROITIN, GLUCOSAMINE, AND/OR COLLAGEN) EXPORTED TO TAIWAN
(Short Form A)

This certificate is only to be used for a shipment/shipping container with dog/cat foods produced by a single manufacturing facility approved to export to Taiwan. Instructions for completion of the certificate are as follows:

1. Leave the “Certificate Number” and “Date” blocks at the top of each certificate page blank. These sections will be completed by the endorsing VS Office.
2. Complete the page number block to indicate the total number of pages in the certificate. [The total number of pages will be 3 unless a continuation page is needed. If one or more continuation pages are used, number accordingly, e.g., 4 of 4, 5 of 5.] The only continuation page allowed is the one provided by VS (“Certificate Continuation Page”), and it may only be used for the purposes approved by VS.
3. Leave the fillable space above the certificate title blank. This space is reserved for the endorsing VS Office and will only be used if a certificate “reissue” is needed.
4. Under the statement “This office has on file a notarized affidavit from,” enter the name of the company providing the notarized affidavit. If the company/exporter providing the affidavit is not the manufacturing company, an additional affidavit from the manufacturing company must be provided to the endorsing VS Office.
5. For statement #1, “The certified dog/cat food was produced at the following manufacturer approved by a competent government authority in the United States for the production of dog/cat food” enter the name and address of the approved manufacturing facility. DO not include the APHIS reference number for the manufacturing facility in this block or in any section of the certificate. NOTE: Until APHIS VS reaches agreement with Taiwan on inspection criteria and processes, only those facilities currently approved by Taiwan will be allowed to export on this certificate. This statement can be endorsed, however, based on the regulatory oversight of U.S. dog and cat food manufacturing facilities by the Food and Drug Administration (FDA).
 - a. The name and address of the manufacturing facility must be exactly as it is on the APHIS/VS database and as Taiwan records indicate. This includes the use of any abbreviations. The only exceptions to the requirement for the information to be exact are for “case” (upper vs. lower case) and State abbreviations (i.e., the standard 2-letter State code may be used in lieu of the entire State name).
 - b. Exporters should have manufacturing facilities consult with their local VS Office regarding any questions about the “exact” name and address of the facility (as recognized by Taiwan) OR if any changes are necessary.
6. For statement #2, approved facilities may only select the first option (facility dedication) until APHIS VS reaches agreement with Taiwan on the re-approval process necessary for facilities to use the other two options (i.e., dedicated line or cleanout/separation protocol). Please see page 12 for an explanation of the facility options and BSE risk materials as defined by Taiwan. Please see pages 13-14 for guidance on using a cleanout/separation protocol.

7. IF the shipment contains products that are not labeled with the EXACT same company name and address of the manufacturer identified under statement #1:
 - a. Add a statement in block #1 stating that “[Insert name and address of manufacturing facility] also produces the products included in this consignment labeled with the following company information: [insert company name(s) and address(es) that appears on the packages in the consignment.]”
 - b. IF there is not enough room for this statement, please use the “Certificate Continuation Page.” Under #1, put “See continuation page [indicate page number].”
 - c. If the “Certificate Continuation Page” is needed, please follow the guidance for this document (link on same page as link for “General Information.”)
8. For statement #3, “The certified dog/cat food was produced,” enter the date of production or the range of production dates.
 - a. Use a range of dates when there are multiple production dates.
 - b. The production date(s) must not be earlier than the date that the manufacturing facility was approved to export to Taiwan.
 - c. IF a range of dates is used, do NOT include future dates. The date or range of dates should not include any dates later than the date the certificate is endorsed.
9. For statement #4, “The certified dog/cat food was derived from animals of the following species,” enter the applicable species of origin of ALL animal origin ingredients in the certified dog/cat food. For dairy-origin ingredients, or fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen, the ingredient type should also be specified (e.g., “dairy (bovine)”).
10. For statement #5, select “A” if the certified dog/cat foods contain no bovine-origin ingredients (except dairy, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen). Select “B” if the dog/cat foods DO contain bovine-origin ingredients other than dairy, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen, and those bovine ingredients are sourced only from negligible BSE risk countries that have never reported a case of BSE. Select “C”** if the dog/cat foods contain bovine-origin ingredients other than dairy, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen, and one or more of those bovine ingredients was/were sourced from countries other than negligible BSE risk countries that have never reported a case of BSE. IF “B” or “C” is selected, list the bovine ingredients and the countries of origin. Exporters must provide the endorsing VS Office with copies of certificates for all imported bovine ingredients to verify country of origin. **NOTE: “C” will not be an option until APHIS VS and Taiwan reach an agreement for re-approval of currently approved facilities.
11. For statement #6 to be endorsed, the certified dog/cat foods must only contain eligible bovine ingredients as explained in footnote “ii.” NOTE: Currently approved facilities may only use the non-exempt bovine ingredients that were included in their initial approval until APHIS VS has a bilateral agreement on a re-approval process.
12. Statements #7 and #8 are stand-alone statements. These statements are not to be altered in any way. Adding, deleting, or amending any of the information in these statements is prohibited.
13. Leave the “Date”, “Signature”, “Printed name and title of the signatory” and “VS Office issuing certificate” sections blank. These sections will be completed by the endorsing VS Office.

14. In Section I, “Product description,”
 - a. Type of product: The type of product is already identified as “Dog/Cat Food.” Do NOT add any information to this description.
 - b. Type of packaging, number of packages and weight: In the fillable space provided, summarize the type of packaging, number of packages, and weights of the certified dog/cat foods. A “total weight” alone is NOT acceptable if items are individually packaged. The information must indicate the number of each type of package included. For example: “*500 pounds dry dog food (10-10 pound bag and 4-100 pound bags); 230 ounces canned cat food (20 -5.5 ounce cans, 40-3 ounce cans).*”
15. In Sections II-III, “Exporter name and address” and “Consignee name and address,” enter the relevant information.
16. In Section IV, “Identification of shipment,” enter pertinent information sufficient to link the products being exported with the certificate (e.g., container numbers, lot numbers or other similar identifying information appearing on other export documents accompanying the shipment).

SUBMISSION OF CERTIFICATE DOCUMENTS TO ENDORSING VS OFFICE:

1. Prior to submitting the certificate (with continuation pages, as applicable) to the endorsing VS Office:
 - a. Verify with the importer that all products to be exported are eligible for entry into Taiwan.
 - b. Ensure that the products being exported meet all limitations for the manufacturing facility’s approval.
 - c. Prepare the certificate and review it for accuracy and completeness (i.e., all applicable sections have been completed; there are no typos or incorrectly spelled words).
 - d. Ensure the supporting notarized affidavits have been prepared (i.e., the exporter’s notarized affidavit and the manufacturer’s notarized affidavit if the exporter is not the manufacturer).
 - e. Email the prepared certificate, together with copies of the required notarized affidavits and supporting export certificates for any bovinæ-origin ingredients other than dairy, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen.
2. **Notify the endorsing VS Office at the time of submission if the certificate is to replace a previously endorsed version.** There are specific procedures that must be followed with reissued certificates. Obtaining a second certificate for a shipment and failing to let the VS Office know that you are requesting a “reissue” could result in rejection of your shipment, or if the shipment is already onhold, a refusal by Taiwan to release it.

For instructions on how to complete the appropriate certificate for dog/cat foods manufactured by two or more facilities approved to export to Taiwan, please proceed to page 8.

**DOG/CAT FOOD CONTAINING ANIMAL ORIGIN INGREDIENTS (OTHER
THAN DAIRY, FISH, GELATIN, DICALCIUM PHOSPHATE,
CHONDROITIN, GLUCOSAMINE, AND/OR COLLAGEN) EXPORTED TO
TAIWAN
(Long Form B)**

This certificate is only to be used for a shipment/shipping container with dog/cat foods produced by multiple (two or more) manufacturing facilities approved to export to Taiwan. Instructions for completion of the certificate are as follows:

1. Leave the “Certificate Number” and “Date” blocks at the top of each certificate page blank. These sections will be completed by the endorsing VS Office.
2. Complete the page number block to indicate the total number of pages in the certificate. [NOTE: A “Manufacturing Facility Addendum” must be completed for EACH of the approved manufacturing facilities that produced dog/cat foods included in the shipment.]
3. Leave the fillable space above the certificate title blank. This space is reserved for the endorsing VS Office and will only be used if a certificate “reissue” is needed.
4. Under the statement, “This office has on file a notarized affidavit from,” enter the name of the company providing the notarized affidavit. The exporting company may or may not be one of the approved manufacturers that produced dog/cat foods included in the shipment. [Please note that notarized affidavits from the approved manufacturing companies must also be provided to the VS Office].
5. For statement #1, “The certified dog/cat food was produced at the following manufacturers approved by a competent government authority in the United States for the production of dog/cat food: See pages,” enter the applicable number of pages (e.g., 4-5, 4-6). This information will be provided on the “Manufacturing Facility Addendum” and there will be one addendum per approved manufacturing facility. The first addendum will be page 4, and subsequent copies of the addendum will be numbered consecutively. NOTE: Until APHIS/VS reaches agreement with Taiwan on inspection criteria and processes, only those facilities currently approved by Taiwan will be allowed to export on this certificate. This statement can be endorsed, however, based on the regulatory oversight of U.S. dog and cat food manufacturing facilities by the Food and Drug Administration (FDA).
6. For statement #2, “The certified dog/cat food was produced: See pages,” enter the page numbers for the addendums as noted in #5 above. The information on production dates or range of production dates will be provided for each approved manufacturing facility on the applicable addendum.
7. For statement #3, “The certified dog/cat food was derived from animals of the following species: See pages,” enter the page numbers for the addendums as noted in #5 above. This information will be provided for each approved manufacturing facility on the applicable addendum.
8. For statement #4, select the options that apply for the manufacturers of the dog/cat foods included in the shipment. If options “B” and/or “C” are selected, provide the information as requested about the non-exempt bovine ingredients and the countries of origin. Exporters must provide the endorsing VS Office with copies of certificates for all imported bovine ingredients to verify country of origin. **NOTE: “C” will not be an option until APHIS VS and Taiwan reach an agreement for re-approval of currently approved facilities.

9. For statement #5 to be endorsed, the certified dog/cat foods must only contain eligible bovine ingredients as explained in footnote “ii.” NOTE: Currently approved facilities may only use the non-exempt bovine ingredients that were included in their initial approval until APHIS/VS has a bilateral agreement on a re-approval process.
10. Statements #6 and #7 are stand- alone statements. These statements are not to be altered in any way. Adding, deleting, or amending any of the information in these statements is prohibited.
11. Leave the “Date”, “Signature”, and “Printed name and title of the signatory”, and “VS Office issuing certificate” sections blank. These sections will be completed by the endorsing VS Office.
12. In Section I, “Product description,”
 - a. Type of product: The type of product is already identified as “Dog/Cat Food.” Do NOT add any information to this description.
 - b. Type of packaging, number of packages, and weight: In the fillable block for “See pages,” enter the applicable number of pages (e.g., 4-5, 4-6). This information will be provided for each approved manufacturing facility on the applicable addendum.
13. In Sections II and III, “Exporter name and address” and “Consignee name and address,” enter the relevant information.
14. In Section IV, “Identification of shipment,” enter pertinent information sufficient to link the products being exported with the certificate (e.g., container numbers, lot numbers, or other similar identifying information appearing on other export documents accompanying the shipment).

MANUFACTURING FACILITY ADDENDUM:

1. As noted in Number 2 on the preceding page, the “Manufacturing Facility Addendum” must be used with the “DOG/CAT FOOD CONTAINING ANIMAL ORIGIN INGREDIENTS (OTHER THAN DAIRY, FISH, GELATIN, DICALCIUM PHOSPHATE, CHONDROITIN, GLUCOSAMINE, AND/OR COLLAGEN) EXPORTED TO TAIWAN (Long Form B).”
2. One “Manufacturing Facility Addendum” is used for EACH of the approved manufacturing facilities that produced dog/cat foods included in the shipment.
3. Instructions for completion of the “Manufacturing Facility Addendum” are as follows:
 - a. Under the statement “This office has on file a notarized affidavit from,” enter the name of the company (exporter) providing the notarized affidavit.
 - b. For statement #1, “The certified dog/cat food was produced at the following manufacturers approved by a competent government authority in the United States for the production of dog/cat food:” enter the full name and address of the pertinent approved manufacturer. NOTE: Until APHIS/VS reaches agreement with Taiwan on inspection criteria and processes, only those facilities currently approved by Taiwan will be allowed to export on this certificate. This statement can be endorsed, however, based on the regulatory oversight of U.S. dog and cat food manufacturing facilities by the Food and Drug Administration (FDA).
 - c. IF the approved manufacturing facility identified on this Addendum produced dog/cat foods included in the shipment which are not labeled with the EXACT same company name and address of the approved establishment, add a statement in this block that “[Insert name and address of manufacturing facility] also produces the products included

in this consignment labeled with the following company information: [insert name(s) and address(es) that appears on the packages in the consignment.]” If a continuation page is needed, enter “See continuation page [indicate page number].” Use the “Certificate Continuation Page” and follow the guidance for this document (link on same page as link for “General Information.”)

- d. For statement #2, approved facilities may only select the first option (facility dedication) until APHIS/VS reaches agreement with Taiwan on the re-approval process necessary for facilities to use the other two options (i.e., dedicated line or cleanout/separation protocol). Please see page 12 for an explanation of the facility options and BSE risk materials as defined by Taiwan. Please see pages 13-14 for guidance on using a cleanout/separation protocol.
 - e. Under #3, “Provide requested information for each product”, complete the table on the “Manufacturing Facility Addendum” per the instructions in #4 below.
4. Completion of “Manufacturing Facility Addendum” table:
- a. In the first column “Product name and/or number,” enter the names (or numbers if applicable) of the products manufactured by the approved facility identified in the section above the table.
 - b. In the second column “Number of packages,” enter the number of packages of each product name/number included in the shipment.
 - c. In the third column “Package size (including unit),” enter the pertinent information for each product identified in the first column (e.g., 1 pound bags; 5.5 ounce cans).
 - d. In the fourth column “Lot/Batch Number(s),” enter the pertinent information for each product identified in the first column.
 - e. In the fifth column “Species of origin of animal-origin ingredients,” enter the applicable species of origin of ALL animal origin ingredients for each product identified in the first column. For dairy-origin ingredients, or fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen, the ingredient type should also be specified (e.g., “dairy (bovine)”). For bovine ingredients other than dairy, gelatin, dicalcium phosphate, chondroitin, glucosamine, and collagen, identify the ingredient and the country of origin. Additional space is provided under footnote “iv.” If more space is needed, use the “Certificate Continuation Page” and note “See continuation page [indicate page number].”
 - f. In the sixth column “Production date(s) (may be range),” enter the date of production or the range of production dates for each product identified in the first column. IF there are multiple production dates, use a range of dates. Note that the production date(s) must not be earlier than the date the manufacturing facility was approved for export to Taiwan. IF a range of dates is used, do NOT include dates in the future. The date or range of dates should not include any dates later than the date the certificate is endorsed.

SUBMISSION OF CERTIFICATE DOCUMENTS TO ENDORSING VS OFFICE:

3. Prior to submitting the certificate (with “Manufacturing Facility Addendums” and continuation pages, if needed) to the endorsing VS Office:
 - a. Verify with the importer that all products to be exported are eligible for entry into Taiwan.

- b. Ensure that the products being exported meet all limitations for the manufacturing facility's approval.
 - c. Prepare the certificate (including each of the Manufacturing Facility Addendums), and review it for accuracy and completeness (i.e., all applicable sections have been completed; there are no typos or incorrectly spelled words).
 - d. Ensure the supporting notarized affidavits have been prepared (i.e., the exporter's notarized affidavit and the manufacturers' notarized affidavits).
 - e. Email the prepared certificate, together with copies of the required notarized affidavits and supporting export certificates for any bovine-origin ingredients other than dairy, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen.
4. **Notify the endorsing VS Office at the time of submission if the certificate is to replace a previously endorsed version.** There are specific procedures that must be followed with reissued certificates. Obtaining a second certificate for a shipment and failing to let the VS Office know that you are requesting a "reissue" could result in rejection of your shipment, or if the shipment is already onhold, a refusal by Taiwan to release it.

Please see page 12 below for an explanation of the facility options (i.e., dedicated facility; dedicated line; use of an approved cleanout/separation protocol) and BSE risk materials as defined by Taiwan. Please see pages 13-14 for guidance on using a cleanout/separation protocol.

Explanation of Facility Options and Taiwan Definition of BSE Risk Materials

Approved manufacturing facilities for dog and cat foods containing non-exempt ingredients intended for export to Taiwan must be dedicated; use a dedicated line for the production of the products for Taiwan; or use an approved cleanout/separation protocol to ensure that products for export to Taiwan are not cross-contaminated or commingled with ineligible materials.

NOTE: Approved facilities may only select the first option (facility dedication) until APHIS VS reaches agreement with Taiwan on the re-approval process necessary for facilities to use the other two options (i.e., dedicated line or cleanout/separation protocol).

- A. Dedicated facility: To meet Taiwan's requirements to be considered dedicated, the facility cannot process any materials or products that contain or may contain BSE risk materials as defined by Taiwan.
- B. Dedicated line: To meet this criteria, the facility must have a separate, dedicated line for the production of dog and cat containing non-exempt ingredients for export to Taiwan or a totally separate line (from receipt through processing to load out) on which NO materials or products are processed that contain or may contain BSE risk materials as defined by Taiwan.
- C. Cleanout/separation protocol: To meet this criteria, the facility must have documented and approved measures (e.g., separate equipment for eligible materials/products; use of cleanout procedures such as physical cleaning, flushing, sequencing or other means, either alone or in combination with separation measures) to prevent cross-contamination of product for export to Taiwan. [See Cleanout/Separation Protocol Guidance below for using this option.]

BSE Risk Materials:

- A. For any country that has reported a case of BSE, regardless of official OIE status, Taiwan defines BSE risk materials as 1) ruminant MBM and greaves; and 2) the tonsils, distal ileum, brains, eyes, spinal cord, skull, and vertebral column from cattle of any age.
- B. For controlled BSE risk countries that have never reported a case of BSE, Taiwan defines BSE risk materials as 1) ruminant MBM and greaves; and 2) the tonsils and distal ileum from cattle of any age; and the brains, eyes, spinal cord, skull, and vertebral column from cattle over 30 months of age at the time of slaughter.
- C. For undetermined BSE risk countries that have never reported a case of BSE, Taiwan defines BSE risk materials as 1) ruminant MBM and greaves; and 2) the tonsils and distal ileum from cattle of any age; and the brains, eyes, spinal cord, skull, and vertebral column from cattle over 12 months of age at the time of slaughter.
- D. For negligible BSE risk countries that have not reported a case of BSE, Taiwan does not define any BSE risk materials.

Cleanout/Separation Protocol Guidance

This guidance is for approved facilities that are not dedicated (i.e., process BSE risk materials/products as defined by Taiwan) and wish to use a cleanout/separation protocol to prevent cross-contamination of dog and cat foods manufactured for export to Taiwan with BSE risk materials as defined by Taiwan. Facilities who choose this option must document the procedures they will use (standard operating procedure) and maintain a log of actions taken. Facilities should be prepared to provide the documentation to APHIS and be able to demonstrate the procedures they use. **NOTE:** Approved facilities cannot use this option until APHIS VS reaches agreement with Taiwan on the re-approval process.

This guidance was extracted from “FDA Guidance for Industry 68” – guidance developed by the FDA to assist U.S. industries comply with the ruminant feed ban which requires prevention of cross-contamination of feeds for ruminants with prohibited materials. The principles developed by the FDA can be used to prevent cross-contamination of products for export to Taiwan with prohibited BSE risk materials as defined by Taiwan.

1. Separation

- Use of separate equipment or facilities for the manufacture, processing, or storage of prohibited and non-prohibited product. This could be entirely separate buildings, rooms, or other locations; or separate storage containers for incoming material and finished product, and separate handling equipment.
- 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. Cleanout

- Cleanout 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. Cleanout 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 cleanout is implemented – who is responsible, how cleanout is monitored and verified; how volume of cleanout flush material was determined; and a description of how cleanout flush material is handled. **OR**

3. Combination of Cleanout and Separation

An example would be use of some separate and some common equipment (cleanout is required for the latter).

- Written procedures should include the procedures followed from the time of receipt of incoming materials until the time of shipment of the finished product. They should reflect what actually happens in your operation.
- Written procedures should have enough detail to provide a clear understanding of your actual procedures.

Examples of Cleanout Measures

- Use cleaning by physical means (e.g., vacuuming, sweeping, washing, etc.).
- Alternatively, flushing, sequencing or other equally effective techniques may be used. Under these methods, the equipment is cleaned through use of non-prohibited product or materials.
- The volume of flushed material should be sufficient to prevent carryover of products or materials that may contain prohibited material. Due to the degree of variability among facilities, each facility should determine their individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. The volume used should be stated in the written procedures, and should be based on a documented analysis or test of the facility's system.
- Non-prohibited material used in the cleaning should be prohibited and should be identified, stored, and handled so that it does not become incorporated in products for export to Taiwan.
- Sequencing should be done on a predetermined basis and be designed to prevent contamination of products for export to Taiwan.