

## Dog and Cat Chews Containing Hide

This protocol is intended to cover dog and cat chews containing hide\* but no other animal origin ingredients except dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, collagen, and/or natural flavorings containing no ruminant-origin ingredients and a maximum level of 0.7% of other animal-origin ingredients.

\***Hide:** As defined by Taiwan, the term “hide” or “hides” refers to rawhide derived from cloven-hooved animals or the skin of poultry/avian species which are dehaired, degreased, dried, clean and free of blood. It does not include ears or other products which contain cartilage or other animal origin ingredients that do not originate from rawhide or skin.

**NOTE:** For dog and cat chews that do not contain hide and/or skin, and contain NO other animal-origin ingredients except dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen, see the document entitled “Dog and cat food containing NO animal-origin ingredients except those derived from dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen.”

### Facility Approval

Facilities that manufacture dog and cat chews that contain hide but no other animal-origin ingredients except dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, collagen, and/or natural flavorings containing no ruminant-origin ingredients and a maximum level of 0.7% of other animal-origin ingredients, must be inspected and approved by APHIS Veterinary Services (VS) to ensure compliance with the requirements for this commodity. These facilities do not, however, need to be approved by Taiwanese authorities.

**NOTE:** Facilities that have been inspected by APHIS VS in the past 365 days do not necessarily need to be re-inspected prior to using the below certificate language. If facilities elect to use the option of a cleanout/separation protocol (see Cleanout/Separation Protocol guidance on previous page of IREGs), they must provide the endorsing [local VS Service Center](#) with a standard operating procedure (SOP) detailing their procedures in accordance with FDA guidance. The endorsing VS Service Center may require a facility re-inspection before this option is utilized.

### Facility Requirements

The manufacturing facilities for dog and cat chews intended for export to Taiwan that meet the product requirements of this protocol must either 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.

- 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.<sup>1</sup>

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<sup>1</sup> **BSE Risk Materials:** 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, brain, eyes, spinal cord, skull, and vertebral column from cattle of any age. 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 brain, eyes, spinal cord, skull and vertebral column from cattle over 30 months of age at the time of slaughter. 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 brain, eyes, spinal cord, skull, and vertebral column from cattle over 12 months of age at the time

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- B. Dedicated Line: To meet this criteria, the facility must have a separate, dedicated line for the production of dog and cat chews 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 the 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 the product for export to Taiwan. [See Cleanout/Separation Protocol Guidance on previous page of IREGs for using this option.]

### Export Certification

Dog and cat chews containing hide but no other animal origin ingredients except dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, collagen, and/or natural flavorings containing no ruminant-origin ingredients and a maximum level of 0.7% of other animal-origin ingredients may be certified on a VS Form 16-4, Export Certificate for Animal Products. If additional pages are need, VS Form 16-4A, Export Certificate for Animal Products (Continuation Page) may be used.

- A. For products produced in a State NOT currently banned by Taiwan for highly pathogenic avian influenza (HPAI) or Newcastle disease, or for products that do not contain poultry/avian skin:
  - a. Statements to appear under the VS Form 16-4 “ADDITIONAL DECLARATIONS”:

This office has on file a notarized affidavit from [*exporter/manufacturer*] verifying the accuracy of the statements below.

1. Products described below were manufactured at the following facility approved by a competent government authority in the United States for the production of dog/cat chews [*insert name and address of manufacturer*].
2. The products were produced [*insert manufacturing date(s)*].
3. Products are packaged in new and never before used packaging materials.
4. The products contain no animal origin-ingredients derived from cloven-hoofed animals or poultry/avian except for exempt flavorings (flavorings containing no ruminant-origin ingredients and a maximum of 0.7% of other animal-origin ingredients) and skin/hide derived from cloven-hoofed animals **or poultry/avian** which is dehaired, degreased, dried, clean and free of blood; and those derived from dairy, fish, gelatin, dicalcium phosphate, chondroitin, glucosamine, and/or collagen.
5. Effective measures were taken to prevent contamination of the dog/cat chews with infectious animal disease pathogens, including BSE, in raw materials and through the manufacturing and packaging process.

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of slaughter. For negligible risk BSE countries that have not reported a case of BSE, Taiwan does not define any BSE risk materials.

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(For dedicated facilities)

6. The certified products were manufactured in a dedicated facility that does not process any materials or products that contain or may contain BSE risk materials as defined by Taiwan.

OR

(For dedicated lines)

The certified products were manufactured on a dedicated line which is not used to process any materials or products that contain or may contain BSE risk materials as defined by Taiwan so as to prevent contamination of the certified products.

OR

(For facilities utilizing separation protocol)

The certified products were manufactured in a facility that uses an approved cleanout/separation protocol to prevent cross-contamination of the certified products with any materials or products that contain or may contain BSE risk materials as defined by Taiwan.

7. (If the product label includes company information that differs from the name and address of the manufacturer noted above):

[Name and address of manufacturing facility] also manufactures products included in this consignment labeled with the following company information: [company name(s) and address(es) that appear(s) on the package(s) in the consignment].

NOTE: If product does not contain poultry/avian skin/hide, please omit the text highlighted in red above from Statement #4.

- B. For products containing poultry/avian hide/skin produced in a currently banned State for HPAI or Newcastle disease:
  - a. Include statements 1-7 per the above guidance under the VS Form 16-4 “ADDITIONAL DECLARATIONS”
  - b. Add the following attestation after statement 7 as noted above:
    8. The rawhide of poultry/avian origin was heat-treated with the core of the product reaching a temperature of 70°C for at least 30 minutes; or 80°C for at least 9 minutes; or 100°C for one (1) minute.

### Product Description

The “Product Description” box of the VS Form 16-4 must contain the following information:

Product name: [e.g. dog chews]\*

Weight and quantity: [e.g. 500 pounds (20-5 pound bags and 40-10 pound boxes)]\*\*

Species of origin: [e.g. bovine and avian]

\*NOTE: A generic product name (e.g. dog chews) should be used instead of listing the name of each item. Information regarding product codes is not required and should not be included on the certificate endorsed by APHIS. If exporters wish to provide this information to their importers, it must be done on other shipping documents. Exporters are advised to provide this information to their importers separate

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from the documents that accompany the shipment to avoid retention of the shipment due to questions as to whether the product codes match the information provided on the product packaging.

**\*\*NOTE:** The quantity must include the total weight, as well as the number of packages. A total weight is not acceptable if the items are individually packaged.

### **Product Identification**

The “Identification” box of the VS Form 16-4 must contain enough information to link the certificate to the product being shipped (e.g. container number(s) or lot number(s)).

### **Certificate Endorsement**

Although APHIS VS must inspect dog/cat chew facilities exporting to Taiwan under these requirements at least once annually, exporters must still provide a notarized affidavit to the endorsing VS Service Center to support the statements being endorsed. As noted above, if the facility uses a cleanout/separation protocol, they must provide a copy of the standard operating procedure (SOP) to APHIS VS.