Trade Samples

The European Union (EU) defines as "trade samples" as:

animal by-products or derived products intended for particular studies or analyses authorized by the competent authority in accordance with Article 17(1) of Regulation (EC) No 1069/2009 with a view to carrying out a production process, including the processing of animal by-products or derived products, the development of feedingstuff, pet food or derived products, or the testing of machinery or equipment.

A. Additional Requirements for Trade Samples if the Chapter 8 (with "trade samples" line-outs) is Required

In the above definition "animal by-products or derived products" refers to only those materials for which the EU would normally (if the materials were not going as trade samples) require to be accompanied by a Regulation (EU) 142/2011 (as amended) certificate for import into the EU.

B. Examples of Scenarios Where the Chapter 8 Would Not Be Appropriate (even if it was lined out as if for "trade samples")

Items not considered "trade sample" as defined above where the Chapter 8 would not be appropriate:

- Items normally under other certifying agencies, e.g. materials for human consumption: For information on sending samples of materials for which the EU would normally (if the materials were not going as trade samples) require a certificate by another agency (e.g. FSIS or AMS), exporters should contact those agencies for more information. Even if materials normally utilized for human consumption are being sent to the EU for "particular studies or analyses", EU authorities have indicated that the Chapter 8 is still not appropriate**.
- Display items: The EU does not consider "display items" to be "trade samples." For information, including the EU's definition of "<u>Display Items</u>", please go back and select the pertinent article.
- Research and Diagnostic samples: The EU does not consider "research and diagnostic samples" to be "trade samples." For information, including the EU's definition of "Research and Diagnostic Samples", please go back and select the pertinent article.
- Items transiting the EU.

C. Additional Requirements for Trade Samples (as defined by the EU) When the Chapter 8 (with "trade samples" line-outs) is Required for <u>DISPATCH</u> to the EU:

1. The importer in the EU must contact the Ministry of Animal Health in the importing EU country and obtain from them an import permit to import the trade sample. The EU authority will explain to the importer their relevant obligations. While this import permit does not become part of the export certificate, it should

accompany the shipment. [*There is an exception regarding France explained below.]

- 2. After the importer has obtained this approval, the Regulation (EU) 142/2011 "CHAPTER 8 Health certificate For animal by-products to be used for purposes outside the feed chain or for trade samples, intended for dispatch to or for transit through the European Union" is required. [Go back to the previous page and select the "Chapter 8 Health Certificate" link for the English version of the pre-lined certificate.]
 - a. Unlike other Regulation (EU) 142/2011 certificates, this certificate (when used for trade samples) does <u>not</u> require APHIS inspection, an APHIS number, nor listing in TRACES of the producer/exporter in most cases. If the APHIS office has any reason to doubt the content of the certificate, inspection would still be required. An APHIS facility number is never included when the Chapter 8 is utilized for trade samples.
 - b. The certificate must be prepared as indicated on this website for "trade samples."
 - c. In section I.11 of the certificate, <u>no</u> "approval number" is listed. No facility number of any kind may be listed.
 - d. Section I.12: Unlike most other certificates for "dispatch" shipments, Section I.12 must be completed for trade samples. The plant in the EU where the trade sample is being sent should be listed. This must be the same facility whose number is listed in Section I.28.
 - e. Section I.26 is always lined out (this certificate cannot be used for "trade samples" transiting the EU).
 - f. In section I.28, instead of the approval number of the manufacturing facility in the U.S., the approval number of the importing facility in the EU is listed. (This number should correspond with the number listed on the "special permission" [sometimes called an "import permit*"] granted by the Ministry of Animal Health in theimporting EU country.)
 - g. The exporter submits a copy of the import permit* (and English translation) to the APHIS office when they submit the draft certificate for evaluation for possible endorsement. Neither this copy nor the original import permit/permission becomes part of the certificate endorsed by APHIS.
 - h. A scan of the label for the material must also be submitted to the APHIS office with the draft certificate. The scan does not become part of the certificate endorsed by APHIS. The scan may be of a label from the outer most packaging of the consignment. It must contain the following exactwording: TRADE SAMPLE NOT FOR HUMAN CONSUMPTION

*Exception regarding France:

France does not issue import permits for trade samples. In lieu of the import permit, the exporter should obtain from the French importer one of the following documents (and an English translation):

- 1. Approval Notification
- 2. Authorization Notification
- 3. Prefact Ruling

That document must demonstrate that the French facility is approved to handle materials similar to those being exported as trade samples (or specifically for testing of the samples). The approval number in that document of the importing facility in France should be utilized in Section I.28. That document (one of the above 3) would have been provided to the French destination facility by the competent government authority in France, when the facility was first approved; therefore the document does not need to be dated recently.

**When the Trade Sample Chapter 8 is Not Appropriate Per EU, but the importing Member State Issues an Import Permission/Permit Saying Otherwise

As indicated above, EU authorities have indicated that the trade sample version of the Chapter 8 may only be used for those materials for which the EU would normally (if the materials were not going as trade samples) be required to be accompanied by a Regulation (EU) 142/2011 (as amended) certificate for import into the EU. This means the EU has indicated it could never be used samples of human food type products.

However, there have been cases of individual Member States rarely issuing in writing import permits/permissions indicating that they would allow samples of other materials (which would not be eligible per EU authorities) to enter if shipped as a trade sample with the trade sample version of the Chapter 8.

In these cases, the exporter would need to prepare the trade sample version of the Chapter 8 as indicated above, and also provide:

- A shipping at their own risk document; and
- Written verification (such as an import permission), and translation, from the French government clearly indicating that the samples would be allowed import to the facility listed in Section I.12 if accompanied by no government documentation other than the trade sample version of the Chapter 8 (it must indicate that all of section II.1 may be lined out of the certificate). The facility number for inclusion in Section I.28 should also be indicated in this document.