# Guidelines for Preparation of Certificates for Export of Animal-Origin Materials for import into the European Union (EU) <u>for the Production of</u> Gelatin/Collagen Intended for Human Consumption

The guidance contains APHIS' best understanding of the proper formatting. APHIS does not confirm prior to endorsement that the majority of the information in Part I of the certificate is completed as required by relevant Border Control Post (BCP) in the importing country. Some of the information in this document is extracted from Annex I of Chapter 4 of Regulation (EU) 2020/2235 as amended. Other information is based upon discussions and other communications with EU authorities.

Prior to shipment from the U.S. facility (listed in section I.11 of the certificate), the exporter should always ensure that they have the required certificate endorsed by APHIS (with a date on or before the actual date [and if different, on or before the date listed in section I.14]), and have their importer confirm with the specific BCP through which the consignment will enter the EU that the certificate is completed in an acceptable fashion for the specific consignment.

# **The certificate must be dated by APHIS prior to the shipment of products from** the Facility Listed in Section I.11 of the certificate.

#### Extra Requirements if the Certificate is to be a Re-Issue/Amendment

If a certificate is submitted to the APHIS Office as an amendment/re-issue for a previously endorsed certificate, the submitter (who must be from the same entity that submitted the certificate to be replaced/amended) must provide the following information to the Office with the submission:

- Written flagging to identify to the APHIS Office upon that the certificate is an amendment/reissue of a previously endorsed certificate;
- Number and date of certificate being re-issued (and any certificates it replaced/amended);
- Scans of the certificate being re-issued (and of any certificates it replaced/amended);
- Detailed description of why the amendment/reissue is being requested, and what has been changed from the previous version (As noted below, there are certain sections of the certificate for which an amendment/reissue cannot be issued, unless there are also other required changes to the certificate);
- The actual original paper certificate (on VS Security Paper) to be replaced/amended. In rare cases where the original paper certificate cannot be returned to the VS Office with the request for the amendment/reissue, the Veterinarian in Charge of the Office may be able to consider waiving this requirement under the following circumstances: The submitter submits with the request a signed (may be electronically if sent by email) statement including verification that/of:
  - The original paper certificate cannot be returned to the Office prior to endorsement of the reissue/amendment;

- The reason the original paper certificate cannot be returned to the Office prior to the endorsement of the reissue/amendment; and
- One of the following:
  - The date and method by which the original paper certificate will be returned to the Office (even if after endorsement of the re-issue/amendment); or
  - Verification that the original paper certificate cannot be returned because it is in the possession of the BCP and the BCP will not return it; or
  - Documentation from the entity that was shipping the certificate indicating it was lost and cannot be found; or
  - Verification of some other plausible reason (that the Office agrees is plausible and consistent with known information) of why the original paper certificate cannot be returned prior to endorsement of the re-issue/amendment (for example: statement that it is with the shipment and documentation that the shipment is on the water and that waiting for it to arrive and be overnighted back to the Submitter or Office would result in delay of submission of the consignment to the BCP for clearance) and verification from the submitter that if (or when) the original paper certificate is eventually returned to them or the importer- it will then be promptly returned to the Office);

#### **Requirement for capitalization:**

The text that is utilized to "fill out" the certificate must be all capitalized (all letters in all words). This includes text (except for the required signatures) added by the APHIS Office during certificate finalization.

#### **Requirement for multilingual certificates:**

The certificates must be in English for APHIS to endorse. The EU requires certificates to be in an official language of the BCP of entry into the EU, as well as sometimes the official language of the specific EU country of destination. Many EU countries recognize several official languages. In these cases, if English is one of these languages, the certificate may be in Englishonly. In cases where APHIS has confirmed the acceptable "official" languages, the information is available on the IREGS under the individual countries.

For APHIS to endorse multilingual certificates, the certificates must be in English as well as the other language(s). In cases were APHIS has multilingual versions of these certificates available, they will be found under the information available on this web site for the specific pertinent EU country.

In other cases, the export has the responsibility of preparing the multilingual certificates. Multilingual certificates must be prepared with the English portion and the other language (or languages) side by side. This must be done either sentence by sentence or paragraph by paragraph.

### Example:

English sentence or paragraph/Spanish sentence or paragraph; English sentence or paragraph/Spanish sentence or paragraph; English sentence or paragraph/Spanish sentence or paragraph.

Certificates may <u>**not**</u> be only partially multilingual, e.g. if page 1 is bilingual, the additional pages must be similarly prepared.

### Some EU Countries May Accept Privately Prepared Separate Translations:

EU authorities have indicated that individual EU countries may decide to accept translations that are not part of the official certificate endorsed by APHIS. In these cases, APHIS would endorse the English-only version of the certificate, and afterwards, the exporter could include (with the materials to be accompany the certificate and be presented to the BCP) a privately prepared translation. The privately prepared translation in these cases is not endorsed by APHIS, is not part of the official certificate, is not numbered as part of the certificate, is not initialled or signed by APHIS, and is not submitted to the VS Office. As of the publications of these guidelines, with the exception of where details are noted on the IREG page specific to the importing EU Member Country, APHIS has not confirmed which EU Member Countries will accept this option.

APHIS would not refuse to endorse an English only certificate unless the IREGS for the specific country verifies that APHIS has confirmed the importing country (or country of initial entry of the consignment into the EU) has specific language requirements.

#### Part I: Description of consignment

#### I.1 Consignor/Exporter

Enter full name and address of consignor (entity in the U.S. exporting the product). This entity is not necessarily the facility from which the consignment ships from the United States. Also enter the following text (noted in blue) which usually pre-entered on the IREGS certificate (unless the address is not in the United States- in which case the blue texts should be changed as appropriate):

- Country: USA
- ISO country code: US

### I.2 Certificate reference

The exporter should leave this box blank- the endorsing APHIS Office will insert a certificate number prior to endorsement on each side of each page of the certificate. The exporter should

verify upon receipt that the APHIS Office has included the same certificate number on each page. (See above "Extra Requirements if the Certificate is to be a Re-Issue/Amendment" section for information which must be provided with the submission which would affect how APHIS will number the certificate is the case of reissues/amendments).

- I.2.a IMSOC reference
  - Leave lined-out.
- I.3 Central competent authority
  - Enter the following text (noted in blue) which usually pre-entered on the IREGS certificate:

APHIS-VS

I.4 Local competent authority

Enter VS APHIS Office endorsing certificate, "VS-XX" [excluding quotation marks], where XX is the State in which the endorsing office is located. (For example, enter "VS-VA" [excluding quotation marks] if the certificate is going to be endorsed by the VS APHIS Office in Virginia.) If there is any doubt, ask the APHIS Office to which the certificate is being submitted how to complete, or to complete prior to endorsement (but in the latter case confirm the section has been completed when the certificate is received from the APHIS Office).

[No section number] QR Code

- Leave lined-out.
- I.5 Consignee/Importer
  - For dispatch shipment:
    - Enter full name and address of the consignee [person (and entity) to whom the consignment is being shipped in the EU], and the "Country" and "ISO country code" of the EU Country in which they are located.
  - For transit shipment:
    - Line out entire section (this is normally already done on the transit versions posted on the IREGs).

**The certificate may not be revised just to amend this section:** If the information in Section I.5 changes after the certificate is endorsed, the operator responsible for the consignment in the EU must notify the BCP of the change. However, the certificate may not be "amended" (re-issued) if this is the only change. No documentation from APHIS should be issued regarding

changes in this information. No alterations may be made to the certificate after endorsement by the APHIS Office.

### I.6 Operator responsible for the consignment

- For dispatch shipment:
  - Line out entire section (this is normally already done on the dispatch versions posted on the IREGs).
- For transit shipment:
  - Enter the name and address (include the EU country name and ISO country code) of the person in EU Country in charge of the consignment when presented to the BCP. This is the person who makes the necessary declarations to the competent authorities on behalf of the importer.

### I.7 Country of origin

This text is usually pre-entered on the IREGS certificate:

- Country of origin: USA
- ISO country code: US

## I.8 Region of origin

Line out entire section (this is normally already done on the transit version posted on the IREGs).

[In rare cases for certain poultry-origin material, "Country of origin" may be "USA" and the ISO country code may be US-1. In those cases, this would be noted on the specific IREG.]

### I.9 Country of destination

Country of destination: insert the name and ISO code of the European Union country of destination of the consignment. [For EU countries: Austria AT; Belgium BE; Bulgaria BG; Cyprus CY; Czech Republic CZ; Denmark DK; Estonia EE; Finland FI; France FR; Germany DE; Greece GR; Hungary HU; Ireland IE; Italy IT; Latvia LV; Lithuania LT; Luxembourg LU; Malta MT; Netherlands NL; Poland PL; Portugal PT; Romania RO; Slovakia SK, Slovenia SL, Spain ES; and Sweden SE. For Northern Ireland: Great Britain GB.]

If the products are in transit, insert the name and ISO code of the third country of destination.

### I.10. Region of destination

Line out entire section (this is normally already done on the transit version posted on the IREGs).

### I.11. Place of dispatch

Enter the following information for the APHIS-listed facility from which the consignment is shipped: Establishment name, APHIS Reference Number, and address <u>(excluding the zip code/postal code)</u>, and APHIS Reference Number. Do <u>not</u> include the zip code (aka postal code).

Also enter the following text which is usually pre-entered on the IREGS certificate:

- Country of origin: USA
- ISO country code: US

Please note the APHIS reference number must appear exactly as it is in APHIS' system. This number is available from the facility's local endorsing APHIS Office. A zero ("0") is not the same as the letter "O". Consignments may be rejected if consignments are received with an "O" noted on the certificate where a zero "0" is actually in the APHIS reference number (which is notified to GB authorities after a facility is listed by APHIS). The same applies to other inconsistencies like a letter "I" where it should be a digit "1", or vice versa.

Please remember that all APHIS reference numbers related to product exports to the EU follow the following format only:

LL-LL<mark>V</mark>-#### where:

- L is always a letter
- *#* is always a numeral
- V is usually a zero, but in some cases may be letter, e.g. C, <u>but may never be a letter</u> <u>"O"</u>.
- I.12. Place of destination:
  - For dispatch shipment:
    - Enter the name and address of the establishment receiving the consignment (including the name and ISO country code of the country in which that place is, and if applicable the number of the establishment). [Some BCPs may not require this section to be completed for "dispatch" consignments but the relevant regulation only indicates it may be lined out for "transit shipments without storage". If the exporter decides to line it out for "dispatch consignments", APHIS should not refuse to endorse just because the section is lined out. However, as always, if the lining out is in a different font than the certificate text, then each lineout must be initialed and sealed by the APHIS veterinarian endorsing the certificate.]
  - For transit shipment with<u>out</u> storage:
    - Line out entire section (this is normally already done on the "transit without storage" version posted on the IREGs).
  - For transit shipment with storage:

- Enter the name, number, address (including the name and ISO country code) of the warehouse in the EU where the consignment is to be stored during transit.
- I.13. Place of loading:

Enter name of place (usually an air or seaport) where the product is loaded onto the means of transport on which the consignment will depart the U.S. <u>Also, indicate if it is a seaport or an</u> <u>airport.</u> (The response should be consistent with the information placed into section I.15.)

I.14. Date <del>and time</del> of departure:

Enter date [in the format of "## MONTH YEAR" where "##" represents the day of the month, and "MONTH" is the relevant month written out using letters, and "## is the day of the month] of expected shipment departure from the U.S. This should be the date the shipment will depart from the port of exit, but may be the date the consignment departs the warehouse for the port of exit. This date may not be before the date of the certificate.

The following format must be utilized for the date. The month may not be indicated prior to the "day" of the month, and the numerical code of the month may not be utilized instead of writing out the name of the month. An example of the format for the date follows:

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<u>The certificate may not be revised just to amend this section</u>: If the information in Section I.14 changes after the certificate is endorsed, the operator responsible for the consignment in EU must notify the BCP of the change. However, the certificate may not be "amended" (re-issued) if this is the only change. No documentation from APHIS should be issued regarding changes in this information. No alterations may be made to the certificate after endorsement by the APHIS Office.

A "time" can <u>not</u> be included. [Time is in the section title only because the certificate format is designed to be utilized for both live animals and products- but the time is only for shipments of live animals.]

- I.15. Means of transport:
  - Type of transport: Select either "Aircraft" or "Vessel" to indicate the means of transport at departure from the U.S. "Vessel" is for when the consignment leaves the United States by sea.
  - Identification:
    - If "aircraft" is selected insert the flight number.
    - If "vessel" is selected insert the "vessel name and number".

Technically, Regulation 2020/2235 requires the specific information above to be indicated (the flight number for the aircraft and the vessel "name and number" for sea vessels). BCP's in the EU are believed to require this information in this section. However, if the exporter choses to not include this information APHIS may potentially

endorse the section with the "identification" section lined out, if <u>all</u> of the following are first done:

- The exporter lines out this section (by entering dashes in the relevant space); and
- The IREG for the specific country in which the BCP listed in section I.16 is located does not indicate otherwise; and
- The exporter submits a "shipping at your own risk" agreement to the APHIS Office.

While APHIS would not refuse to endorse a certificate simply because the "Identification" section is lined-out (unless there has been confirmation that a particular country will not accept certificates this way as indicated on the IREG for the country where the BCP is located), the "shipping at your own risk" agreement is required because the consignment may be rejected if this section is not completed with the vessel name or flight number.

### Regarding all of I.15:

<u>The certificate may not be revised just to amend this section</u>: If the information in Section I.15 changes after the certificate is endorsed, the operator responsible for the consignment in the EU must notify the BCP of the change. However, the certificate may not be "amended" (re-issued) if this is the only change. No documentation from APHIS should be issued regarding changes in this information. No alterations may be made to the certificate after endorsement by the APHIS Office.

Box I.16. Entry Border Control Post:

Enter the name of the BCP that is the port of entry into the EU.

<u>The certificate may not be revised just to amend this section</u>: If the information in Section I.16 changes after the certificate is endorsed, the operator responsible for the consignment in EU must notify the BCP of the change. However, the certificate may not be "amended" (re-issued) if this is the only change. No documentation from APHIS should be issued regarding changes in this information. No alterations may be made to the certificate after endorsement by the APHIS Office.

#### Box I.17. Accompanying documents:

BCPs may have different interpretations regarding this section- in all cases exporters should have their importers confirm with the relevant BCP prior to shipment that the information provided is acceptable for the consignment.

• Type/Code: This section is for referencing any other documents required by the importing country and/or BCP of entry into the EU. These documents do not become part of the APHIS certificate. APHIS does not review or verify

these documents. Exporters should have their importers confirm with the BCP if any of these types of documents are required. If none is believed to be required- the fillable area should be filled with dashes (lined-out). If a commercial document is required, then the BCP may expect the same number to be included as the "Code" as is included for the "Commercial document reference".

- Country/ISO country code: If a document (other than the certificate being submitted to VS for endorsement) is required, and the document was created in the United States, then the Country/ISO country code for the United States is:
  - Country: USA
  - ISO country code: US
- Commercial document reference: APHIS believes that some BCPs may be willing to accept certificates with this space lined out, however, APHIS recommends the number of one of the following commercial documents be placed into this space (the referenced document must be available to the BCP but does not become part of the certificate and is not verified nor endorsed by APHIS):
  - Airway bill number
    - Bill of lading number

If the exporter chooses to not enter either of these numbers, the section must be filled with dashes (lined-out), and the exporter must provide a "shipping at their own risk" document.

- Box I.18. Transport conditions:
  - Select type of temperature (ambient, chilled, frozen) at which products are maintained during transport. Only one type may be selected.
- Box I.19. Container No/Seal No:

The container number must be provided if the goods are transported in closed containers. In the case of the RCG and the TCG, the container number must be included.

Per the EU Regulation: "Only the official seal number must be stated. An official seal applies if a seal is affixed to the container, truck or rail wagon under the supervision of the competent authority issuing the certificate." The seal number must be stated on the TCG and RCG. APHIS and the EU have agreed that during APHIS' evaluation of the facility for listing, APHIS can confirm the effectiveness of the facility's standard operating procedures for ensuring the sealing of the container (and that the applicable seal number is noted on the certificate prior to submission) as part of the APHIS listing process, and this allows the seal number to be included on the certificate.

- Box I.20. Certified as or for:
  - Select "Products for human consumption". This option is usually preselected on the IREGS certificate

Box I.21. For Transit:

- For dispatch shipment:
  - Line out entire section (this is normally already done on the dispatch versions posted on the IREGs).
- For transit shipment:
  - Select the box (this is normally already done on the transit versions posted on the IREGs). Insert the name and ISO country code of the third country of destination.

Box I.22. For internal market:

- For dispatch shipment:
  - Select the box.
- For transit shipment:
  - Do not select the box. Line out the entire section (this is normally already done on the transit versions posted on the IREGS).

Box I.23. Not applicable to the TCG or RCG.

• Line out the entire section (this is normally already done on the versions posted on the IREGS).

Box I.24. Total number of packages:

• For bulk consignments: The section is optional- and APHIS recommends lining it out. If the exporter opts to fill it out, it should be the total number of "packages" of the "type of package" listed in section I.28 under "Type of packaging". Line this section out (by entering dashes in the relevant space). [This is sometimes already done on the versions posted on the IREGS].

Box I.25. Total quantity:

• Exporters should have their importers confirm with the relevant BCP the BCP's expectations for this section (prior to shipment). Some border control posts may consider this section optional for products. If no value is inserted, the section should be lined out (by entering dashes in the relevant space). If a quantity is inserted, the unit of measure should be included (e.g. "1 container"), and should not be contradicted by any other information entered on the certificate.

Box I.26. Total net weight/gross weight (kg):

- Total net weight: Enter the total net weight: the mass (weight) of the products themselves, without immediate containers or any packaging
  - This must be the same as the "Net weight" entered in section I.27.

• Total gross weight: Enter the total gross weight: the mass (weight) of the products and of the immediate containers and all their packaging, but excluding transport containers and other transport equipment.

Enter the net weight before the gross weight. We recommend the following format to ensure there no confusion:

Net: ###kg; Gross: ###kg

Where the "####" are replaced by the applicable numbers. Technically, BCPs should accept with the "kg" unit since the unit is provided in the "title" of the box, but APHIS recommends including it to prevent potential confusion at the BCPs.

- Box I.27. Description of consignment Unless otherwise indicated below, insert the information the certificate indicates is required, but do not include any extra information except as indicated below
  - Insert the referenced information, but do not include any extra information with (for the TCG) the following exception: Both certificates require the "Nature of the Commodity" to be included in Box I.27, but unlike the RCG, the TCG (as amended) was not published to contain a place holder for it. Follow the directions below for the "Nature of the Commodity".

Further guidance on certain sections of Box I.27 (where guidance is not provided, insert information the certificate indicates is required, but no additional text:

#### • Nature of commodity:

It is required, both for the RCG and the TCG, to include the "Nature of the Commodity" (using the exact terms noted below) in Box I.27. However, unlike the RCG, the TCG (as amended) was not published to contain a placeholder (heading) for it.

- RCG: in the space after "Nature of commodity" insert the applicable of the following exact terms:
  - HIDES
  - SKINS
  - BONES
  - TENDONS
  - SINEWS
- TCG:

- If, on the relevant TCG version on the IREGS, a section in Box I.27 has been inserted entitled "Nature of commodity", insert into that space the applicable of the following exact terms (not including the "bullet symbol"):
  - HIDES
  - SKINS
  - BONES
  - TENDONS
- If, on the relevant TCG version posted on the IREGS, a section in Box I.27 has <u>not</u> already been inserted entitled "Nature of commodity":
  - The fillable area for "Type of packaging" allows at least 2 lines of text to be inserted. After the required information for "Type of packaging" is inserted into that space, use the remaining space to insert the following text (not including the quotation marks): "NATURE OF COMMODITY:"
  - 2. After the inserted "NATURE OF COMMODITY:" text (not including the quotation marks), skip a space (after the colon), and insert the applicable of the following exact terms (not including the "bullet symbol"):
    - HIDES
    - SKINS
    - BONES
    - TENDONS
- CN code:

Indicate the relevant Harmonised System (HS) code and the title defined by the World Customs Organisation as referred to in Council Regulation (EEC) No 2658/87<sup>1</sup>. This value should be consistent with the relevant note at the end of the certificate (the first 4 digits of the code should match those in the note).

• "Cold store"

Select the box if the consignment is transported under refrigeration. [This box should almost always be selected for the RCG (it will often been pre-selected on the RCG versions on the IREGS.]

• Type of packaging:

Identify the type of packaging using terms according to the definitions given in Recommendation No 21<sup>2</sup> of UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business).

<sup>&</sup>lt;sup>1</sup> Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

<sup>&</sup>lt;sup>2</sup> Last version: <u>www.unece.org/uncefact/codelistrecs.html</u>

#### **Additional steps:**

- 1. A single diagonal line should be drawn through any unused space on the certificate. APHIS Offices will print the certificates duplexed on VS Security Paper prior to endorsement. If the number of pages in the certificate is an "odd" number, a page should be added with a single diagonal line so that no side of the VS Security Paper is printed blank.
- 2. The certificate is not transferred to any letterhead.
- 3. Each side of each page must be numbered as "Page X of Y".
- 4. The APHIS Office will add the following to the certificate prior to endorsement. Exporters should check the certificate when they receive it from the endorsing office to ensure the below has been added:
  - a. Certificate number on each side of page
  - b. Full name of endorsing APHIS veterinarian (in "Official veterinarian" box)
  - c. Date (in "Official veterinarian" box)
  - d. Official title of endorsing APHIS veterinarian (in "Official veterinarian" box)
  - e. Full signature of APHIS veterinarian: Each side of each page must be signed (not just initialed) by the endorsing APHIS veterinarian (in "Official veterinarian" box)
  - f. Colorless raised embossment: Each side of each page must be embossed over the signature.

#### No additional pages may be included with the certificate.

Please contact the VS APHIS Office serving the state in which you are located with any additional questions.

Please note it is the responsibility of the exporter to have their importer confirm prior to shipment with the BIP that all requirements have been met. This includes (but is not limited to) ensuring: that the certificate that has been endorsed is acceptable to the BIP, that the consignee has all necessary approvals from their government to receive the consignment for the intended purpose, and that all TRACES requirements have been met.