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HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate G - Veterinary and International affairs
G2 - Animal health

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Guidance on the implementation of the certification procedures established in Commission Regulation (EU) No 142/2011

Working document
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Presented at the meeting of the Standing Committee on the Food Chain and Animal Health, section Animal Health and Welfare
on 7 February 2012

Abbreviation:

ABP:	animal by-products
ABP Regulation:	Regulation (EC) No 1069/2009[1]
Implementing Regulation:	Regulation (EU) No 142/2011[2]
BIP:	Border Inspection Post referred to in Article 4 of Directive 97/78/EC[3]

1. **If antibodies are grown from bacteria- with no animal origin material involved- is any certification required?**

Purified antibodies are not considered animal by-products.

However where bacteria-grown antibodies are contained within a stabilizer / carrier substrate that is an ABP (i.e. Bovine serum albumin (BSA) or Foetal Bovine Serum (FBS)), the additional documentation may be required from the Member State concerned.

2. **Are blood products derived in third countries from the blood of equidae collected in the European Union eligible for export to the EU with the Chapter 4(A) Health Certificate (even though EU countries are not listed in Annex XIV, chapter 2, row 3 (raw material for equidae blood products)?**

Pending the adoption of a forthcoming amendment to Regulation (EU) No 142/2011, the Commission would not act against Member States that accept consignments of products produced from blood of equidae accompanied by a health certificate in accordance with the model in Chapter 4(A) of Annex XV to Regulation (EU) No 142/2011 which indicates one or more Member States of the EU as the country of origin for raw material for equine blood products.

3. **Can the pre-amble ("in addition as regards TSE:") be deleted in the following text, which is only applicable to ovine/caprine milk origin materials intended for feeding to ruminants on certificates for materials that do not contain ovine/caprine milk and/or for materials not intended for feeding to ruminants?**

in addition as regards TSE:

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1 OJ L 300, 14.11.2009, p. 1.
2 OJ L 54, 26.2.2011, p. 1.
3 OJ L 24, 30.1.1998, p. 9.

[2]either [in case of animal by-products intended for feeding ruminants and containing milk or milk products of ovine or caprine origin….

No, the pre-amble should remain, but all options under the preamble may be deleted.

4. **Is it true that no batch number is required on the Chapter 4(A) Health Certificate?**

Yes, it is not required / indicated in box I.28.

5. **Is it true that "note 1[c]" in Annex XV, Ch 3(F), section II.1.2 [and similar language in Annex XV, Ch 5(A), II.3 and Annex XV, Ch 8, II.2.1] can be interpreted as "the country of origin of the source material" and not the "country of export"?**

Yes. It can be used for certificates 5(A) and 8, but not for 3(F) which specifically says "exporting country".

However, if the country of origin or export is not on the list of authorized countries for the export of the commodity in question, such exports to the EU can not be realized.

6. **How are section II.2.1 and II.2.2 of the Chapter 8 Health Certificate [and similar sections of the Chapter 3(F) Health Certificate] to be prepared for fish, egg, and dairy byproducts?**

II.2.1: Fish and invertebrates collected in the ocean are considered caught in the territory of the country in which the collection vessel is registered.

II.2.1: Indicate only the territory but delete both either/or options and in II.2.2 delete everything for dairy and egg-origin byproducts.

II.2.2: Delete everything for aquatic.

7. **Regarding the following text from the Chapter 4(A) Health Certificate, section II.7(d), are serum derivatives, plasma, and plasma derivatives classified the same as "serum":**

   in the case of blood products <u>other than serum</u>, vesicular stomatitis for six months;]?

Yes, a raw serum is source for other serum products and all references to serum should be applicable for serum products. Plasma and plasma derivatives are not the same as serum and serum derivatives, so they cannot be classified as 'serum'.

8. **Is it true that no specified risk material (SRM)-related certification is required related to cervid materials (e.g. in pet food)?**

Yes, there is no specific indication of cervidae but all other TSE guaranties should be respected.

9. **Is it true that border inspection posts can allow materials being imported with certification for human consumption to be downgraded for other uses?**

Yes, that may be an option. This is not a routine procedure but rather case by case decision. It can not be used for regular imports of particular commodity. .

However, there may be instances where the human consumption product will not be able to meet the requirements of ABP not for human consumption (i.e. milk/ apiculture products).

Consideration has to be taken as to the reason why the product imported is no longer fit for the purpose it was intended.

Products intended for human consumption which fail inspection controls at the import should be 'downgraded' as an ABP and can only be defined as Category 2 material referred to in Article 9(e) of Regulation (EC) No 1069/2009.

10. Is any certification (or listing in TRACES) required for fur meeting the requirements of Article 25, point 2(b)?

No, only a commercial document verifying the treatment is required. All establishments or plants should be listed in the TRACES unless it is indicated different in the Implementing Regulation.

11. Is the Chapter 8 Health Certificate ever the appropriate certificate for materials derived from carcasses of animals not slaughtered for human consumption, e.g. rodents?

DG Sanco will propose to Member States to amend the health certificate Chapter 8 of Chapter XV to support imports of Category 3 material referred to Article 10(m) of Regulation (EC) No 1069/2009.

12. Is it true that no government certificate is required for research and diagnostic samples?

The EU import requirements for import and transit of research and diagnostic samples (Article 27) and display items (Article 28) are laid down in Regulation (EU) No 142/2011. The legal requirement to allow the import of such consignments is at the discretion of the national authority of the Member State of destination.

However, where such consignments are allowed, the Regulation (EU) No 142/2011 sets down the minimum requirements that must be applied by each Member State.

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13. **Is it true that facilities exporting research and diagnostic samples to the EU do not need to be listed in TRACES?**

Facilities exporting research and diagnostic samples to the EU do not need to be listed in TRACES but shall be subject to authorisation of the Member States of destination of research and diagnostic samples. Please see reply to point 12.

14. Is it true that no certificate is required and exporting facilities in third countries do not need to be listed on TRACES to export several samples to the EU?

Please apply the following scheme:

Commodity	List of third countries	Health requirements	Health certificates	Notification of exporting establishment into the TRACES
Research and diagnostic samples	All third countries at the discretion of the national authority of the Member State of destination	at the discretion of the national authority of the Member State of destination	at the discretion of the national authority of the Member State of destination	No
Trade samples	row 14 of Table 2 of Section 1 of Chapter II to Regulation (EU) No 142/2011	at the discretion of the national authority of the Member State of destination	Certificate Chapter 8 of Annex XV to Regulation (EU) No 142/2011	No
Display items	row 14 of Table 2 of Section 1 of Chapter II to Regulation (EU) No 142/2011	at the discretion of the national authority of the Member State of destination	at the discretion of the national authority of the Member State of destination	No

15. In the Chapter 5(A) Health Certificate, shouldn't the first two paragraphs below be noted "3" as in the last paragraph?

> ***[in the case of hides and skins from bi-ungulates, animals that come from holdings in which there has been no outbreak of foot-and-mouth disease in the previous 30 days, and around which within a radius of 10 km there has been no case of foot-and-mouth disease for 30 days;]***
>
> ***[in the case of hides and skins from swine, animals that come from holdings in which there has been no outbreak of swine vesicular disease in the previous 30 days, or of classical or African swine fever in the previous 40 days, and around which within a radius of 10 km there has been no case of these diseases for 30 days;]***
>
> ***[animals that have shown no evidence of [foot-and-mouth disease], [rinderpest], [classical swine fever], [African swine fever] or [swine vesicular disease][(3)] during ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter;]***

(3) ***Delete diseases not applicable to the species concerned.***

No, the principle requirements for FMD and those more specific for major infectious diseases in pigs are already conditioned to the kind of consignment and remain as such valid.

Indeed, the absence of clinical signs for FMD must always be certified. The guarantee for rinderpest is limited to the absence of clinical signs in susceptible animals, i.e. must

be certified in case of hides and skins derived from domestic or wild artiodactyls (see OIE) and must therefore be certified in all cases – according to OIE list of susceptible animals.

Absence of clinical signs for specific pig diseases depends on the consignment and not on the individual pig disease, i.e. in case of pig skins, absence of all named pig diseases must be certified..

16. Regarding the Chapter 6(A) health certificate, section I.11 and I.28, if a game trophy is treated and packaged at one facility, but then exported through a different warehouse, how is the certificate completed? [For other certificates, the treatment facility number would go in I.28, and the warehouse facility number would go in I.11, but there is no place for the treatment facility number in I.28.]

Enter both establishments into box I.11. A game trophy establishment should be listed into the TRACES under the Section VI and storage under the Section IX.

17. In the Chapter 8 Health Certificate, shouldn't the "(3)" note in the below be a "(2)"?

II.2.2. have been obtained from animals:

(2)either [(a) coming from holdings:

(i) where, for the following d….. situated in their vicinity within 10 km, during the prior 30 days; and

(ii) ….. 30 days; and

(b) which:

(i) were not killed to eradicate any epizootic disease;

(ii) have remained in their holdings of origin for at least 40 days before departure and which have been transported directly to the slaughterhouse without contact with other animals which did not comply with the same health conditions;

(iii) at the slaughterhouse, have passed the ante-mortem health inspection during the 24 hours before the slaughter and have shown no evidence of the diseases referred to above for which the animals are susceptible; and

(iv) have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EC(5) on the protection of animals at the time of slaughter or killing]

(3)or [(a) captured and killed in the wild in an area:

(i) in which within 25 km there has been no case/outbreak of any of the following diseases for which the animals are susceptible: foot-and-mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza during the prior 30 days nor of classical or African swine fever during the prior 40 days; and……

It is a typo mistake in certificate. Pending the adoption of a forthcoming amendment to Regulation (EU) No 142/2011, the Commission would not act against Member States that accept consignments of animal by-products to be used for the purpose outside the feed chain or for trade samples that are accompanied by a health certificate in accordance

with the model in Chapter 8 of Annex XV to Regulation (EU) No 142/2011 in which the third country has electronically changed the "(3)" to a "(2)".

18. **In the Chapter 15 Health Certificate, shouldn't the "3" note for II.5 and II.8 be a "2" (delete as appropriate) not?**

It is a typo mistake in certificate. Pending the adoption of a forthcoming amendment to Regulation (EU) No 142/2011, the Commission would not act against Member States that accept consignments of Egg product not intended for human consumption that could be used as feed that are accompanied by a health certificate in accordance with the model in Chapter 15 of Annex XV to Regulation (EU) No 142/2011 in which the third country has electronically changed the "(3)" to a "(2)".

19. **Can processed animal protein (other than manure) be imported for fertilizer/soil improvers? If so, with which certificate?**

Yes. It would have to be imported with the Chapter 1 Health Certificate and go directly to an organic fertilizer approved establishment. However if it was a hydrolyzed protein, it would have to be imported with the Chapter 12 Health Certificate.

20. **Are there any by-products not listed in the *TECHNICAL SPECIFICATIONS FOR THE COMPETENT AUTHORITIES OF THIRD COUNTRIES* that third countries would be required to have listed in TRACES?**

No, please see the last amended version of the *"TECHNICAL SPECIFICATIONS FOR THE COMPETENT AUTHORITIES OF THIRD COUNTRIES"* published on the DG SANCO web page:

http://ec.europa.eu/food/food/biosafety/establishments/docs/technical_specifications_d7177%202010_rev1_01%203%202011.pdf

21. **Regarding the Chapter 8 Health Certificate, section II.2.5 [have been packed in new packaging preventing any leakage or in packaging which has been cleaned and disinfected before use and in containers sealed under the responsibility of the competent authority, bearing the label indicating 'ANIMAL BY-PRODUCTS ONLY FOR THE MANUFACTURE OF DERIVED PRODUCTS FOR USES OUTSIDE THE FEED CHAIN' and the name and address of the EU establishment of destination] and Note I.23 [Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included], what exactly does "in containers sealed" mean?**

The statement regarding "containers" does not apply to "parcels" and can be endorsed without being verified for Fed Ex type shipments (parcels). The statement only applies to shipping containers.

22. Annex XIV, Ch 2, Section 6(a) states *"Treated feathers and parts of feathers and down may be imported:*

(a) if they are treated decorative feathers, treated feathers carried by travellers for their private use or consignments of treated feathers or down sent to private individuals for non-industrial purposes;"...

These feathers don't have to come from facilities listed in TRACES, do they?

No, the commodity is not a subject to Border Veterinary checks.

23. Can the typo in following section of the English pdf version of the Chapter 10(B) Health Certificate be corrected by third countries?

(2)and/or [- taquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]

Yes.

24. Can third countries electronically correct the typos in the English version of the Chapter 4(C) Health certificate to:

[II.5.4.		*In addition, in case of Suidae and Tayassuidae:*
[II.5.4.1.		*[in the country or region of origin no case of swine vesicular disease, classical swine fever and African swine fever has been recorded for at least 12 months and vaccination has not been carried out against those diseases for at least 12 months in the susceptible species]]*
(2)[II.5.4.2.	*either*	*[in the country or region of origin no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for 12 months and in which vaccination has not been carried out against this disease for at least 12 months;]*
(2)[II.5.4.2.	*or*	*[in the country or region of origin vesicular stomatitis seropositive animals are present(4);]]]*

Yes.

25. What specific terminology is acceptable in Section I.28 of the health certificates for the "species (scientific name)"?

Please indicate the scientific name of the species if not requested different information.

26. In the Chapter 11 Health Certificate, the preambles to sections II.6 and II.7 seem to be specific to "gelatin." Should these sections be lined-out for certificates for "collagen"?

At the time being it is applicable only to gelatine. Please note this issue is subject to internal debate and it might be changed.

27. Is it acceptable to prepare section I.5 of the Health Certificates as follows for consignments that are only transiting the EU?

I.5. ~~Consignee~~ Border inspection post through which consignment is intended to leave the EU Name Address ~~Postal code~~ ~~Tel.~~

Yes, it is possible but any change of certificate should be verified by official veterinarian who signs the certificate.

However, proposed change of particular parts of text in box 1.5 is not necessary at all. For more information please see detailed explanation in Commission Decision 2007/240/EC (OJ L 104 of 21.4.2007, p.) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:104:0037:0050:EN:PDF which lays down the TRACES-format for all model import certificates in the animal health field. Page 44 of this decision contains the explanations for the different boxes of the certificates. The reference to box I.5 states the following:

"Box I.5: Consignee: Please give the name and address (street, town and post code) of the physical or legal person to whom the consignment is shipped in the Member State of destination. This information is not compulsory for goods in transit through the EU."

28. Regarding the following section of the Chapter 4(C) and 4(D) Health Certificates: The following line appears on the 4C and 4D certificates:

material from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC, the import of the material being permitted in accordance with Article 35(a)(ii) of Regulation (EC) No 1069/2009;]

Should the section instead read as the following sections on the 10(B) certificate?

(2)and/or	***[-***	***animal by-products which have been derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;]***
(2)and/or	***[-***	***animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive***

96/23/EC, if such residues exceed the permitted levels laid down by Union legislation or, in the absence thereof, by legislation of the Member State of importation;]

Until the revision it should stay as it. .

29. Is anything changing regarding the import of yellow grease intended for biodiesel production?

The issue is under debate with Member States.

30. Does the new Annex 14, Chapter 2, Section 1, point d established by Regulation (EU) 749/2011 expand the facilities in third countries which must be listed on TRACES?

No. R&D, display items and trade samples do not have to come from TRACES facilities. Other commodities, unless specifically indicated in the animal and health requirements should come from an establishment or plant entered into the TRACES system.