UK questions for clarification – version 13

UK letter of 14 May 2021

1. UK Third Country Listing

a) Live Bovines for Slaughter

Part I of Annex II to Regulation 2021/404 (amended by Regulation 2021/634 for UK listing) indicates that the United Kingdom (GB-United Kingdom) is listed for the export of bovine animals for further keeping (BOV-X) but not bovine animals for slaughter (BOV-Y).

Under the previous legislation, Commission Implementing Regulation 206/2010, the United Kingdom was listed for both bovines for further keeping and bovines intended for slaughter. Please can you confirm that the omission of the UK from the list of countries eligible to export bovines for slaughter to the EU is an error that will be amended by 21 August?

DG SANTE answer:
We will correct it in the next amendment (ongoing).

b) Bluetongue (BTV) freedom

We would like to clarify with the Commission why the UK (GB-United Kingdom) is not listed as a BTV-free zone under Part 1 of Annex II to Regulation (EU) 2021/404 (amended by Regulation 2021/634 for UK listing). The last case of BTV in the UK was in 2008 (GB restriction zone lifted in July 2011) and we implement a robust surveillance programme consisting of passive and risk-based surveillance in high-risk counties in the UK. The UK has been recognised as BTV free since 2011 and has submitted annual information and reports regarding BTV surveillance to the Commission.

In Regulation 206/2010, there was no specific condition for BTV freedom recognition in third countries and so the bluetongue attestation in the respective health certificates is/was simple to certify. In the model live animal certificates in AHL Regulation 2021/403, the 'free from infection of bluetongue virus' statement cannot be certified unless the country is formally recognised as free of BTV by the EU.

We would like to confirm whether the Commission intends to recognise this historical freedom.

DG SANTE answer:
It is not an automatic recognition. UK needs to demonstrate the disease freedom in accordance with requirements of Regulation (EU) 2020/689 (Article 10 of Regulation (EU) 2020/692). Only then guarantees can be recognised and formalised in legislation. Currently UK is not listed as BTV free in Annex II to Commission Implementing Regulation (EU) 2021/404, as it was not in Regulation 206/2010.

c) Hay and straw

Article 9 and Annex V of Commission Regulation 136/2004 ceased to apply on April 21st. These articles provided the list of third countries which were permitted to export hay and straw to the EU. Under Commission Implementing Regulation 2021/632 we understand that hay and straw are still subject to veterinary checks at a border control post, however we are not aware of any legislation providing a list of third countries authorised to export hay and straw to the EU. Please can you confirm if such a regulation is forthcoming, and whether the UK be included in the relevant list?

DG SANTE answer:
According to Art. 241 of Regulation (EU) 2016/429, the Commission is empowered to establish in a delegated act the animal health requirements for the entry of hay and straw into the EU.
It was agreed with Member States that, pending this evaluation, they will restrict the entry of hay and straw based on the former conditions laid down in Regulation (EC) No 136/2004. This issue was discussed in the Committee and it will be discussed again in June.

d) Fish, live bivalve molluscs and crustaceans

Commission Implementing Regulation 2021/634 adds the United Kingdom (GB-United Kingdom) and the Crown Dependencies of Jersey, Guernsey and the Isle of Man to the lists of third countries approved to export certain live aquatic animals and their products of animal origin to the EU outlined in Commission Implementing Regulation 2021/404. Part I of Annex XXI of 2021/404 is amended to provide listing for the export of certain live aquatic animals intended for aquaculture establishments, release into the wild or other purposes other than direct human consumption. We note that the UK, Jersey & Guernsey have only been given entries in column 3 headed 'fish' with columns 4 and 5 headed 'molluscs' and 'crustaceans' left blank. We would expect an entry in all three columns to be present for this listing to be consistent with the previous listing under Commission Regulation 1251/2008. As the legislation acknowledges that the UK, Jersey and Guernsey have been listed for 'all relevant species' we assume this is an error and will be corrected, but we would appreciate your confirmation.

DG SANTE answer:
As you will be aware, Regulation (EC) 1251/2008 was amended by Regulation (EU) 2020/2202 in December 2020, showing that the United Kingdom, Guernsey and Jersey were authorised for the import into the European Union of consignments of fish, molluscs and crustaceans. The Isle of Man was authorised for the import of consignments of fish into the European Union. Unfortunately, a formatting error occurred when these listings were transferred to Implementing Regulation (EU) 2021/634, which amends Annex XXI to Regulation (EU) 2021/404, thereby leaving columns 4 and 5 blank. However, given that in all cases, the names of the certificates which can be used for the entry into the Union of specific commodities are set out in column 6 of this Annex, we do not foresee issues arising when such commodities are presented at BCPs for inspection. This error will be corrected as soon as possible.

e) Dairy products subject to risk mitigating treatment

Annex XVIII of Commission Implementing Regulation 2021/404 - as amended by Commission Implementing Regulation 2021/634 to include the United Kingdom (GB- United Kingdom) and the Crown Dependencies - provides a list of countries approved to export milk, subject to risk mitigating treatment, to the EU. GB – United Kingdom and the Crown Dependencies are not included in Annex XVIII.

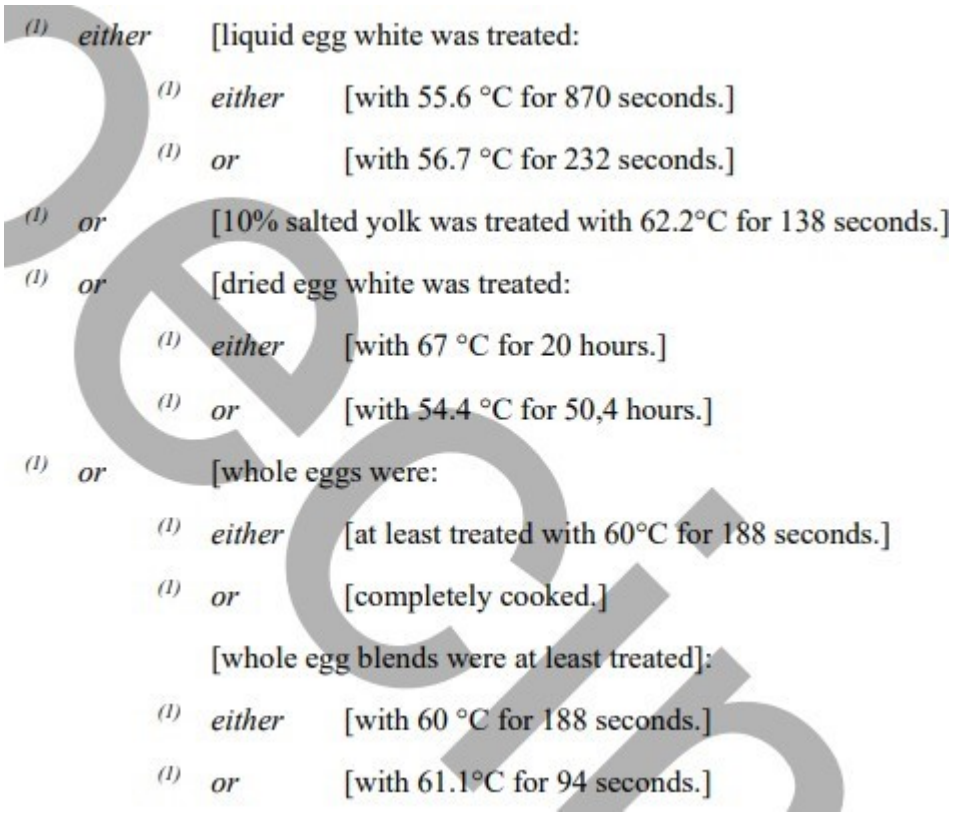
We would appreciate clarification as to whether triangular trade in dairy products subject to risk mitigating treatment, imported into GB from countries listed in Annex XVIII, and re- exported from the GB to the EU, will be possible without GB-United Kingdom being separately listed in Annex XVIII. We understand that these products would require the model Dairy-Products-ST EHC from Commission Implementing Regulation (2020/2235) which we do not believe we can use without listing in Annex XVIII.

DG SANTE answer:
Re-certification of products originating and processed in other third countries from UK to the Union is not possible. UK can only certify products processed in its territory, in compliance with the relevant rules for triangulation.

2. Composite Products

a) Export Health Certificate - Heat treatment options for dried egg yolk

Please could you confirm the appropriate heat treatment requirements for the import of composite products containing dried egg yolk? We understand this is a common ingredient in some composite products including mayonnaise. The options set out in the model certificates (COMP and TRANSIT-COMP) are copied below:


(1) *either* [liquid egg white was treated:
(1) *either* [with 55.6 °C for 870 seconds.]
(1) *or* [with 56.7 °C for 232 seconds.]
(1) *or* [10% salted yolk was treated with 62.2°C for 138 seconds.]
(1) *or* [dried egg white was treated:
(1) *either* [with 67 °C for 20 hours.]
(1) *or* [with 54.4 °C for 50,4 hours.]
(1) *or* [whole eggs were:
(1) *either* [at least treated with 60°C for 188 seconds.]
(1) *or* [completely cooked.]
[whole egg blends were at least treated]:
(1) *either* [with 60 °C for 188 seconds.]
(1) *or* [with 61.1°C for 94 seconds.]

Is it appropriate to certify the treatment that is applicable for whole eggs?

DG SANTE answer:
The risk mitigation treatments for the inactivation of HPAI in egg products are laid down in Annex XXVIII to Delegated Regulation (EU) 2020/692. That Annex does not provide for such treatment of dried egg yolk. Therefore, egg products containing dried egg yolk can only be prepared from eggs obtained from animals kept in establishments in which and within a 10 km radius of which, during the period of 30 days prior to the date of collection of the eggs, no outbreak of HPAI was confirmed (options II.3.D.1 of certificate COMP and II.1.C.1 of certificate TRANSIT-COMP).

b) Export Health Certificate – Products containing unpasteurised dairy content

We understand that the Commission have queried content on GOV.UK which implies that composite products containing unpasteurised dairy cannot be exported to the EU. Our reading of the available Export Health Certificates for composites is that certifying such a product (e.g. a frozen ready meal or a chilled 'Caesar salad' containing parmesan cheese made from unpasteurised milk) is not possible.

Both the EHC provided in Implementing Regulation 2020/2235 and the pre-April 21st EHC provided by Commission Regulation 28/2012 require the certifier to attest to one of a range of heat treatments for the relevant dairy content. An option for dairy products that have been 'matured' rather than 'pasteurised' is not available. We understand that unpasteurised dairy products do not meet the necessary requirements for certification (unless the entire product has been pasteurised or subject to an equivalent heat treatment

after the unpasteurised dairy product is added).
Please could you confirm if this understanding is correct?

DG SANTE answer:
UK is authorized to enter raw milk to the Union so it is not required any specific treatment to products processed from milk obtained and processed in UK or from milk obtained from TC listed in Annex XVII of 2021/404 and processed in UK. The ongoing amendment to Article 163 of DR 2020/692 will reflect this possibility and point 10 of the attestation laid down in IR 2020/2235 will be amended accordingly.

c) Animal Health Regulation EHC – Box I.11 Place of dispatch

The guidance note in the COMP and COMP-TRANSIT model health certificate advises that, for Box I.11, the details of the "establishment(s) of production of the composite products" should be inserted. In contrast, the guidance in Chapter 4 of Regulation (EU) 2020/2235 clearly states that "only the establishment shipping the products is to be named". We believe the guidance in the certificate is incorrect as it does not recognise the change in Box I.11 from "Place of Origin" in the old certificates to "Place of Dispatch" in the new models. Please can you confirm that the establishment(s) of origin do not need to be listed in Box I.11 in cases where they are not the "last third country establishment of the export chain from which the consignment is transported to the Union"? We note that the relevant "Manufacturing Plants" will be listed in Box I.27 so there should be no need to include these in Box I.11.

DG SANTE answer:
We confirm this is a mistake in the footnotes of model certificates COMP and COMP-TRANSIT, as it should read "*Name, address, and registration/approval number if available, of the establishments **where the products come from**. Name of the country of dispatch which must be the same as the country of origin in box I.7*".

d) Private Attestation – Shelf stable composite products containing honey

In the case of shelf stable composite products containing no meat where the only POAO contained in the product is honey (e.g. a breakfast cereal with honey flavour). Is it acceptable for the EU importer to delete point 5 of the model Private Attestation, as there is no requirement laid down for honey in Annex III to Regulation (EC) No 853/2004

DG SANTE answer:
We confirm that, in the case where the only processed product of animal origin contained in the composite product is honey, there is no need to indicate the approval number of the establishment, where the honey ingredient originates from, in point 5 of the private attestation.

NB:
The reply provided assumes the honey contained in the cereal is a processed product of animal origin. But honey is a primary product. It is not a processed POAO. So the UK should clarify if honey in those breakfast cereals is processed or not.
Assuming this is natural honey that remains unprocessed, the resulting breakfast cereals ARE NOT a composite product. And then the product when imported should be accompanied by the certificate applicable to honey.
If on the contrary, this natural honey is processed, then the reply as provided is correct.

e) Private Attestation – Direct to consumer consignments

Your response to my letter of March 29th helpfully clarified that if a shelf-stable composite product containing no meat is sent directly to a consumer, and not otherwise exempted from BCP checks under Article 10 of 2019/2122, a Private Attestation document is required if the product is subject to BCP checks under the composite export rules.

Please can you clarify the position for composite products exempted from BCP checks under Commission Delegated Regulation 2021/630 sent directly to consumers? We assume that these products do not require a Private Attestation if being sent directly to a consumer in the EU, as they are not being placed upon the EU market, but we would appreciate your confirmation.

DG SANTE answer:
Composite products which meet the requirements of Article 10 of Regulation 2019/2122 are exempted from official controls at BCPs and they are not intended to be placed on the market. Therefore, the private attestation is not required in this case.

3. Meat Products containing poultry (MPST)

We understand that the listing of the United Kingdom (GB-United Kingdom) in Annex XV of Commission Implementing Regulation (EU) 2021/404 (as amended by Implementing Regulation (EU) 2021/634) that poultry products obtained from fresh meat originating in zones with the code GB-2 must be subject to at least the specific 'Treatment D' prior to their export to the EU.

We would appreciate your advice on how the model certificate MPST should be completed for the export of meat products containing poultry meat (POU) originating from "GB-2" zones in respect of the following:

a). Section II.2.1 refers to the establishment where meat products are "processed in and dispatched from". If the establishments of processing and dispatch are different and one (the establishment of processing) is in "GB-1" and the other (establishment of dispatch) is in "GB-2", is it appropriate to certify "GB-2" in the certificate on the basis that this applies the stricter "treatment D" requirements?

b) Section II.2.2 provides several options primarily referring to the locations of the animals from which the fresh meat was obtained and the subsequent treatment(s) applied. There are four "either/or" options [II.2.2] depending on whether the products contain processed meat from:

(1) Only one species of animal
(2) Poultry, and the fresh meat has undergone at least treatment D
(3) Mixing meat of different species (either before or after final treatment)
(4) Either one species or mixing from different species where the fresh meat has undergone 'Treatment B'

If products contain only poultry meat then we understand that option (2) can be certified instead of option (1).

If products contain a mixture of poultry meat and meat from different species is it appropriate to certify option (2) for the poultry meat and options (3) for the meat of other species?

There are certain scenarios where we believe the current wording in option (3) unnecessarily restricts poultry meat exports. To resolve this, we propose that allowing option (2) to be certified for the poultry meat product that have undergone treatment D should be permitted, even if the meat product contains a mixture of products from different species.

The issues in option (3) arise with the second [II.2.2.1] paragraph copied below:

[II.2.2.1. has been **mixed after the final treatment** and, before the mixing, has undergone the

specific treatment(s)_____,_____,_____[7], as specifically assigned in a list of third countries and territories adopted by the Commission in accordance with Article 230(1) of Regulation (EU) 2016/429 to the different species of origin of the fresh meat and to the zone referred to in point II.1.1, and has been obtained from animals kept in an establishment located in:

(1) *either* [II.2.2.1.1. the zone referred to in point II.2.1., and:

– the establishment was not subject to national restriction measures for animal health reasons, including the listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 and emerging diseases at the time of dispatch to the slaughterhouse, and

– in and around the establishment, in an area of 10 km radius including where appropriate the territory of a neighbouring country, such diseases have not been reported in the 30 day period prior to dispatch to the slaughterhouse.]]

(1) *or* [II.2.2.1.1. the zone with code_____[3] which, at the date of issue of this certificate, is listed in a list of third countries and territories adopted by the Commission in accordance with Article 230(1) of Regulation (EU) 2016/429 for entry into the Union of fresh meat of the species from which the meat product has been processed.][6]]

(1) *or* [II.2.2.1.1. a Member State.]]

SCENARIO A: The yellow highlighted text appears to require that, if poultry meat products are both processed (treatment D) in and obtained from animals in a “GB-2” zone, then exports are not permitted for the first 30 days after a case of Highly Pathogenic Avian Influenza is reported within a 10km radius of the establishment where the animals came from.

We believe this restriction is not necessary for poultry meat that has undergone at least the specific Treatment D

SCENARIO B: There does not appear to be an option to certify meat that has been dispatched from a “GB-1” zone but obtained from animals kept and the meat processed in a “GB-2” zone. This is the case even if this meat has been subjected to at least Treatment D.

c) We also note that there is a typographic error in the text in blue highlight above. We believe this should state “II.2.1”.

DG SANTE answer:

The animal health requirements for entry into the Union of meat products are laid down in Delegated Regulation (EU) 2020/692. In particular, Articles 147 to 149 lay down the requirements in relation to the risk mitigating treatment and Article 150 lays down the requirements in relation to the establishment of origin of the meat of animals from which the fresh meat for the production of the meat products was obtained.
According to Article 150 “*Consignments of meat products shall only be permitted to enter the Union if they have been processed from fresh meat which originate from animals coming from an establishment, or, in the case of wild animals, from a place in and around which, in an area of 10 km radius, including where appropriate the territory of a neighbouring country, none of the listed diseases, relevant for the species of origin of the meat products in accordance with Annex I, has been reported during the period of 30 days prior to the date of dispatch of the consignment to the Union*”.
Therefore, it is not possible to certify consignments of meat products from meat obtained from establishments within the 10km zone of an outbreak.
This requirement applies to all meat products.
Furthermore, this was also a requirement for the entry into the Union of meat products of poultry in

Decision 2007/777/EC, which applied until 20 April 2021.

We will review the attestations in the certificate for meat products to ensure that the requirement of Article 150 of Delegated Regulation (EU) 2020/692 is correctly reflected.

Furthermore, in reply to the rest of the questions on this section, please note:

- Section II.2.1 refers to the establishment where meat products are "processed in and dispatched from". If the establishments of processing and dispatch are different and one (the establishment of processing) is in "GB-1" and the other (establishment of dispatch) is in "GB-2", is it appropriate to certify "GB-2" in the certificate on the basis that this applies the stricter "treatment D" requirements?

Both GB-1 and GB-2 are listed in Annex XV to Implementing Regulation (EU) 2021/404.
In point II.2.1 you should indicate the zone where the product was processed in and dispatched from to the Union.

- If products contain a mixture of poultry meat and meat from different species is it appropriate to certify option (2) for the poultry meat and options (3) for the meat of other species?

Options (2) and (3) are mutually exclusive, as they are an "either/or" option. Therefore, only one of those can be certified.

- We also note that there is a typographic error in the text in blue highlight above. We believe this should state "II.2.1".

Thank you. It is corrected in the next amendment of the certificate.

4. EU origin Meat products – Attestation II.2.1

Thank you for your response to Question 13 in the letter sent on 19 April 2021 (version 12) regarding triangular trade of EU origin meat products and meat preparations.

We welcome the news that the meat preparations certificate will be amended to reflect the well-established triangular trade of meat preparations. We would like to clarify when the Commission intend to publish the amended certificate. Will this be before 20 August?

We would also like to seek clarification on what is meant by the comment made in relation to meat products, regarding maintaining 'status quo'. Since 1 January 2021, meat products have been produced in Northern Ireland or EU Member States and consolidated/packaged in GB and exported to EU. The current model meat product certificate in Decision 2007/777/EC permits this, simply requiring the ISO code of the country of origin to be included in Column C of the table in II 1.1 of the certificate (and the relevant region code from Decision 2007/777 in the case of regionalisation).

We have not been informed by the Commission that the re-export of EU origin meat products to the EU is a prohibition or restriction. If meat preparations can be re-exported to the EU, then it would be logical to also apply this to re-export of EU origin meat products. Could you confirm the Commission's intention on this matter?

DG SANTE answer:
According to the animal health requirements of current EU legislation, this kind of triangulation is prohibited as the certifying country providing the animal health guarantees on processing, as required in model certificates, must be the one which applied the processing.

5. Germinal Products

a) Identification of donor animals at collection centres

Article 21 of Commission Delegated Regulation 2020/692 requires the identification of ungulates to include the code of the exporting country in accordance with ISO Standard 3166 in the format of two-letter code. This means applying the GB ISO code on the identifiers of the donor animals.

We welcome your confirmation that you are in the process of amending Article 83 to Regulation 2020/692 to remove the ISO code reference requirement when marking consignments of germinal products and replacing it with the following: "the unique approval number of the germinal product establishment of collection or production, processing and storage of those germinal products". This means that the use of 'UK' as part of the unique approval number of establishments will continue to be acceptable.

We would like to ask if the Commission intend to also amend Article 81 in line with the same principles. This would mean that donor animals could continue to be identified with a UK tag. If any of these donor animals are intended for export to the EU, we accept that they will need to comply with Article 21 and be identified with a GB tag.

We understand from the Commission's previous response to the germinal product questions in the letter sent on 12 April (version 11), that currently approved germinal product establishments should adapt to the new AHR requirements from 21 April onwards. In line with this, and if there is no intention to amend the legislation, we would like to request that the Commission takes a proportionate approach to enforcement to enable germinal products collected, processed and stored from 21 April to 20 August and exported after 20 August, and marked with the 'UK' identifier of donor animal on the straw markings, to be allowed entry into the Union.

DG SANTE answer:
The Commission is currently not planning to change Article 21 of Delegated Regulation (EU) 2020/692. The same refers to Article 81.

b) Species reference on germinal product straws

Article 83 to Commission Delegated Regulation 2020/692 refers to the requirement to include the species reference on the markings of the straws. The inclusion of the centre approval number (which will be species specific) on the straw would cover this requirement. Could the Commission confirm that this is acceptable as semen collected to date does not include the species reference.

If the intention it to request a separate additional reference to species on the straws, then we would like to confirm that:

- Reference to the 'species code' on the straws would be sufficient, e.g. references like 'POR' for porcine, 'BOV' for bovine, 'EQUI' for equine etc.
- The Commission would take a proportionate approach to enforcement where the germinal products are collected, processed and stored from 21 April to 20 August and exported after 20 August to not include species reference on the straws during the time of adapting to the AHR requirements.

DG SANTE answer:
Commission Implementing Regulation (EU) 2020/999 provides that "*the information on species of donor animal(s) may be omitted in the marking of straws where the species of donor animal(s) may be established based on information printed or written on the straw related to either the approval number of the germinal product establishment of collection or production, processing and storage of the semen, oocytes or embryos or the breed of donor animal(s)*". However this provision is based on Article 123 of Animal Health Law which means that it refers to the rules for marking of straw on the territory of the European Union. Regulation (EU) 2020/692 does not foresee such option.

Regulation (EU) 2020/692 does not specify the format of information on species of donor animals to be printed or written on the straw. Therefore there is a flexibility in presenting that information.

c) GP-STORAGE-ENTRY Certificates– Self declaration for internal movements

The 'Notes' section of the relevant 'Storage Entry' certificates e.g. for bovine, ovine/caprine, porcine, equine species (outlined in Commission Implementing Regulation 2021/403) refers to guidance for box I.17, as follows:

> *Box reference I.17: "Accompanying documents": Number(s) of related original certificate(s) shall correspond to the serial number of the individual official document(s) or health certificate(s) that accompanied the semen, oocytes and/or embryos described in Part I from the semen collection centre where the semen was collected, and/or the embryo collection and/or production team by which the oocytes and/or embryos were collected or produced, and/or the germinal product processing establishment where the semen, oocytes or embryos were processed and stored, and/or the germinal product storage centre where the semen, oocytes or embryos were stored to the germinal product storage centre described in Box I.11. The original(s) of those document(s) or those certificate(s) or the officially endorsed copies thereof must be attached to this certificate.*

We would like to confirm that the document that is used to accompany the germinal products when shipped from a collection centre store to a storage centre under the same ownership and the same veterinary supervision should be a self-declaration. We believe this to be in line with Article 27.1(b) of Commission Delegated Regulation 2021/686, which makes specific reference to "the animal health certificate or the self-declaration document" and with a previous steer given to EFFAB RepVet by Commission Officials.

The self-declaration would be serially numbered, and signed by the centre authorised veterinarian, who is officially approved by Defra. The document will certify that the germinal product listed in the schedule meets the relevant requirements and is being transported under conditions as least as strict as described in the relevant 'A-ENTRY' certificate.

DG SANTE answer:
This is correct. When a consignment of i.e. semen is moved from a semen collection centre to a germinal product storage centre and both are located on the territory of UK this consignment shall be accompanied by "official document(s)", under conditions at least as strict as described in relevant health certificates (i.e. BOV-SEM-A-ENTRY). In those official documents those conditions should be stated and signed.

d) Quarantine and collection centres – Single establishment principle

In the SEM-A-ENTRY EHCs (for bovine, porcine and ovine/caprine) outlined in Commission Implementing Regulation 2021/403, attestation II.4.5/II.4.5.2 requires the donor animal to have been kept for a period of at least 30 days prior to the date of collection of the semen, and during the collection period, in a single establishment free of a wide range of diseases. Historically in the UK, the pre-entry quarantine premises have not been regarded as part of the collection centre to protect the health status of the main stud if there is an adverse test result on animals during quarantine. Can we confirm that with such arrangement the pre-collection period of 30 days includes time the donor animals spent in the pre-quarantine premises?

DG SANTE answer:
This requirement comes from Article 80(b)(ii) of Regulation (EU) 2020/692. In this provision focus is on 30-day period prior first collection and collection period during which category D disease relevant for the species were not reported. So it is in any place (establishment, quarantine accommodation (28 days of quarantine) and semen collection centre. Quarantine accommodation (Article 2(25) of Regulation (EU) 2020/686) is a facility authorised by the competent authority for the purpose of isolation of animals before they are admitted to a semen collection centre.

e) Annual testing of resident donor animals

We would like to confirm if donor bovine, ovine and caprine animals which have not been resident on a centre for 12 months or more need to be subjected to any further tests listed in the Commission Delegated Regulation 2020/686. We understand the Commission have provided advice to industry via EFFAB that annual testing only applies to donor animals which are still resident on the centre at the time of the annual test. Could you confirm that short-term resident donor bovine, ovine and caprine animals do not require exit testing as porcine animals do?

DG SANTE answer:
Annex II to Regulation (EU) 2020/686 provides that each donor animal (bovine, ovine, caprine, porcine) kept at semen collection centre must be tested at least once a year for relevant diseases. Except porcine animals, it is not specified what shall be done with animals kept shorter than 12 months in the centre.
Article 19 of Regulation (EU) 2020/686 provides a possibility to move donor animals between semen collection centres without quarantine or testing, before and after the movement, under particular conditions. However, routine testing during 12-month period must be completed by each donor irrelevant of the semen collection centre where it is kept.
However the provision foreseen by Article 19 of Regulation (EU) 2020/686 is not available for third countries as it is not provided for in Regulation (EU) 2020/692.

f) BOV-SEM-A-ENTRY - Bluetongue statement

Attestation II.4.8.1 (in this certificate, as outlined in Commission Implementing Regulation 2021/403) requires that the animals *"have been kept for a period of at least 60 days prior to and during collection of the semen in a third country, territory or zone thereof free from infection with bluetongue virus (serotypes 1-24) where no case of infection with bluetonguevirus (serotypes 1-24) has been confirmed during the last 24 months in the targeted animalpopulation"*. Assuming Commission accepts that GB is free of bluetongue (Point 1.b aboverefers), we believe the above option can be certified. We consider that our conclusion is reinforced by Chapter 8.3.9 of the OIE TAHC.

DG SANTE answer:
It is not an automatic recognition. UK needs to demonstrate the disease freedom in accordance with requirements of Regulation (EU) 2020/689 (Article 10 of Regulation (EU) 2020/692). Only then a status can be recognised and formalised in legislation. Currently UK is not listed as BTV free in Annex II to Commission Implementing Regulation (EU) 2021/404.

g) POR-SEM-A-ENTRY - Classical Swine Fever (CSF) testing

Attestations II.4.8.3 and II 4.9.3 (in this certificate, as outlined in Commission Implementing Regulation 2021/403) refer to animals coming from Member States or zones thereof. We believe this is an attestation erroneously copied from the intra trade certificate and may require amendment to better reflect the scope of the entry certificate from third countries, including where a donor animal may originate from an EU Member State. Please could you confirm if this is correct and, if so, what the correct text should be?

DG SANTE answer:
Yes, it is a mistake and should be "third country, territory or zone thereof". However, this guarantee concerns the animal health situation of the country where the donor is located, and not where the donor was born or originating, i.e. it should always be in GB in your case.

h) Importing equine semen into the EU

We have identified a typographic error in the English version of model certificate section D for importing equine semen into the EU, at page 111 of Regulation 2018/659. Point II.2.2 should read as 'Regulation 2018/659' instead of 657.

Please confirm that you would be content for us to amend our certificate to correct this?

DG SANTE answer:
Yes, it should be Regulation (EU) 2018/659.

6. Mycobacterium tuberculosis (MTB) complex testing in caprine and camelid animals – follow up comment

Thank you for your response to our Question 8 in the letter sent on 28 March 2021.

We note that the European Commission has delegated to the EU Reference Laboratory (EURL) for MTB Complex the decision to lay down the EU-approved diagnostic methods for annual TB surveillance programmes in goat and camelid establishments laid down in Annex II to Delegated Regulation (EU) 2020/688. The UK welcomes the EURL's endorsement of serological tests for antibodies against MTB complex as the in vitro diagnostic method of choice to supplement the tuberculin skin test in camelids. We agree the 'cascade principle' laid down in Article 6(1) of Regulation 2020/689 should be observed too.

However, with respect to TB blood testing in camelids, the standard operating procedure published by the EURL on 20 April (SOP/005/EURL) only specifies one commercial antibody ELISA kit (namely, the INGEZIM Tuberculosis DR Kit from Eurofins Technologies)[1]. This is not one of the three serological tests validated and approved in GB for use in South American camelids. The INGEZIM kit has not been evaluated in GB and it is not available at APHA. APHA conducted a peer-reviewed study in 2010-11 about the validation of the IDEXX ELISA, Enferplex TB and DPP antibody tests in British alpacas[2].
We are aware EURL are consulting with our experts in the National (and OIE) Reference Laboratory for bovine TB in APHA Weybridge to evaluate the IDEXX ELISA test validated in GB. Therefore, given the practical implementation of this and scientific evidence to support the use of the GB validated tests and that it falls under the cascade principle, we will continue with the diagnostic methods mentioned in the letter sent on 28 March 2021. We hope that the evaluation of the IDEXX ELISA test conducted by EURL will conclude that this is another approved diagnostic test for MTB complex in camelids in the EU.

Furthermore, the EURL lists the IFN-γ test (ThermoFisher's Bovigam kit) as the only officially approved blood test for TB in goats. This IFN-γ test kit is routinely used in APHA to supplement the skin test in cattle in the GB, but it is not currently optimised, validated and available for private or statutory use in goats at APHA. This means that any prospective exporters of live goats from GB to the EU would have to in the immediate term send their blood samples by airline courier to the EURL or an accredited lab in the EU that is able to offer this test for goats. As you are aware, this would cause several logistical issues given the need to process the blood within 24 hours of collection after transportation in temperature-controlled packaging.

We would like to propose that we will review the IFN-γ test for goats in GB. However, scientific literature

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[1] European Union Reference Laboratory for bovine tuberculosis (2021). Detection of antibodies against the*Mycobacterium tuberculosis* complex for the detection of tuberculosis infection in Camelids. INgezim Tuberculosis DR (Eurofins Technologies). SOP/005/EURL – rev 1.
https://www.visavet.es/bovinetuberculosis/databases/bt-protocols.php#

[2] Rhodes S, Holder T, Clifford D, et al. (2012). Evaluation of Gamma Interferon and Antibody Tuberculosis Tests in Alpacas. Clinical and Vaccine Immunology, Vol. 19, No 10 (1677–1683).
https://cvi.asm.org/content/19/10/1677

indicates that the skin test followed by an antibody test could be an optimal alternative testing regime for TB in goats. Also, APHA are currently reviewing the IDEXX antibody test in goat herds as preliminary data suggest high specificity and we can engage with EURL on this. But in the immediate term, given logistical issues with implementing IFN-γ testing, GB will continue to apply the testing regime that is in place as mentioned in letter sent on 28 March.

DG SANTE answer:
As indicated in Art 6 of Regulation 2020/689, aspects related to the collection of samples, the techniques, validation and interpretation of the relevant prescribed diagnostic method listed in Annex I to Regulation 2020/688 are made available in the SOPs that are made available here https://www.visavet.es/bovinetuberculosis/databases/bt-protocols.php
As indicated in Regulation 2014/652, each EURL is responsible for keeping "up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;" that are to be incorporated to the above referred SOPs.
All SOPs from all EURL are therefore subjected to regular review and updates in the light of new scientific evidence. EURLs are also expected to be "collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC)".

In consequence, only the SOPs for testing Mycobacterium tuberculosis (MTB) complex testing in caprine and camelid animals available here https://www.visavet.es/bovinetuberculosis/databases/bt-protocols.php are considered valid. Other testing regimes and/or SOP can only be accepted once the EURL includes it in its list Protocols Database in accordance with EU legislation.

7. Bio-enzymes of animal origin: approval and listing for export

Could you please confirm that it is not necessary for bio-enzymes of animal origin to be processed in or dispatched from establishments that meet the requirements for approval under Annex III of Regulation (EC) 853/2004? Whether it is necessary for bio-enzymes of animal origin to be dispatched from establishments registered under Regulation (EC) 852/2004?

These products are made to food grade standards (HS code 35079090).

DG SANTE answer:
According to Regulation (EU) 2021/632, these products under CN 3507 90 90 are subject to official controls at BCPs.

- If this bio-enzyme is rennet, it can be classified as "highly refined product" according to in Section XVI of Annex III to Regulation (EC) No 853/2004. According to Article 6(d) of Regulation (EU) 2019/625, the requirements for establishment listing do not apply, as they fall under CN 3507. For completeness, they should be accompanied by the certificate laid down in Chapter 46 (Model HRP) to Annex III of Regulation (EU) 2020/2235.
- If this bio-enzyme is not rennet, it is classified as "other product of animal origin" for which no specific requirements are laid down in Annex III of Regulation (EC) No 853/2004. Listing of the establishments in accordance with Article 5 of Regulation (EU) 2019/625 is therefore not required. For completeness, they should be accompanied by the certificate laid down in Chapter 49 (Model PAO) to Annex III of Regulation (EU) 2020/2235.