UK questions for clarification – version 12

UK letter of 19 April 2021

Critical issues for 21/04/21

1. EHCs - Transitional Arrangements – Originally raised in my letter of 05/03/21

We are grateful for your verbal confirmation that the transitional arrangements contained within Commission Implementing Regulations (EU) 2020/2235 and 2236 and 2021/403 will enable the continued use of existing model EHCs for live animals, products of animal origin and germinal products until October 20th 2021, provided they were signed before 21st August 2021. We would appreciate your confirmation of this in writing.

DG SANTE answer:
As already explained, transitional provisions will apply as you can read in Art. 35 of Regulation (EU) 2020/2235, in Art. 10 of Regulation (EU) 2020/2236 and in Art. 27 of Regulation (EU) 2021/403, with the respective amendments provided by Regulation (EU) 2021/619.

2. Establishment approval – Originally raised in my letter of 29/03/21

We are grateful for your confirmation that our germinal product establishment listings will be rolled over. Please can you confirm that the UK's listed establishments for the export of POAO and ABP will also be rolled over and that no further action on our part is necessary to ensure currently listed establishments can continue to export?

DG SANTE answer:
Please see our previous answer (question 2 of 29.03.2021 document).

3. Germinal product exports, Transitional arrangements – (a.) originally raised in my letter of 29/03/21. (b.) originally raised in my letter of 12/04/21. (c.) not previously raised.

a. You confirmed in the technical discussions on 13/04/21 that germinal products collected both before and on/after the 21/04/21, can continue to use the same EHC that third countries currently use for export to the Union provided it has been certified before 21/08/21. We would appreciate confirmation in writing.

DG SANTE answer:
Please see our previous answer (question 4 of 29.03.2021 document).

b. We understand (frozen) stocks of germinal products collected on or after 21/04/21 could not be certified after 20/08/21 using the current certificates and the model EHCs in AHR will need to be used. This implies that establishments contemplating this trade will need to have been approved in accordance with new AHR requirements at the time such semen is collected. You confirmed in our recent technical discussions that GB approved germinal product establishments will be rolled over under the AHR. Please could you confirm whether products collected between 21/04/2021 and 20/08/2021, in an establishment for which the approval has been rolled over, will be exportable from 20/08/2021 using the relevant AHR EHC?

DG SANTE answer:
Please see our previous answer (question 3 in v11 document).

c. You suggested the unique approval numbers of germinal product establishments will need a ‘GB’ prefix in line with Regulation 2020/686. Could you confirm that UK establishments may continue to use the approval numbers with ‘UK’ prefix until 21 August. For germinal products collected after the 20 August, the straws will be marked/labelled with ‘GB’ prefix to reflect the ‘GB’ approval number of the establishments. This will be in line with the transitional provisions in the AHR. To avoid disruption at BCPs as a result of a possible mismatch between the label/mark on the straws (where those produced before 21 August will be marked with a ‘UK’ prefix) and the approval number of the establishments listed in TRACES-NT which will have a ‘GB’ prefix, would it be possible to also clarify that the ‘UK’ prefix for germinal products collected before 21/08/21 is acceptable. We would appreciate confirmation in writing that the former is correct and the later possible

DG SANTE answer:
In accordance with the next amendment to Delegated Regulation (EU) 2020/692, its Article 83(a)(iii) will read: “*(iii) the unique approval number of the germinal product establishment of collection or production, processing and storage of those germinal products*”.
Therefore, the format of unique approval number will no longer be structured.

4. Composite product exports – questions (a.) and (b.) originally raised in my letter of12/04/21. (c.) and (d.) originally raised in my letter of 29/03/21. (e.) not previously raised.

a. We welcome the recent draft proposals to enable shelf stable composite products containing no meat and including pasteurised dairy from third country listed for dairy exports to be exported using the private attestation.

We would also appreciate if you could confirm our understanding that the proposed amendments will enable shelf stable composite products, containing no meat and containing pasteurised dairy content, to be exported to the Union using the private attestation in the following scenarios:

i. where the dairy content is of EU origin as well as originating in a third countrylisted for the export of dairy products to the EU, and
ii. where the dairy content, in the product, was manufactured prior to 21/04/21 butthe composite product is exported to the EU on or after such date.

DG SANTE answer:
Please see our previous answer (question 1 of v11 document).

b. Sections II.3.C (fishery products) and II.3.D (egg products) of the COMP model certificate (Implementing Regulation 2020/2235) require that fishery and/or egg products that are contained in a composite product must originate from a country that is:

- For fishery products: “authorised for entry into the Union” (footnote 11)
- For egg products: “a zone in accordance with a list of third countries and territories adopted by the Commission in accordance with Article 230(1) of regulation (EU) 2016/429” (footnote 12)

We note from the discussion this week that it is not your intention to exclude EU member state origin fishery or egg products. Please can you advise on how these can be certified?

DG SANTE answer:
Please see our previous answer (question 2 of v11 document).

c. If a shelf-stable composite product not containing meat is being sent directly to an EU consumer and does not otherwise meet the requirements of Article 10 of Commission Delegated Regulation (EU) 2019/2122, would a private attestation still be required, given these goods are not being placed on the market in the EU? If so, is the purchaser of the goods expected to complete the attestation and

present it at the BCP if needed? If yes, would that also apply where the consignment is sent from a private individual in the UK to another private individual in the EU and not placed on the market in the EU?

DG SANTE answer:
Please see our previous answer (question 3c of 29.03.2021 document).

d. Your written response to our letter sent on 05/03/21 clarifies that for composite products “the private attestation is not required in case of transit through the EU territory.”

In your response you referenced Article 14 of 2019/625 which outlines that, in the case of products exempted from BCP checks, the attestation is needed at the point the product is placed upon the market. Please can you clarify that a private attestation is also not required for composite products in transit that are subject to BCP checks?

In our discussion on 23/03/21, you emphasised that is the responsibility of the EU importer to obtain the private attestation. We understand that composite products transiting the EU never require a private attestation as these products do not have an EU importer and are not placed upon the market.

DG SANTE answer:
Please see our previous answer (question 3d of 29.03.2021 document).

e. You have been clear that it is the responsibility of the importer to make the private attestation available at the BCP. Please can you confirm that it is acceptable for this private attestation to be provided to BCPs electronically (e.g., a scanned copy of the document)? If so, is this something we should discuss with individual BCPs or are you happy to confirm that it is acceptable and for us to share that with UK exporters for them to make their arrangements with their EU importers?

DG SANTE answer:
Again, this question should not be of any concern for UK(GB) authorities, as the requirement applies to EU operators. But we can clarify that, in the case where consignments are subject to BCP controls, the scan copy of private attestation can be uploaded in TRACES with the CHED prenotification.

Non-critical issues for 21/04/21

5. Word versions of live animal EHCs – Originally raised in my letter of 31/03/21

You kindly shared MS word versions of Commission Implementing Regulation 2020/2235 and 2020/2236, and their annexes, with us. Please can we be sent word versions of Commission Implementing Regulation 2021/403, including annexes, (live animal and germinal product certificates) in all EU languages as soon as possible?

DG SANTE answer:
The documents were emailed to your services on 20.04.2021.

6. Composite product exports - Originally raised in my letter of 29/03/21.

a. Your recent guidance indicates that if a composite product is not covered by the CN codes outlined in Article 12 of 2019/625 it is 'not subject to the requirements of that regulation'. We understand that the CN codes listed in Article 12 will be amended by Commission Implementing Regulation 2021/573, with further CN codes added to the list in Article 12. Can you confirm what documentation is required for composite products falling outside of the CN codes given in Article 12 (once amended)?

DG SANTE answer:
If the CN code is not included in Article 12 of Regulation (EU) 2019/625 then no attestation or certificate is required because those products are not subject to the composite products legislation.
These goods fall under Article 44 of Regulation (EU) 2017/625, which leaves MS the choice of the location where to check these goods that are not subject to Art. 47, you may liaise with the Member States in order to know their national requirements (please also see question 4 of v11 document).

b. For heat treatments of dried egg white, the composite product EHCs give an option to treat at "54.4 degrees centigrade for 50.4 hours" (in line with OIE recommendation to inactivate avian influenza virus). However, in Annex XXVIII of 2020/692 the duration required is "513 hours". Is this intentional? The same reference appears in the Egg Products EHC outlined in 2020/2235.

DG SANTE answer:
Please see our previous answer (question 3b of 29.03.2021 document).

c. We have noted that the EU EHC for the Export of Composite Products and the EHC for the Transit of Composite Products contain incomplete references to EU legislation. Specifically, 'Article 230(1) of Regulation EU 2016/' – The statement is missing '429' (e.g., Part III, A2, third indent). This will be replicated in our EHCs but we would ideally like to amend so the references are accurate. Can you confirm if you are content for us to do this?

DG SANTE answer:
Please see our previous answer (question 3b of 29.03.2021 document).

d. Please can you clarify if there are any specific language requirements for the private attestation for shelf stable composite products not containing meat submitted by the EU importer (Annex V to Implementing Regulation (EU) 2020/2235). Will these requirements mirror the requirements of an EHC – i.e., in one language understood by the importer signing the document and one language understood by the authority conducting checks on the product (e.g., the BCP of entry).

DG SANTE answer:
Please see our previous answer (question 3c of 29.03.2021 document).

e. The private attestation requires the approval number of the establishments that have produced the processed POAO within the composite product. We are assuming that establishment numbers for premises further back in the supply chain are not required but would appreciate confirmation of this.

DG SANTE answer:
Please see our previous answer (question 3c of 29.03.2021 document).

7. Germinal product exports – originally raised in my letter of 12/04/21.

We would welcome confirmation that semen donor animals that are already resident on approved centres (or in pre-entry quarantine) can remain on the centres (or enter the centre) after 21/04/2021 in accordance with current requirements if the establishment is re- approved under AHR. This should not compromise the health status of any new entrants which undergo pre-entry testing in accordance with AHR requirements, except in the case of porcine semen where AHR has introduced a test for an additional disease – PRRS. It will be useful to have your views on how to 'upgrade' the status of the donor boars already resident on the centre to comply with AHR requirements without having to put them through pre-entry quarantine and get them tested for PRRS in the process. This will avoid disruption to the business.

DG SANTE answer:
Please see our previous answer (question 3d of v11 document).

8. Completing box I.27 on POAO certificates – Originally raised in my letter of 29/03/21.

a. Chapter 4 of Commission Implementing Regulation (EU) 2020/2235 states, in box I.27 of the EHCs for POAO, the date entered under the heading "Date of collection/production" should be the oldest date of collection/production. Can you confirm this means the earliest date items in the consignment have been produced/packaged, and not the date of primary processing of raw materials?

DG SANTE answer:
Please see our previous answer (question 3a of 29.03.2021 document).

b. Box I.27 on the EHCs for POAO contains a field for the 'approval or registration number of plant/establishment/centre.' On certain EHCs there are already separate fields for the approval number and ISO codes of the establishments relevant to the product. For example, the bovine meat certificate contains separate fields for the approval number and ISO code of the 'slaughterhouse,' 'manufacturing plant' and 'cold store.' Please can you explain what is expected in this field, when the certificate already contains separate fields for the approval numbers of the establishments in the product's supply chain as in this case?

DG SANTE answer:
Please see our previous answer (question 3b of 29.03.2021 document).

9. Equine live animal exports – Originally raised in my letter of 29/03/21.

a. The residency and isolation requirements contained in the AHR EHC for the export of live equines not intended for slaughter (EQUI-X) are different from those detailed in the table in Annex III of Commission Delegated Regulation 2020/692. In particular, the period of residency in the country of origin for equines that are not registered, appears to have been reduced from 3 months (Annex III) to 40 days (in EHC) and the isolation requirement for the same animals appears to have been increased from 15 days (Annex III) to 30 days (EHC). We understood in our recent meeting that the EHC was correct in relation to the residency period and the legislation would be updated, but were not clear about the isolation period and whether the intention is to keep it at 15 days. Please can you confirm the position in writing?

DG SANTE answer:
Please see our previous answer (question 6a of 29.03.2021 document).

b. Article 19.1 of 2020/692 requires equines that are not registered, to be transported directly and remain on the destination establishment for 30 days, as detailed in Article 26. Article 19.3 states that this requirement shall not apply to the entry into the Union of registered equine animals from third countries and to the re-entry after temporary export of registered horses. However, Article 26 refers to an exemption for 'horses entering for competition, races and cultural equestrian events'. We understood that you confirmed in our recent meeting that the exemption applies to all registered equines animals as per Article 19.3. Please can you confirm this in writing?

DG SANTE answer:
Please see our previous answer (question 6b of 29.03.2021 document).

10. Live animal exports – Originally raised in my letter of 29/03/21.

The AHR EHC for certain live animal export, e.g., BOV/OVI EHC in II.2.2(ii), refers to 'in the establishment of origin since birth or for a period of time of at least 40 days prior to the date of their dispatch to the Union, into which during this period no animals (of the same species or other species listed for the same diseases) have been introduced'. Can you confirm if it is sufficient for any animals introduced on to the relevant holding during this period of time to be held in isolation instead?

DG SANTE answer:
Please see our previous answer (question 5 of 29.03.2021 document).

11. Racing pigeons – Originally raised in my letter of 29/03/21 but expanded following industry discussions.

a. We understand from the Commission's recent correspondence with a UK stakeholder that racing pigeons must fall under the AHR export requirements for captive birds. Is this correct?

DG SANTE answer:
Please see our previous answer (question 7 of 29.03.2021 document).

b. If the answer is yes, would the derogation suggested under Article 62 of 2019/692 enable racing pigeons to continue to enter the Union with reduced requirements? Article 62 provides legal provisions to permit the Union to grant derogations for certain third countries based on equivalent standards/guarantees. If so, how can we apply for this and what derogations can be applied to the UK?

DG SANTE answer:
Article 62 of Delegated Regulation (EU) 2020/692 provides for a derogation from the rules for the entry into the Union of captive birds for third countries or territories that have provided equivalent guarantees in relation to animal health. That derogation is, therefore, possible for those third countries and territories for which equivalency of animal health is recognized in specific agreements with the Union.

12. Mycobacterium tuberculosis complex testing in camelid and caprine animals – Originally raised in my letter of 29/03/21.

We would like to seek the Commission's agreement to the UK's **pre-export annual surveillance programme** testing**,** with respect to *Mycobacterium tuberculosis* (MTB) complex (*M. bovis, M. caprae, M. tuberculosis*), in kept camelid and caprine animals forexports to the EU, including situations where TB is confirmed in the establishment.

Article 23(2) to Delegated Regulation (EU) 2020/692 refers to establishments of origin complying with the requirements for MTB complex set out in Annex IX to this regulation.

Annex IX to Delegated Regulation (EU) 2020/692 refers to Annex II to Delegated Regulation (EU) 2020/688.

Articles 15 and 23, Part I and II of Annex II to this regulation (2020/688) cover the minimum requirements of the pre-movement surveillance programme in camelid and caprine animals that third countries would be required to comply with. Point 3 to Part I andII states that if MTB complex has been reported in camelids or caprines in the establishment, 6 week or older animals must be sampled (for testing) no earlier than 42 days after removal of last confirmed case.

In the case of **camelids**, given the very low sensitivity of the tuberculin skin tests in camelids, and the fact that the interferon-gamma test is not validated in the UK or supported by the Animal and Plant Health Agency (APHA) for use in those species, we would like to seek the Commission's agreement to the UK supplementing the annual surveillance tuberculin skin test of exporting camelid herds in the UK with one or two of thethree Defra-approved TB antibody tests for camelids (either the Enferplex test, or a combination of DPPVetTB - IDEXX tests in serial interpretation). The antibody test/s will be performed in all the skin test-negative animals 10-30 days after the injection of tuberculin. Camelid keepers in England and Wales are already familiar with this combined skin and antibody testing regime, which has been in operation for the last five years for TB screening of unrestricted herds.

In the case of **caprines**, for annual surveillance of exporting caprine herds, we would usethe comparative intradermal tuberculin test due to the moderate-good sensitivity and extremely high specificity of this test in goats.

If infection with MTB complex has been confirmed in animals kept on an exporting establishment, we will follow our existing testing protocol for herds of each of thosespecies that sustain a TB incident in England, Scotland, or Wales. This includes:

- for **camelid** herds, single intradermal (bovine-only) tuberculin skin test at 90-day intervals, supplemented by at least one round of two of the three Defra-approved antibody tests mentioned above, using parallel interpretation. Again, this is the official TB testing regime used by Defra's delivery agency (APHA) and agreed withthe British Alpaca and Llama Societies for infected herds in England and Wales.

- for **caprine** herds, we will not apply any supplementary (parallel) TB blood testing since no blood test has been validated for caprines in the UK and the skin test has a good sensitivity in this species. So, we would only carry out repeat skin testing of the affected herd at 60-day intervals (with a severe interpretation in bacteriologicallyconfirmed TB incidents). APHA may supplement the skin test with the DPPVetTB test on a discretionary basis and in caprine herds with persistent and bacteriologically confirmed *M. bovis* infection.

In summary, we would like to assure the Commission that the UK will follow the AHR, but we would like to give much greater assurances for testing in camelid and caprine animals.

We would like to seek the Commission's confirmation that this TB testing regime for camelids and caprines is in compliance with the health attestation II.2.11.6 in the Model CAM-CER, OV/CAP-X and OV/CAP-Y certificates in the draft regulation, including camelidor caprine herds in which a TB case had been confirmed more than 42 days prior to exportto the EU. This will, of course, be in addition to all the other requirements in Parts I and II of Annex II to Regulation (EU) 2020/688.

DG SANTE answer:
Please see our previous answer (question 8 of 29.03.2021 document).

13. EU origin Meat products and Meat Preparations – Attestation II.2.1 – Follow up question to one raised in my letter of 05/03/21.

We would like to confirm that the UK, and other third countries, can continue to export to the Union meat products/meat preparations of EU origin using the new AHR EHCs.

The model EHC for meat products in Regulation (EU) 2020/2235 does not provide an option, in the animal health attestation at II.2.1, to allow meat products to originate from an EU Member State. It only contemplates the scenario where the fresh meat originated from a listed third country or an EU Member State. This implies that EU origin meat products exported to GB, consolidated and packaged in GB cannot be re-exported back to the Union. However, the existing EU model EHC for meat products, laid down in Decision 2007/777, does indeed permit EU origin meat products to be re-exported back to the Union.

The AHR model EHC for meat preparations also implies, in II.2.1, that the fresh meat cannot originate from an EU Member State. Although, the public health attestation II.1.12 does imply that fresh meat can be imported from an EU Member State. Therefore, this may cause some confusion for export certification of meat preparations to the Union from third countries. The existing Model EHC for meat preparations laid down in Decision 2000/572 provides a specific option for meat preparations originating from an EU Member State in both the animal and public health attestations.

We understand this confusion will likely cause severe problems to food supply chains across GB, EU and NI. We would like to understand the Commission's intention for re- export of EU origin meat products and meat preparations and if such trade can continue tobe permitted.

DG SANTE answer:
As regards meat products, we have maintained the status quo. Similarly to Reg. (EU) 2020/2235, the certificate laid down in Decision 2007/777/EC did not provide any option to re-export EU meat products back to the EU.

Concerning meat preparations, you are right that we forgot the option of using EU fresh meat in the new import certificate in Regulation 2020/2235. This model will need to be amended. In the meantime, you can use the old model.

14. Deletion of II.2 animal health attestation in FISH-CRUST-HC and MOL-HC model health certificates – Follow up question to one originally raised in letter of 05/03/21.

In FISH-CRUST-HC and MOL-HC model health certificates provided in Regulation (EU) 2020/2235, footnote 2 provides conditions where Part II.2 Animal health attestation can be deleted. It is our understanding from point (a) and (b) of footnote 2 that II.2 can be deleted if the species are not listed in Regulation 2018/1882 or if aquatic animals (or their products) have been wild-caught. However, we would appreciate some clarification on point (c) of footnote 2. From this we infer that II.2 can be deleted if the consignment comprises aquatic animals which are no longer alive but fit for human consumption as long as they are not intended for further processing in the Union prior to human consumption.
An example will be eviscerated farmed salmon. Is this the intention?

Commission Delegated Regulation (EU) 2020/692 states that “Products of animal origin from aquatic animals other than live aquatic animals represent a lower risk than aquatic animals, and the measures to be taken in relation to such products entering the Union for further processing, are therefore, less rigorous than those which apply to live animals.” Therefore, we would expect to be able to delete II.2 for

consignments of POAO whether they are entering the Union for further processing prior to human consumption or not, but this is not our understanding of the certificate.

Would you please be able to clarify the meaning of point (c) in footnote 2 and confirm our understanding of points (a) and (b)?

DG SANTE answer:
The meaning of point (c) in footnote 2, is that Part II.2 of the model certificates does not apply and should be deleted if the consignment comprises products of animal origin which are no longer alive, and which enter the Union ready for direct human consumption.

Part II.2 of the model certificate does however, apply to products of animal origin which enter the Union intended for further processing, but because of the lower risk they present, Parts II.2.3.1, II.2.3.2 and II.2.4 do not apply to fish which are slaughtered and eviscerated before dispatch to the Union.

Recital (85) specifically mentions fish which are slaughtered and eviscerated prior to dispatch and the fact that such products do not have to originate from disease free areas.