UK questions for clarification – version 9

UK letter of 24.03.2021

1. Exports of raw milk direct from the farm to the EU

Raw milk is considered primary production and hence the farm where it is collected only needs to be registered, and not approved.UK producers want to export raw milk for furtherprocessing in the EU, rather than producing raw milk for human consumption in GB.

Can you clarify whether the production holdings intending to export raw milk need to be listed, and if so, would this be under Section IX ('Raw milk, dairy products, colostrum andcolostrum-based products').

DG SANTE answer:
Establishments handling products of animal origin for which Annex III of Regulation (EC) No 853/2004 lays down requirements, must be approved and hence listed. The derogation from such approval does not refer to primary products, but to primary production. Unless primary producers (farmers) directly export to the EU, the establishment handling raw milk for export to the EU (e.g. collection centre), must be approved and listed.

2. Treatments for meat

EHC 'Meat products, treated stomachs, bladders and intestines': in the Table II.1.1 column (B) requires that the treatment specified in Annex II to Decision 2007/777/EC is declared. However, Annex I, point 2 (a) (ii) of the same Regulation reads that 'the products have undergone at least the specific treatment set out in Annex II.

Could you please clarify if the letter to be inserted in column B should be the actual treatment or that with which the country has been listed in Annex II?

DG SANTE answer:
As indicated in part II.1.1 of the model certificate laid down in Annex III to Decision 2007/777, the treatment code to be entered in column (B) is the one actually used for each meat constituent of the final meat product.
However, Regulation (EU) 2020/2235 provides for a specific certificate for meat products processed in countries authorised for the entry into the Union of fresh meat and therefore authorised to enter meat products not subject to specific treatments (Chapter 25).

3. Country of Origin for meat

EHC 'Meat products, treated stomachs, bladders and intestines': in the Table II.1.1 column (C) asks for the ISO code of the country of origin. Given that the EHC talks about the 'relevant meat constituents', one would be led to believe that (C) asks for the country of origin of the meat used to produce the meat product, rather than the country where the meat product itself is made.

Could you please clarify if this is the case?

DG SANTE answer:
As indicated in part II.1.1 of the model certificate laid down in Annex III to Decision 2007/777, the ISO codes to be entered in column (C) are the ones of the country of origin for each meat constituent used to produce the final meat product.
Please note that the origin of the fresh meat is certified later on in the certificate and only certain specific situations are covered.

4. Transits of chilled meat preparations

For direct imports of meat preparations into the EU we are aware of the current public health requirement for products to be frozen.

The meat preparation transit model certificate does not require public health requirements to be certified so we understand that meat preparations do not have to be frozen in order to transit EU territory.

This is clear in the new model certificate published by the EU for meat preparations in IMPLEMENTING REGULATION (EU) 2020/2235 (Chapter 24) due to be implemented by the Animal Health Regulation on 21st April but we would appreciate your confirmation that our understanding is correct for when the current certificate is being used.

Please can you confirm if the transit of chilled meat preparations across EU territory is permitted?

DG SANTE answer:
Your interpretation is correct. Part II.1 of model certificate MP-PREP can be deleted in the case of transit where the EU is not the final destination of the meat preparation. Therefore, the requirements of products being "*frozen to an internal temperature of not more than -18°C*" does not apply in the case of transit.

5. Lab reports

We are aware of certain Border Control Posts requesting original copies of laboratory reports issued by APHA to accompany a consignment to the BCP and be attached to the EHC as a schedule, signed and stamped by the Certifying Officer. This has arisen specifically in the context of the EHC for blood products not for human consumption to be used in feed.

We understand from the footnotes of the relevant certificate (footnote (7) relating to II.12) that the operator responsible for the consignment is the individual responsible for ensuring that the lab test results are provided. As such, we would not necessarily expect them to be provided as part of a schedule, signed and stamped by the OV.

We would appreciate your view on whether this is necessary.

DG SANTE answer:
According to the model certificate laid down in Chapter 4(B) of Annex XV to Regulation 142/2011 for blood products used as feed material, point II.12 indicates that this is the responsibility of the consignor to provide the analyses report and footnote (7) clarifies that this is the responsibility of the operator responsible for the load to present the analyses report to the BCP. Considering that statement II.12 is placed in the part covered by the signature of the official inspector/veterinarian, the existence of this analyses report must be ascertained at the time of issuance of the certificate. However, there is no legal requirement for this analyses report to be signed and stamped by the official inspector/veterinarian.

6. Bulk Vitamin D3 (cholecalciferol) capsules derived from sheep wool (lanolin) for human consumption

Vitamin D3 is derived from lanolin. The commercial manufacture of vitamin D3 includes multiple chemical conversion steps to develop the finished pure crystalline vitamin D3 – a highly refined product. It is a chemical entity of negligible animal health risk which has been processed beyond the 'end-point'.

Please can you confirm whether capsules filled with Vitamin D3 derived from lanolin are considered a POAO and if so, whether/which certificate is required and whether they are subject to veterinary checks at an EU Border Control Post? Furthermore, in the case of food of plant origin which has been fortified with vitamin D3 of lanolin origin, would the food be considered a composite product subject to checks?

DG SANTE answer:
Vitamin D3 derived from lanolin should be considered as an "*other product of animal origin*".
Therefore:

- The PAO certificate in Chapter 49 of Annex III to Regulation (EU) 2020/2235 must be used
- Listing of country is required (list for fresh meat of small ruminants
- No listing of establishments is required (no specific requirements in Annex III of Regulation (EC) No 853/2004.

In the case where food of plant origin has been fortified with vitamin D3 of lanolin origin, the resulting product is a composite product, and indeed submitted to the relevant checks.