Food Standards Agency
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DVMs for distribution

Border Inspection Posts (England) – for action
Chief Port Health Officers – for action
Official Fish Inspectors – for action

cc:
Nominated officers for Imported Food (England)
APHA
CIEH
APA
Trading Standards Institute
Health Protection England

28th December 2016 Reference: OVS/2016/33

Dear Colleagues,

AMENDMENT TO COMMISSION DECISION 2007/275/EC

1. This letter is addressed to Border Inspection Posts, Chief Port Health Officers, Official Veterinary Surgeons and Official Fish Inspectors in England only.

2. Subsequent to the publication of Decision (EU) 2016/1196 and guidance from the European Commission, below is advice on the import of gelatine capsules and other products affected by the changes:

- Gelatine capsules must be considered as products derived from gelatine and not gelatine itself, therefore the import conditions for gelatine do not apply to capsules made from gelatine;

- Unfilled gelatine capsules for *animal feed* are already under veterinary import control and they need to be accompanied by the certificate laid down in Chapter 11 of Annex XV to Regulation (EU) No 142/2011;

- Unfilled gelatine capsules made with products of animals origin (POAO) for *food* will be subject to veterinary checks from 1st January 2017;

3. Currently Regulation (EU) No 1079/2013 provides that Article 6(1) of Regulation (EC) No 853/2004 shall not apply to imports of products of animal origin for which no harmonised public health import conditions have been established. Instead, imports of such products shall comply with the public health requirements of the Member State of destination. As there are no harmonised rules for gelatine products (which include empty or filled gelatine capsules) this derogation applies. We are in the process of drafting general authorisations for certain filled and unfilled gelatine capsules which will be available shortly on the GOV.UK website.

4. Suppliers of unfilled gelatine capsules made of, or containing, ruminant (cattle, sheep and goat) material and identified by the corresponding CN codes must provide a copy of the 'Certificate of Suitability' issued by the EDQM (European Directorate for the Quality of Medicines): https://www.edqm.eu/en. Great Britain interprets this to mean a TSE 'Certificate of Suitability'. The original TSE 'Certificate of Suitability' is the property of the manufacturer of the gelatine capsules. Therefore a copy of the Certificate should accompany each consignment of empty capsules that is imported.

5. The import of filled or empty gelatine capsules made of non-ruminant material, e.g. porcine, fish or vegetable, should be accompanied by the manufacturer's declaration confirming the material from which the capsules are made. Please note that gelatine capsules made from vegetable material are not subject to veterinary checks, unless they contain POAO.

6. The CN codes for filled capsules will depend on the content of the capsule. Filled gelatine capsules for food use made from ruminant raw material other than hides and skins, must be accompanied, at import, by a TSE declaration, signed by the manufacturer of the capsules to confirm that the gelatine capsules do not contain and are not derived from specified risk material (SRM), as defined in Annex 5 of Regulation (EC) 999/2001. If the imported product is subjected to veterinary checks, the TSE declaration must be checked at the Border Inspection Post (BIP). If, however, the product is not subjected to veterinary checks, i.e. they are listed in Annex II of Decision 2007/275/EC or fall within the requirements of Article 6 of Commission Decision 2007/275 (EC) they fall under Article 15 of Regulation (EC) No 882/2004 and checks may be carried out inland.

7. Import conditions for filled gelatine capsules are dependent on the nature of the filling, e.g. capsules filled with fish oil would need the certificate for fishery products plus the TSE declaration, referred to in paragraph 6 if the gelatine is of ruminant origin, except if it is derived from hides and skins. Official Fish Inspectors can carry out veterinary checks on fishery products in gelatin capsules, but will have to consult an OVS should there be any issues with the TSE declaration. Please note that for composite products, the calculation of the amount of animal products applies to the filling only. The

amount of the gelatine used to manufacture the capsule itself can be disregarded.

8. Composite products that meet all of the requirements of Article 6 of Decision 2007/275/EC as amended are not subject to veterinary checks. In addition, food supplements packaged for the final consumer, containing small amounts (in total less than 20 %) of processed animal products (including glucosamine, chondroitin and/or chitosan) other than meat products (CN codes ex 2106 10 and ex 2106 90 apply) are also exempt from veterinary checks at the BIP. However, they are covered by Article 15 of Regulation (EC) 882/2004, so checks may be carried out inland. Food supplements packaged for the final consumer, which contain glucosamine, chondroitin, or chitosan (GCC), have been exempt from veterinary checks at the BIP. Decision (EU) 2016/1196 requires veterinary checks on these commodities if they contain more than 20% of GCC, and the relevant import health certificate will be required.

9. Food supplements that fall outside the descriptions referred to in paragraph 8 that contain POAO and that are not composite products e.g. gelatine capsules containing 100% POAO or a mixture of POAO and water, will be subject to veterinary checks at the BIP.

10. It is worth remembering that empty gelatine capsules for pharmaceutical use remain outside the scope of veterinary checks.

11. The European Commission has advised that meat extracts and meat concentrates should be treated as meat products. Import conditions for meat products are in the Import Information Note (IIN) here:

http://ahvla.defra.gov.uk/documents/bip/iin/mpmp-2.pdf

We are aware that some countries may not be able to sign a meat product certificate for food supplements containing meat powders. We are preparing a General Authorisation to cover these products, but if importers are unable to meet the requirements they will need to apply to APHA's Centre for International Trade for a specific authorisation.

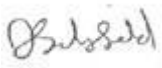
12. BIPs should allow consignments containing gelatine capsules already despatched prior to the 1st January 2017 entry into Great Britain in accordance with previous instructions as set out in OVS note 2006/31. Included in Annex 1 to this note is a template for authorised officers to record any issues with this policy and submit to the Food Standards Agency at: imported.food@foodstandards.gsi.gov.uk. This will ensure enforcement issues are raised and discussed at the next European Commission Expert Working Group meeting.

13. For all other products which will be subject to veterinary checks on the 1st January 2017 (due to the changes in Decision (EU) 2016/1196), BIPs should continue to apply the same import conditions as before, until further notice. Examples of such products are amino acids derived from POAO and creatine. Importers should be advised to contact APHA to obtain an Authorisation for these products.

14. The Commission have asked for Member States to demonstrate a flexible approach to consignments that are not accompanied by a BSE attestation immediately after Implementing Decision (EU) 2016/1196 comes into force on 1st January 2017. They are also keen to discuss the new measures at the next European Commission Expert Working Group meeting in 2017 and to that end, enforcement officers are requested to record the main issues that they encounter on the attached template.

15. If you have any other enquires please contact the Imports Policy Team at imported.food@foodstandards.gsi.gov.uk

Yours sincerely



Alex Schofield
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Annex 1: Amendments to Decision 2007/275/EC – issues at BIPs

CVED Reference	
Product	
CN Code	
Country of Origin	
Issue	