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GAIN Report

Global Agricultural Information Network

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Gelatin Capsules to Denmark No Longer Require a TSE

Attestation

Report Categories:

FAIRS Subject Report

SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports

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Report Highlights:

The Danish Veterinary and Food Administration (DVFA) no longer requires a TSE (Transmissible Spongiform Encephalopathies) attestation for gelatin capsules made from materials of ruminant origin.

General Information

Commission Implementing Decision 2016/1196 updated the list of products that are subject to a veterinary check upon arrival in the EU and no longer explicitly excluded empty gelatin capsules from such border controls. This update created some differences in interpretation on the exact EU import requirements for gelatin capsules. The ambiguity concerned the need for a BSE statement from the U.S. Food and Drug Administration for gelatin capsules containing materials partly or fully of ruminant origin, in accordance with Commission Regulation (EC) No 999/2001.

Danish authorities had viewed the capsules as gelatin (and not as a gelatin derived product) and had decided that the TSE statement should be according to Annex IX of Regulation (EC) No 999/2001 and come from the U.S. Food and Drug Administration.

Other EU Member States had a different interpretation of Commission Implementing Decision 2016/1196.

Providing further clarification, the European Commission (EC) indicated: “Annex IX to Regulation (EC) No 999/2001 is not clear and some EU Member States consider that the BSE attestation is required for gelatin, but not for derived products from gelatin such as gelatin capsules. Unfortunately, we (the European Commission) have no legal grounds to go against this position.”

The Danish Veterinary and Food Administration informed FAS The Hague that beginning May 17, 2018 they have lifted the requirement for a TSE attestation. Empty as well as filled gelatin capsules for human consumption from countries outside the EU no longer must be accompanied by an official certificate with the relevant TSE attestations.