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For feed and food law enforcement, and port health authorities in England

BTOM Implementation - Gelatine Capsules

Summary: A concise note to clarify the situation concerning the risk categorisation for empty or filled gelatine capsules imported into Great Britain.

Dear colleague,

This note is to clarify the situation regarding gelatine capsules imported to Great Britain.

Empty gelatine capsules imported from non-EU countries that are comprised of ruminant material should be regarded as medium risk under the Border Target Operating Model (BTOM) risk categories. If they are from permitted countries where the BSE (Bovine Spongiform Encephalopathy) risk is undetermined and low for ruminant products from permitted countries where the BSE risk is negligible or controlled. Unfilled capsules from the EU (European Union) would also be considered as low risk.

If the gelatine capsules, whether empty or filled, are classed as pharmaceutical grade, and produced in an establishment that is found on the [EDQM website](#), they should be imported using the authorisation process.

If the capsules are filled with a POAO (Products of Animal Origin) from either the EU or non-EU, this would make it a compound product. The type of POAO that it is filled with would determine whether it is categorised as low or medium risk. The medium risk element would require certification.

It should be remembered that goods considered as low or medium risk would still be required to comply with the full import requirements.

For capsulated fish oil, such commodities would be a 'fishery products (including crustaceans) other than those mentioned in Category II.' Category II are those products which are not in hermetically sealed containers intended to render them stable at ambient temperature. This would mean that they are low risk as they are shelf stable at ambient temperature and sterilised.

The BTOM risk categories (medium or low risk), will determine if certification is required.

However, if the fish oil is from Chinese aquaculture, assimilated Decision 2002/994 would require them to be accompanied by a declaration of the Chinese competent authority stating that each consignment has been subjected, pre-export, to a chemical test to ensure that the products concerned do not present a danger to animal or human health. That chemical test must be conducted to detect the presence of chloramphenicol as well as nitrofurans and its metabolites. In addition, the fish oil must have been assessed for the presence of malachite green, crystal violet and their metabolites. The results of those chemical tests shall be included in that declaration.

All Products of Animal Origin items, i.e. the gelatine capsules and/or filling, must come from an approved country and an approved establishment. As per [Import Information Note BLGC/1](#), POAO except for highly refined goods, must come from a country with an appropriate approved veterinary residue plan.

Yours sincerely,

Simon Petty

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