

Guidance for Industry

Frequently Asked Questions about

ASEAN Guidelines for Minimising the Risk of Transmission of Transmissible Spongiform Encephalopathies in Traditional Medicines and ASEAN Guidelines for minimising the Risk of Transmission of Transmissible Spongiform Encephalopathies in Health Supplements; Version 2.0

Introduction

This document is a collation of Questions and Answers (Q&A) which provide clarification and references that may be referred by the industry in order to have a better understanding of the ASEAN guidelines. It is developed by HSA based on discussions between HSA and the industry experts.

The industry may refer to this Q&A for products intended for the Singapore market. For products to be marketed in other ASEAN Member States, industry is advised to refer to regulatory guidelines provided by the regulatory authorities of the respective ASEAN Member State where your product would be exported to.

This document may be revised from time to time, to include new Q&As or to update the information due to changes made to the ASEAN guidelines.

Questions & Answers

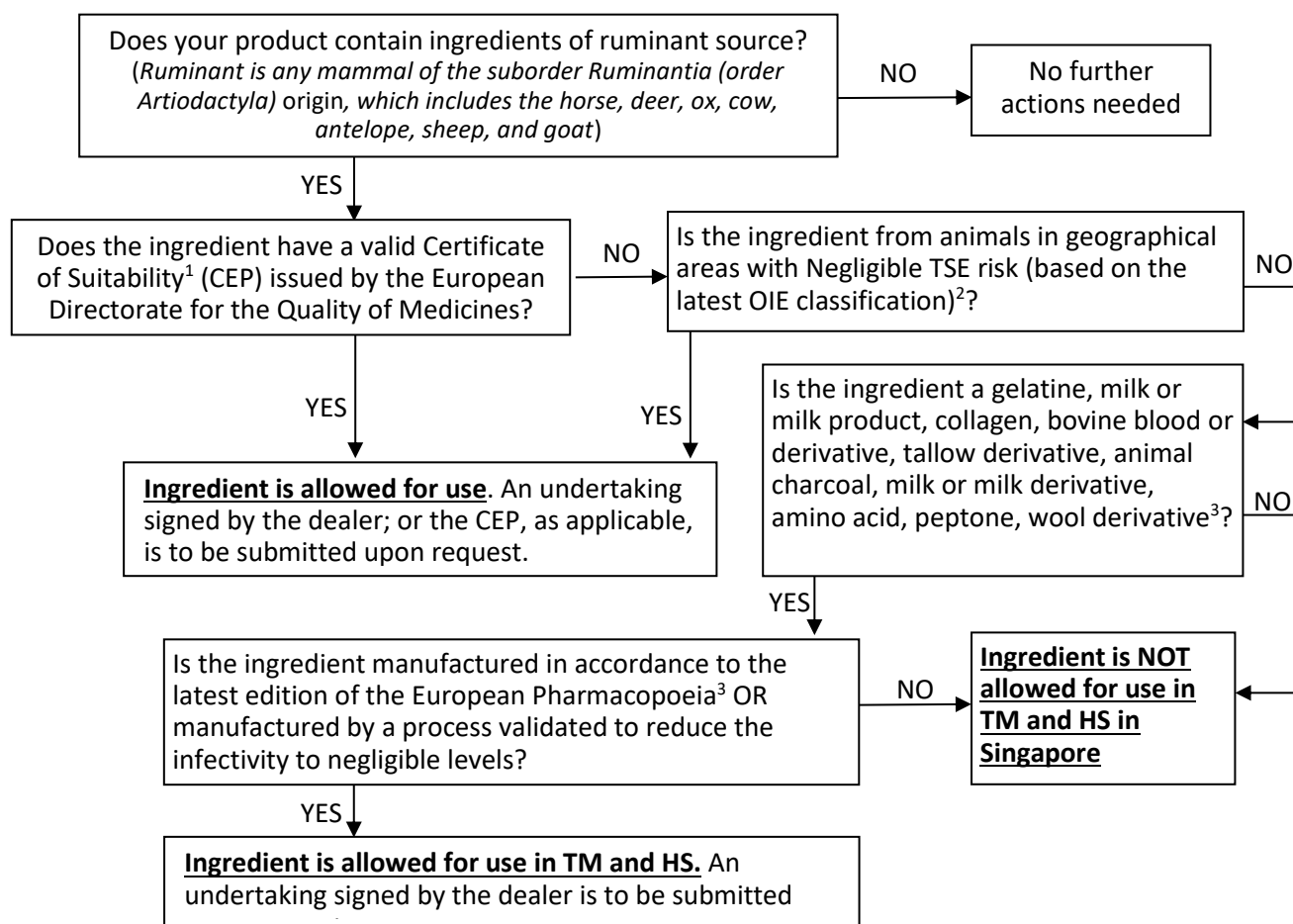
1. What are the concerns with Transmissible Spongiform Encephalopathies (TSEs)?

TSEs are a group of chronic degenerative diseases that include Bovine Spongiform Encephalopathy (BSE) in cattle and Creutzfeld-Jakob Disease (CJD) in humans. The World Health Organisation had concluded a causal link between Variant CJD (vCJD) and BSE. Studies have also shown that human exposure to BSE is mainly via BSE-contaminated food.

PrP^{TSE}, which has been identified as the protein agent responsible for TSEs, is highly resistant to deactivation treatments. As such, it is prudent to introduce measures to minimise risk of TSE transmission to humans via the use of ruminant materials in TM and HS products.

2. How can I determine the risk of my TM or HS ingredient?

You may refer to the following flowchart to guide your self-assessment.



¹ Refer to EDQM website at https://extranet.edqm.eu/publications/recherches_CEP.shtml for more information.

² Refer to the World Organisation for Animal Health (Office International des Epizooties (OIE)), Status of BSE risk <http://www.oie.int/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/> for more information.

³ Refer to the European Pharmacopoeia General Texts "Minimising The Risk of Transmitting Animal Spongiform Encephalopathy Agents Via Human and Veterinary Medicinal products, Special Considerations" for information