

Which types of material require a TSE risk assessment?



You are here:

[EDQM FAQs](#) / [EDQM FAQs in English](#) / [CERTIFICATION OF SUBSTANCES FOR PHARMACEUTICAL USE](#) / [General information on the CEP procedure](#) / [TSE](#) / Which types of material require a TSE risk assessment?

Answer:

All materials submitted for certification that are derived from animals that carry the risk of transmitting agents of animal spongiform encephalopathies (TSE) require a TSE risk assessment, as described in the general monograph *Products with risk of transmitting agents of animal spongiform encephalopathies (1483)* and general chapter 5.2.8 of the Ph. Eur., which is identical to the EMA [Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products](#). The Certification procedure requires the presentation of a dossier as described in the EDQM guideline [Content of the dossier for a substance for TSE risk assessment \(PA/PH/CEP \(06\)2\)](#).

Assessment of certification applications is based on the criteria of general chapter 5.2.8 of the Ph. Eur.