

# Which types of material require a TSE risk assessment?



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## 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.