European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

IMPLEMENTATION OF THE REVISED "NOTE FOR GUIDANCE ON MINIMISING THE RISK OF TRANSMITTING ANIMAL SPONGIFORM ENCEPHALOPATHY AGENTS VIA HUMAN AND VETERINARY MEDICAL PRODUCTS" (EMA/410/01 Rev. 3)

Dear Sir or Madam,

The revised EMA "Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" has been published in the Official Journal of the European Union, and the corresponding general chapter 5.2.8 of the European Pharmacopoeia will be revised shortly and will come into force on 1 July 2011.

You hold a certificate of suitability for the TSE risk. The certificates of suitability refer to the specific and general European Pharmacopoeia monographs in force and therefore are revised when necessary according to any new supplement and/or new Edition of European Pharmacopoeia, as well as according to any change in regulatory requirements.

The new requirements of the Note for Guidance require an update of some dossiers for TSE certificates of suitability. You are therefore asked to update your dossier if necessary in compliance with the new requirements, by following the instructions below.

- For **any TSE risk material** if:

- source country(ies) has(ve) been downgraded (e.g. Brazil, China, etc) based on the OIE classification
- or tissues have been downgraded for their infectivity,

a discussion of the impact on the TSE risk and demonstration of compliance with the new requirements should be provided.

In addition to this documentation, depending on the nature of the TSE risk material involved, the following information should be submitted:

- **Bone gelatin and other materials derived from bovine bones** (e.g. collagen, peptone):

- You are asked to confirm that vertebrae are removed from the source material obtained from cattle over 30 months from category B or C countries. Should this not be the case, you should propose appropriate actions that will be undertaken to obtain vertebrae free material.

Address: 7, allée Kastner, CS 30026
F - 67081 Strasbourg (France)
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Internet : http://www.edqm.eu

- You are asked to confirm that the acid process performed to produce bone gelatin is in compliance with the new requirements. Should this not be the case, you should update the process.
- For bone collagen, in addition to these requirements, you are asked to support the safety of your product by providing a process evaluation based on the similarities of the collagen processing steps, as compared to known inactivation steps of the manufacture of gelatin.

- **Bovine blood and blood derivatives:**

For adult bovine donor serum, you are asked to confirm that an age limit of 36 months is applied, whatever the source country. Should this not be the case, you should propose appropriate actions that will be undertaken to obtain material from cattle less than 36 months old.

For adult bovine serum and plasma from OIE-category B or GBR-II/III countries, you are asked:
- *either* to confirm that an age limit of 21 months is applied,
- *or* if the age limit of 21 months cannot be met, to demonstrate that cross contamination of blood with CNS material can be clearly ruled out (e.g. halal slaughter).

For adult bovine serum derivatives from OIE-category B or GBR-II/III countries, you are asked:
- *either* to confirm that an age limit of 21 months is applied,
- *or* if the age limit of 21 months cannot be met, to demonstrate prion reduction during manufacture and to confirm that an age limit of 30 months is respected.

- **Peptone with muscle tissue as protein source material:**

For tissues from category B countries, you are asked to confirm that the animals are not older than 30 months and are fit for human consumption. Should this not be the case, you should propose appropriate actions that will be undertaken to meet these requirements.

- **Sheep and goat milk and milk derivatives:**

You are asked to confirm that milk is sourced from healthy animals in the same conditions as milk collected for human consumption.

Should your product be a mixture of several TSE risk materials, relevant information for all the substances involved is to be submitted. Should your certificate of suitability depend on another TSE certificate of suitability, please provide a copy of the relevant revised certificate as soon as available.

TSE risk materials not concerned by the above mentioned points are considered to be in compliance with the revised Note for Guidance. As a consequence no reply to this letter is expected.

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The requested information should be supplied within 3 months after receipt of this letter. You should provide information even if the data are already included in your dossier. Please submit them again or give clear reference to your documentation, so as the evaluation process can start.

If changes are made to comply with the revised Note for Guidance, updated sections of your dossier should be provided.

Upon receipt, the dossier will be reviewed and you will be informed of the outcome of the evaluation within 3 months.

This procedure is free of charge, unless you submit, at the same time, a request for revision or renewal of the concerned certificate of suitability not related to the demonstration of compliance of your TSE risk material with the revised Note for Guidance.

You are encouraged to submit electronic documentation, through our secure Dropbox, for which you need access codes that can be obtained upon request at cep@edqm.eu. For more details, please visit our website, where the requirements are described.

Failure to reply to this request and to comply with the above requirements may lead to the suspension of the concerned granted certificate/s.

For any question concerning this procedure, please contact us at cep@edqm.eu

Yours sincerely,

Certification of Substances Division

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