European Medicines Agency
Veterinary Medicines and Inspections

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Recommendations of the Focus Group Meeting on Substances of Animal Origin

The focus group highlights that the ultimate objective of the guidance documents available on the provision of details on the geographic origin of starting materials is to have authorised veterinary medicinal products free of live extraneous agents.

Definition: The focus group defines starting materials as all components used in the production of the veterinary medicinal product as they are introduced into the manufacturing process.

The focus group stresses that the specific guidance on TSE and bovine serum requirements remain applicable and the recommendations below additionally clarify the need to take into account details of the geographic origin of starting materials.

1) The focus group recommends that a risk assessment regarding the safety of the product in terms of extraneous agents is provided in the dossier for all starting material of animal origin used in the manufacture of veterinary medicinal products or contained in the finished product.

2) The focus group recommends that the details of the geographic origin of starting materials of animal origin should be defined in the dossier unless it can be demonstrated in the risk assessment that the geographic origin of the substance has no impact on the safety of the product with regards to extraneous agents.

3) The focus group recommends that the extent of any geographic region specified in the risk assessment should be defined.

4) The focus group points out that Annex 5 section 34 of the EU GMP Guide specifically requires the details of the geographic origin to be defined in internal manufacturing specifications for starting materials of animal origin.

5) The focus group suggests that implementation of these recommendations is applicable to new Marketing Authorisation applications and should be taken into account for any relevant changes to existing Marketing Authorisations.

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