ANNEX I

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IF1ANNEX I

CHEMICAL, PHARMACEUTICAL AND ANALYTICAL STANDARDS, SAFETY AND RESIDUE TESTS, PRE-CLINICAL AND CLINICAL TRIALS IN RESPECT OF TESTING OF VETERINARY MEDICINAL PRODUCTS

Textual Amendments

F1 Substituted by Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (Text with EEA relevance).

INTRODUCTION AND GENERAL PRINCIPLES

9. The environmental risk assessment connected with the release of veterinary medicinal products containing or consisting of Genetically Modified Organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council⁽¹⁾ shall be provided in the dossier. The information shall be presented in accordance with the provisions of Directive 2001/18/EC and Regulation (EC) No 726/2004 of the European Parliament and of the Council⁽²⁾, taking into account guidance documents published by the Commission.]

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- (1) [F1OJ L 106, 17.4.2001, p. 1.]
- (2) [F1OJ L 136, 30.4.2004, p. 1.]

Textual Amendments

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