



NOTE REGARDING THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR NORGESTOMET

An application for the establishment of maximum residue limits for norgestomet was submitted to the European Commission in 1992 under Article 7 of Council Regulation (EEC) No 2377/90, as a so-called "old substance". The Safety of Residues Working Party of the Committee for Veterinary Medicinal Products (CVMP) assessed the data in January 1993 and agreed a list of questions to be addressed by the applicant.

The response to the list of questions was submitted in August 1997 to the EMEA. The CVMP concluded the assessment of the data in July 1998 and considered that there was no need to establish maximum residue limits for norgestomet, mainly taking into account the fact that the substance is rapidly and extensively metabolised and excreted. Therefore, the CVMP recommended the inclusion of norgestomet in Annex II of Council Regulation 2377/90, for bovine species, restricted to zootechnical use.

In May 1999 the European Commission requested the CVMP to re-consider the assessment of sexual hormones in view of the opinion of the Commission's Scientific Committee on Veterinary Measures Relating to Public Health. The CVMP concluded the re-evaluation of the concerned hormones in December 1999 and for norgestomet confirmed its previous recommendation of inclusion in Annex II of Council Regulation (EEC) No 2377/90. The European Commission decided, in view of the opinion of the SCVPH, to propose the establishment of control limits for norgestomet. The proposal for inclusion of norgestomet in Annex I did not receive a favourable opinion in the Standing Committee and was subsequently submitted to the European Council. The Council rejected the proposal in December 2001.

In April 2002 the Commission requested the CVMP to consider if, based on the existing data, quantitative maximum residue limits could be proposed for norgestomet on a temporary basis. Taking into account the residue data available and the ADI established for norgestomet, the CVMP suggested limits of 0.5 µg/kg for muscle, fat, liver and kidney and 0.15 µg/kg in milk. Subsequently the Commission adopted the Commission Regulation (EC) No 665/2003¹ establishing provisional MRLs for norgestomet as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Norgestomet	Norgestomet	Bovine	0.5 µg/kg 0.5 µg/kg 0.5 µg/kg 0.5 µg/kg 0.15 µg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.1.2008. For therapeutic and zootechnical purposes only

Article 12 of Council Regulation (EEC) No 2377/90 requires that, after amendments to the annexes of the Regulation, the summary of the assessment of the substances concerned that have been examined by the CVMP be published. The summary report on norgestomet, now published on the EMEA web site, is the summary of the assessment carried out by the CVMP, which recommended inclusion of norgestomet in Annex II of Council Regulation (EEC) No 2377/90. For the reasons given above, the MRLs adopted by the European Commission are not consistent with the recommendation of the CVMP.

[Norgestomet summary report](#)

¹ OJ L 96, 14.4.2003, p. 7