

**COUNCIL REGULATION (EC) No 2584/2001
of 19 December 2001**

amending Annexes I and III of Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin ⁽¹⁾, and in particular Article 7 thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) In accordance with Regulation (EEC) No 2377/90, maximum residue limits are to be established progressively for all pharmacologically active substances which are used within the Community in veterinary medicinal products intended for administration to food-producing animals.
- (2) Maximum residue limits should be established only after examination within the Committee for Veterinary Medicinal Products of all the relevant information concerning the safety of residues of the substance concerned for the consumer of foodstuffs of animal origin and the impact of residues on the industrial processing of foodstuffs and taking into account all publicly available relevant scientific information concerning the safety of residues of the substance concerned for the consumer of foodstuffs of animal origin, including for example opinions of the Scientific Committee on Veterinary Measures Relating to Public Health, reports from the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or reports from internationally renowned research organisations.
- (3) In establishing maximum residue limits for residues of veterinary medicinal products in foodstuffs of animal origin, it is necessary to specify the animal species in which residues may be present, the levels at which they may be present in each of the relevant tissues obtained from the treated animal (target tissue) and the nature of the residue which is relevant for the monitoring of residues (marker residue). In the case of veterinary medicinal products intended for use in lactating animals maximum residue limits shall be established for milk.

- (4) Regulation (EEC) No 2377/90 provides that the establishment of maximum residue limits shall in no way prejudice the application of other relevant Community legislation.
- (5) For the purpose of monitoring residues, as provided for in appropriate Community legislation, maximum residue limits should usually be established for the target tissues of liver or kidney. However, as the liver and kidney are frequently removed from carcasses moving in international trade, maximum residue limits should consequently be established always for muscle or fat tissues.
- (6) The substances chlormadinone, flugestone acetate and altrenogest are hormones and are therefore subject to restrictions and control of use as provided for in Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists ⁽²⁾. Under certain conditions, these hormones may be administered to farm animals for therapeutic or zootechnical purposes only. In particular, these conditions require the administration of these substances by a veterinarian or under his direct responsibility. In addition, the type of treatment, the types of products authorised, the date of treatment and the identity of the animals treated must be officially recorded by the veterinarian.
- (7) Furthermore, the conditions laid down in Directive 96/22/EC prohibit the administration of hormones for therapeutic or zootechnical purposes to breeding animals during the fattening period at the end of their reproductive life. Moreover, they provide that meat or products from animals to which hormones have been administered for therapeutic or zootechnical treatment should not be placed on the market for human consumption unless they have been treated in accordance with Directive 96/22/EC and insofar as the withdrawal period laid down was observed before the animals were slaughtered.
- (8) The overall evaluation of the available risk assessments of these substances and of the entire body of available scientific information and data indicate that, as concerns the excess intake of hormone residues and their metabolites, and in view of the intrinsic properties of hormones and epidemiological findings, a risk to the consumer has been identified.

⁽¹⁾ OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 2162/2001 (OJ L 291, 8.11.2001, p. 9).

⁽²⁾ OJ L 125, 23.5.1996, p. 3.

- (9) Furthermore, given the intrinsic properties of sexual hormones and as it is not possible to exclude that good veterinary practice is not systematically applied, and that therefore the authorities should be provided with means of control of illegal use of these hormones, Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products ⁽¹⁾, requires the authorities to carry out investigations in the case of suspected animals or positive laboratory results.
- (10) Taking into account the identified potential adverse effects to human health from the administration of these hormones to farm animals for any purpose and after consideration of the current need to continue to make available on the Community market some of these substances that are currently used for therapeutic or zootechnical treatment of farm animals and, taking also into account the strict conditions under which Directive 96/22/EC authorises the use of these substances for therapeutic or zootechnical purposes, it is appropriate to proceed with the consideration of these substances under Regulation (EEC) No 2377/90 for the purpose of setting up maximum residue limits.
- (11) Provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard for the health of the consumer, maximum residue limits should be established in Annex I or Annex III to Regulation (EEC) No 2377/90. However, given the overall evaluation on the risk assessments of sexual hormones, as concerns possible excess intake of hormone residues and their metabolites, a possible risk to the consumer needs to be regularly reviewed on the basis of any new scientific evidence.
- (12) It is thus considered appropriate, without prejudice to other provisions of Community law, in particular Directive 96/22/EC, that chlormadinone and flugestone acetate (for ovine milk) be inserted into Annex I to Regulation (EEC) No 2377/90 and that, in order to allow for the completion of scientific studies, altrenogest and flugestone acetate (for caprine milk) be inserted into Annex III thereto.
- (13) However, it has to be stressed that, as a result of new information or a re-assessment of existing information, Regulation (EEC) No 2377/90 can be amended in order to protect human or animal health, in accordance with the procedures provided for in this Regulation.
- (14) The Standing Committee on Veterinary Medicinal Products referred to in Article 8 of Regulation (EEC) No 2377/90 has not delivered a favourable opinion on the Commission proposed measures,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and III to Regulation (EEC) No 2377/90 are hereby amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities*.

It shall apply from the sixtieth day following that of its publication.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 December 2001.

For the Council

The President

A. NEYTS-UYTTEBROECK

⁽¹⁾ OJ L 125, 23.5.1996, p. 10.

ANNEX

A. The following substances are hereby inserted in Annex I to Regulation (EEC) No 2377/90 (List of pharmacologically active substances for which maximum residue limits have been fixed)

'6. Agents acting on the reproductive system

6.1. Progestogens

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Chlormadinone	Chlormadinone	Bovine	4 µg/kg 2 µg/kg 2,5 µg/kg	Fat Liver Milk	For zootechnical use only
Flugestone acetate	Flugestone acetate	Ovine	1 µg/kg	Milk	For intravaginal use for zootechnical purposes only'

B. The following substances are hereby inserted in Annex III to Regulation (EEC) No 2377/90 (List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed)

'6. Agents acting on the reproductive system

6.1. Progestogens

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Altrenogest	Altrenogest	Porcine	3 µg/kg 3 µg/kg 3 µg/kg	Fat Liver Kidney	Provisional MRLs expire on 01/01/2003; For zootechnical use only
		Equidae	3 µg/kg 3 µg/kg 3 µg/kg	Fat Liver Kidney	
Flugestone acetate	Flugestone acetate	Caprine	1 µg/kg	Milk	Provisional MRLs expire on 01/01/2003; For intravaginal use for zootechnical purposes only'