COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24.09.1996
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Proposal for a

COUNCIL REGULATION (EC)

amending Annex II of Council Regulation (EEC) N° 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

(presented by the Commission)

EXPLANATORY MEMORANDUM

A. Regulatory framework

Pursuant to Council Regulation (EEC) No 2377/90 of 26 June 1990,[1] the Commission must adopt legally binding maximum residue limits for veterinary medicinal products in foodstuffs of animal origin. These limits (hereinafter MRL) are established in accordance with the regulatory committee procedure following scientific evaluation by the Committee for Veterinary Medicinal Products, which then recommends classification in one of the four annexes to the Regulation:

- Annex I: reserved for substances for which a MRL can be set following evaluation of the toxicological risk they pose to human health;

- Annex II: substances for which there is no need to set a MRL;

- Annex III: substances for which, given the lack of scientific data, a MRL cannot be set definitively but which, without compromising consumer health, may be given a provisional MRL for a defined period calculated according to the time needed to complete the scientific studies. This period may be extended once only in exceptional cases;

- Annex IV: substances for which it appears no MRL can be set because they pose a risk to human health in whatever quantity.

[1] OJ L 224, 18.8.1990, p.1.

B. Scientific evaluation

The Commission produced a draft Regulation (III/5425/95) amending the Annex to Regulation (EEC) No 2377/90 to include, *inter alia*, somatosalm.[2]

This followed scientific evaluation of this substance by the Committee for Veterinary Medicinal Products.

The Committee recommended that somatosalm (a substance produced by a biotechnological process, belonging to the family of somatotrophins), when used on young salmon, be included in Annex II on the following grounds:

- it is a protein with a very short half-life (<30 min) in fish;
- the method of administration is a single injection of the active substance 1 or 2 years before killing the fish.

[2] Along with five other substances, viz: azamethiphos, streptomycin, dihydrostreptomycin, gentamicin and neomycin, for which MRL were then established separately.

C. Regulatory procedure and referral to the Council

1. On 16 October 1995 the Commission sent the Committee on the Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products (regulatory committee) a draft implementing regulation adding (*inter alia*) somatosalm, on the above grounds, to Annex II of Regulation (EEC) No 2377/90.

   The draft failed to elicit a favourable opinion from the Committee.

2. Indeed, claiming that the moratorium adopted by the Council[3] on bovine somatotrophin (BST) would be "indirectly" called into question if another somatotrophin appeared on the Community market, the representatives of four Member States opposed the very principle of classifying somatosalm in one of the annexes to Regulation (EEC) No 2377/90.

   It should be noted in this connection that (a) the abovementioned Council moratorium applies only to bovine somatotrophin and not all somatotrophic substances and (b) it emerges from the assessment report by the Committee on Veterinary Medicinal Products (and from the file submitted by the pharmaceutical company concerned) that, unlike BST, somatosalm is used neither to promote growth nor to boost animal productivity, but solely to make it easier for young freshwater salmon to adapt to seawater. This single statement explains its specific method of administration, which is a single injection of active substance one or two years before the fish is killed.

   Following the Commission's request in April 1996 for further information **to take account of arguments put forward by the representatives of certain Member States opposed to the classification of somatosalm**, the Committee on Veterinary Medicinal Products looked at the possibility of the substance being used fraudulently as a growth promoter in salmon and other species. Its opinion, delivered on 28 June 1996, is unequivocal: somatosalm is only active in salmon, while its use as a performance enhancer in this species may be considered impossible owing to the substance's pharmacological properties and the method of administration, which guarantee its efficacy (it must be injected directly into the stomach of each fish).

   The Commission would also stress that the establishment of a MRL for this substance is without prejudice to the contents of any decision to be taken should a request be made for marketing authorization, such a decision being subject, under Community law, to autonomous assessment criteria and procedures.

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3 Council Decision 94/936/EEC of 20 December 1994 amending Decision 90/218/EEC on the marketing and administration of bovine somatotrophin (OJ L 366, 31.12.1994, p. 19).

3. As the draft measures are not in accordance with the opinion of the Committee on the adaptation to technical progress of the Directives intended to remove technical barriers to trade in the veterinary medicinal products sector, the Commission is sending the Council a proposal for a regulation under the procedure laid down in Article 8 of Regulation (EEC) No 2377/90.

By virtue of the same Article, the Council is invited to adopt the proposed measures within three months of the date of referral.

PROPOSAL FOR A

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amending Annex II of Council Regulation (EEC) N° 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) N° 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], as last amended by Commission Regulation (EC) N° 1433/96[2] and in particular Articles 6 and 8 thereof;

Having regard to the proposal from the Commission

Whereas, in accordance with Regulation (EEC) N° 2377/90, maximum residue limits must 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;

Whereas maximum residue limits should be established only after the 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;

Whereas, 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 which may be present in each of the relevant meat tissues

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[1] OJ N° L 224, 18.08.1990, p 1
[2] OJ N° L 184, 24.07.1996, p 21

obtained from the treated animal (target tissue) and the nature of the residue which is relevant for the monitoring of residues (marker residue);

Whereas Somatosalm should be inserted into Annex II to Regulation (EEC) N° 2377/90 ;
Whereas a period of 60 days should be allowed before the entry into force of this Regulation in order to allow Member States to make any adjustment which may be necessary to the authorisations to place the veterinary medicinal products concerned on the market which have been granted in accordance with Council Directive 81/851/EEC[3], as last amended by Directive 93/40/EEC[4] to take account of the provisions of this Regulation;

Whereas, in accordance with the procedure laid down in Article 8 of Council Regulation (EEC) No 2377/90, the draft of the measures to be adopted was submitted to the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector; whereas the Committee was not able to deliver an opinion; whereas the Commission therefore proposed the measures to be adopted to the Council;

(3) OJ N° L 317, 06.11.1981, p 1
(4) OJ N° L 214, 24.08.1993, p 31

HAS ADOPTED THE FOLLOWING REGULATION :

Article 1

Annex II of Regulation (EEC) N°2377/90 is hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on the sixtieth day following its publication in the Official Journal of the European Communities;

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

Done at Brussels,

For the Council

ANNEX

A. Annex II is modified as follows

2. Organic chemicals

Pharmacologically active substances	Animal species	Other provisions
2.68. Somatosalm	Salmon	

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DOCUMENTS

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