COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.04.1995
COM(95) 133 final

Proposal for a

COUNCIL REGULATION (EC)

amending Annex IV to Council 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

(presented by the Commission)

EXPLANATORY MEMORANDUM

A. Regulatory framework

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

- Annex I is for substances for which a MRL can be set following evaluation of the toxicological risk the substance poses to human health;

- Annex II contains substances for which a MRL is unnecessary;

- Annex III contains substances for which a lack of scientific data makes it impossible to set a definitive MRL but which, without compromising consumer health, can be given a provisional MRL for a specific period to allow scientific studies to be completed;

- Annex IV contains substances for which no MRL can apparently be set, since they pose a risk to consumer health in whatever quantities they are present. If a substance is listed in Annex IV, its administration to food-producing animals will be banned from the moment the relevant implementing regulation enters into force.

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[1] OJ L 224, 18.08.1990, p. 1

[redacted]

B. Evaluation of dimetridazole

The CVMP began assessing the innocuity of dimetridazole residues long before Regulation (EEC) No 2377/90 entered into force. The initial evaluation prompted a series of questions addressed to companies wishing to keep their dimetridazole-based products on the market. These questions focused on the potential carcinogenic nature of the compound. On 19 March 1992, on the basis of the CVMP's initial recommendations, the Commission adopted an initial implementing Regulation (EEC) No 675/92[2], placing dimetridazole in Annex III together with a provisional MRL of 10 µg/kg valid until 31 December 1993. This was to give the companies time to provide additional scientific data proving conclusively that the compound was not carcinogenic.

The companies in question worked together in an effort to prove the innocuity of dimetridazole residues in foodstuffs of animal origin. They submitted their data to the Commission in September 1993, shortly before the provisional MRL was due to expire. As allowed by Regulation (EEC) No 2377/90, the Commission followed the recommendation of the CVMP and extended the validity of the provisional MRL for dimetridazole (Regulation (EEC) No 3426/93[3]) by one year, up to 31 December 1994.

Evaluation of the additional data showed that the threat of cancer cannot be ruled out. In the mean time, scientific publications have suggested that compounds related to dimetridazole (e.g. metronidazole) could be genotoxic. This second factor (genotoxicity) rules out any possibility of a MRL, since a single molecule has the potential to cause irreversible damage to the human genome.
All this information has been examined and discussed within the CVMP. Following a meeting on 27 September 1994 with the companies concerned, the Committee drafted a report concluding its evaluation of dimetridazole.

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2 OJ L 73, 19.03.1992, p. 8
3 OJ L 312, 15.12.1993, p. 15

Since the opinions of the members of the Committee as expressed in the report were divided, especially regarding the potential genotoxicity of dimetridazole, the Commission proposed including the substance in Annex IV. The Commission based its decision on the absolute priority which must be accorded to human health, taking care to remain consistent with its earlier decisions, taken in the same context, on potential carcinogens such as the compounds of the nitrofuran group or, more recently, ronidazole (which belongs to the same chemical family as dimetridazole). It is worth pointing out here, on the subject of similar risks, that the United States administration banned the use of dimetridazole in turkeys (the main target species) as long ago as July 1987.

On 24 November 1994 the Commission presented the Committee for the adaptation to technical progress of the directives on the removal of technical barriers to trade in the veterinary medicinal product sector with a draft implementing regulation placing dimetridazole in Annex IV to Regulation (EEC) No 2377/90.

As the Committee was unable to deliver a favourable opinion on the proposed measures, the Commission is sending this proposal to the Council in accordance with Article 8 of Regulation (EEC) No 2377/90.

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amending Annex IV to Council 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

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] as last amended by Commission Regulation (EC) No .....,[2] and in particular Articles 7 and 8 thereof,

Having regard to the proposal from the Commission,

Whereas, in accordance with Regulation (EEC) No 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 examination within the Committee for Veterinary Medicinal Products of all relevant information concerning the safety of residues of the substance concerned for consumers 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 obtained from the treated animal (target tissue) and the nature of the residue which is relevant for the monitoring of residues (marker residue);

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1 OJ L 224, 18.08.1990, p. 1

2 OJ L ...., ... 1994, p. ...

Whereas, for the control of residues, as provided for in the relevant Community legislation, maximum residue limits should usually be established for the target tissues of liver or kidney; whereas, however, the liver and kidney are frequently removed from carcases moving in international trade, and maximum residue limits should therefore also always be established for muscle or fat tissues;

Whereas, in the case of veterinary medicinal products intended for use in laying birds, lactating animals or honey bees, maximum residue limits must also be established for eggs, milk or honey;

Whereas it appears that maximum residue limits cannot be established for dimetridazole because residues, at whatever limit, in foodstuffs of animal origin might constitute a hazard to consumer health; whereas dimetridazole should therefore be added to Annex IV to Regulation (EEC) No 2377/90;

Whereas a period of 60 days should be allowed before the entry into force of this Regulation to allow Member States to make any necessary adjustments to the authorizations 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 the Committee for the Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products has been consulted in accordance with the procedure laid down in Article 8 of Regulation (EEC) No 2377/90; whereas the measures envisaged are not in accordance with the opinion of the Committee; whereas, under the same procedure, the Commission must propose to the Council the measures to be adopted,

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EEC) No 2377/90 is hereby amended as set out in the Annex hereto.

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3 OJ L 317, 06.11.1981, p. 1

4 OJ L 214, 24.08.1993, p. 31

[redacted]

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 is binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Council

[redacted]

ANNEX

Annex IV is modified as follows

List of pharmacologically active substances for which no maximum levels can be fixed

5. Dimetridazole

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DOCUMENTS

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