COMMISSION DIRECTIVE 97/6/EC

of 30 January 1997

amending Council Directive 70/524/EEC concerning additives in feedingstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [1], as last amended by Commission Directive 96/66/EC [2], and in particular Article 11 thereof,

Whereas, pursuant to Article 11 of Directive 70/524/EEC, a Member State which, as a result of new information or of a reassessment of existing information made since the provisions in question were adopted, has detailed grounds for establishing that the use of one of the additives listed in Annex I constitutes a danger to animal or human health or the environment may temporarily suspend the authorization to use that additive;

Whereas Denmark and Germany prohibited the use on their territories of the antibiotic avoparcin in animal feedingstuffs on 20 May 1995 and 19 January 1996 respectively; whereas in accordance with the provisions of Directive 70/524/EEC these two Member States each notified the other Member States and the Commission of the reasons for their decision, duly substantiated by detailed arguments; whereas this information was transmitted by Denmark on 20 May and 13 July 1995, and by Germany on 5 March 1996;

Whereas Denmark and Germany, arguing that, through the feed given to animals, this glycopeptide antibiotic produces resistance to glycopeptides used in human medicine, take the view that avoparcin presents a danger for human health; whereas in their view this transfer of resistance may limit the effectiveness of a major category of antibiotics reserved exclusively for the treatment or prevention of serious infections in humans and consequently one of the conditions required under Directive 70/524/EEC for authorizing the use of an additive is not met;

Whereas the Commission has consulted the Scientific Committee on Animal Nutrition; whereas, after thoroughly examining the situation, that Committee has concluded, in the opinion expressed on 21 May 1996, that, given the absence of elements critical to establishing cause and effect with regard to a role for glycopeptide resistant organisms of animal origin (enterococci) or their genes in human disease, it is not necessary to reserve the use of glycopeptides exclusively for human medicine; whereas, however, the Committee accepts that the reports from Denmark and Germany raise serious questions, and states that it would propose that the feed-additive use of avoparcin be reconsidered at once should it be shown that transfer of resistance were possible from animal to man; whereas, moreover, as a precautionary measure, the Committee recommends that no further glycopeptide sharing the same site and mechanism of antibiotic action as avoparcin should be approved until it is satisfied with the results of research still to be carried out;

Whereas, while there are insufficient data to establish conclusively the risk of transfer of resistance invoked by Germany and Denmark, available evidence does not allow the risk to be excluded with certainty, in the absence of further scientific information;

Whereas various investigations should be undertaken to pinpoint the problem of possible resistance to antibiotics induced by the use of additives in animal feed and transferred to man; whereas a scheme for the surveillance of microbial resistance in animals which receive antibiotics must be swiftly established;

Whereas in this climate of uncertainty it is preferable to show extreme caution, and to avoid taking any risk of reducing the effectiveness of certain glycopeptides, such as vancomycin, which are essential in human medicine;

Whereas the prohibition on the use of avoparcin ought to be perceived as an interim protective measure taken as a precaution, which could be reconsidered were the doubts expressed about additive use of avoparcin to be dissipated in the light of the investigations which will have been carried out and of the surveillance programme which will have been established;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 70/524/EEC is hereby amended as set out in the Annex hereto.

[1] OJ No L 270, 14. 12. 1970, p. 1.
[2] OJ No L 272, 25. 10. 1996, p. 32.