COMMISSION DIRECTIVE 98/19/EC

of 18 March 1998

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 97/72/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 Germany prohibited the use on its territory of ronidazole in turkey feed on 19 January 1996; whereas in accordance with Directive 70/524/EEC, on 15 April 1996 Germany notified the other Member States and the Commission of the reasons for its decision, duly substantiated by detailed arguments;

Whereas Germany argued in its notification that it suspected ronidazole of mutagenic, carcinogenic and genotoxic properties and, in view of this worrying situation for the health of consumers, this Member State took the view that its use in animal feed should be banned at Community level;

Whereas in its reasoned argument Germany concluded that the use of ronidazole in animal feed resulted in some residues remaining in animal tissue, even with a six-day withdrawal period in accordance with the rules; whereas in view of the carcinogenic and mutagenic properties that ronidazole as the parent substance might have and the possibility that its nitroimidazole structure might be released from bound residues, a risk to consumer health cannot be ruled out, even where the withdrawal period is complied with;

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 26 September 1997 and reinforced on 5 November 1997, that, while ronidazole clearly shows a mutagenic effect on prokaryotic cells, there are no data on its possible genotoxic effect on eukaryotic cells; whereas it was not possible to evaluate conclusively the carcinogenic mechanism because raw data on the experiments into carciongenisis were not available; whereas it is therefore impossible to evaluate the risk to consumers; whereas the data on metronidazole cannot be used to make inferences about ronidazole since chemical substances belonging to the same family may have totally different toxicological properties; whereas information is lacking on the metabolic fate of ronidazole in turkeys, such as the nature of the faecal metabolites, or its presence in various tissues after the withdrawal period; whereas it should be noted, however, that the substantial information available on pigs could be reasonably applied to turkeys, where justified; whereas, on the other hand, the limited amount of data that does exist on the presence of trace quantities of a nitroimidazole compound released chemically from these bound residues is strongly suggestive of analytical artefact;

Whereas the Scientific Committee on Animal Nutrition has finally concluded that, while not all the scientific arguments submitted by Germany to prohibit ronidazole can be accepted, some important issues have not been resolved and, in the absence of the additional data, an acceptable daily dose of ronidazole residues cannot be established to ensure consumer safety;

Whereas, in view of the uncertainty still surrounding the safety of ronidazole, its use as an additive in turkey feed should be prohibited to protect consumer health;

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 L 270, 14. 12. 1970, p. 1.
[2] OJ L 351, 23. 12. 1997, p. 55.

Article 2

1. Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive by 31 May 1998. They shall immediately inform the Commission thereof.

They shall apply the measures from 1 June 1998.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of domestic law which they adopt in the field governed by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States,

Done at Brussels, 18 March 1998.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX

In Annex I to Directive 70/524/EEC, Part D: 'Coccidiostats and other medicinal substances', item E 759, 'Ronidazole' and all references to it (chemical formula, description, species or category of animal, maximum age, minimum content, maximum content, other provisions) are hereby deleted.