

COMMISSION REGULATION (EC) No 2788/98
of 22 December 1998
amending Council Directive 70/524/EEC concerning additives in feedingstuffs as
regards the withdrawal of authorisation for certain growth promoters

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Act of Accession of Austria, Finland and Sweden, and in particular Article 151 in conjunction with Annex XV, Title VII(E)(4) thereof, and to the amendments to the Treaties on which the European Union is founded,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs⁽¹⁾, as last amended by Commission Directive 98/19/EC⁽²⁾, and in particular Article 11(3) thereof,

Whereas Sweden was authorised under Annex XV to the Act of Accession to maintain its legislation in force before accession until 31 December 1998 with regard to the prohibition of the use in feedingstuffs of additives belonging to the groups of growth promoters; whereas on 10 April 1997 and 2 February 1998 it submitted applications for adjustments in respect of carbadox and olaquinox, accompanied by detailed scientific reasoning; whereas the Commission is required to take a decision on the adjustment applications submitted by Sweden not later than 31 December 1998;

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 the Directive constitutes a danger to animal or human health or the environment may temporarily suspend the authorisation to use that additive;

Whereas the Kingdom of the Netherlands prohibited the use on its territory of carbadox in feedingstuffs on 6 September 1997; whereas it communicated the detailed grounds for that decision to the other Member States and the Commission on 18 July 1997;

Whereas by virtue of Article 3a(b) of Directive 70/524/EEC authorisation of a substance is not to be given if,

in view of its conditions of use, it has an adverse effect on human or animal health;

Whereas the Commission has consulted the Scientific Committee on Animal Nutrition (SCAN) on whether, based on the information given to the Commission, use of the quinoxaline-N-dioxides carbadox and olaquinox presented a risk to consumers, to operators or to the animal itself;

Whereas, having studied the information supplied to the Commission, SCAN noted in its opinion issued on 10 July 1998 that it was maintaining its previous opinions on the acceptability of the quinoxaline-N-dioxides carbadox and olaquinox, within their previously defined conditions of use;

Whereas, however, SCAN has acknowledged that neither of these two substances has had an ideal safety profile in laboratory animal tests and that it is unlikely that other additives with such genotoxic properties will be developed in future;

Whereas SCAN acknowledged that carbadox was genotoxic and carcinogenic for rodents and that olaquinox was genotoxic and tumorigenic for rodents;

Whereas SCAN notes, and the Commission for its part fully agrees, that the possible exposure of workers is undoubtedly a risk, since they are exposed to the parent molecules; whereas individuals changing air filter mats in feed plants are at special genotoxic or carcinogenic risk following possible exposure through the skin or by inhalation; whereas the possibility of absorbing the parent substance by individuals exposed to the additives in the factory or on farm exists;

Whereas SCAN is aware that many conditions must be met before these substances can be safely used; whereas SCAN would like to know if these conditions are met in practice; whereas SCAN recommends in particular that exposure to carbadox and olaquinox in the workplace be re-evaluated and that epidemiological studies of the health status of additive-exposed workers be carried out;

⁽¹⁾ OJ L 270, 14. 12. 1970, p. 1.

⁽²⁾ OJ L 96, 28. 3. 1998, p. 39.

Whereas the Commission, for its part, believes that it is not possible to set a threshold for a genotoxic additive below which it presents no risk to the consumer, since even a small quantity of residues of the additive can provoke a tumour-inducing mutation; whereas a time limit for withdrawal that will ensure consumer safety cannot therefore be fixed;

Whereas the Commission believes that precise description of the composition of the preparations and recommendations to wear masks and protective clothing are not sufficient to guarantee the protection of operators at plant or farm level; whereas cases have indeed been reported to the Commission of livestock farmers who, lacking protection, have been exposed through inhalation or skin contact to the genotoxic and potentially carcinogenic parent substances;

Whereas, in view of their possible adverse effect on human health, the authorisations for the growth promoters carbadox and olaquinox should be withdrawn;

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

HAS ADOPTED THIS REGULATION:

Article 1

The entries in Annex B to Directive 70/524/EEC for the following growth promoters are deleted:

- Carbadox,
- Olaquinox.

Article 2

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

This Regulation shall apply from 1 January 1999.

However, in case a Member State has not banned conforming to the Community law at the date of the entering into force of this Regulation one or more of the growth promoters referred to in Article 1 of this Regulation, this or these growth promoters remain authorised in this Member State until 31 August 1999.

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

Done at Brussels, 22 December 1998.

For the Commission
Franz FISCHLER
Member of the Commission
