DIRECTIVES

COMMISSION DIRECTIVE 2008/82/EC

of 30 July 2008

amending Directive 2008/38/EC as regards feedingstuffs intended for the support of the renal function in case of chronic renal insufficiency

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES.

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes (1), and in particular Article 6(c) thereof,

Whereas:

- Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes (2) includes as a particular nutritional purpose the 'support of renal function in case of chronic renal insufficiency'.
- By Regulation (EC) No 163/2008 (3), the Commission authorised the preparation lanthanum carbonate octahydrate as a zootechnical feed additive for cats. This authorisation was based on an opinion of the European Food Safety Authority of 18 September 2007 (4). In that opinion that Authority considered that supplementation of diets with that preparation results in a decrease in phosphorus excretion via urine and an increase in its excretion via faeces, linked to a decrease in apparent phosphorus digestibility. It concluded that that preparation can reduce the phosphorus absorption of adult cats.
- Directive 2008/38/EC already includes feed with a low level of phosphorus in the line 'support of renal function in case of chronic renal insufficiency'. The same positive effect can be obtained if the absorption of phosphorus contained in the feed is reduced. Lanthanum carbonate octahydrate should therefore be included in the line 'Support of renal function in case of chronic renal insufficiency' in the list of intended uses in Part B of the Annex I to Directive 2008/38/EC.
- Directive 2008/38/EC should therefore be amended (4)accordingly.

The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

The Annex I to Directive 2008/38/EC is amended in accordance with the Annex to this Directive.

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 February 2009 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 30 July 2008.

For the Commission Androulla VASSILIOU Member of the Commission

⁽¹⁾ OJ L 237, 22.9.1993, p. 23. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 62, 6.3.2008, p. 9.

⁽³⁾ OJ L 50, 23.2.2008, p. 3. (4) The EFSA Journal (2007) 542, 1-15.

(*) If appropriate the manufacturer may also recommend use for temporary renal insufficiency.

(**) If the feedingstuff is recommended for temporary renal insufficiency the recommended period for use shall be two to four weeks.

EN

In Part B of the Annex I to Directive 2008/38/EC, the line of the particular nutritional purpose 'Support of renal function in case of chronic renal insufficiency' is replaced by the following:

ANNEX

of Other provision	Initially up to 6 months (**) recommended that a veterinarian's opinion be sought before use or before extending the period of use." Indicate in the instructions for use: "Water should be available at all times."	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use or before extending the period of use." Indicate in the instructions for use: "Water should be available at all times."
Recommended length of time for use	Initially up to 6 mon	Initially up to 6 mon
Labelling declarations	 Protein source(s) Calcium Phosphorus Potassium Sodium Content of essential fatty acids (if added) 	 Protein source(s) Calcium Phosphorus Potassium Sodium Lanthanum carbonate octahydrate Content of essential fatty acids (if added)
Species or category of animal	Dogs and cats	Adult cats
Particular nutritional purpose Essential nutritional characteristics	Low level of phosphorus and restricted level of protein but of high quality	or Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate
Particular nutritional purpose	Support of renal function in Low level of phosphorus and case of chronic renal insufficiency (*) of high quality	