DIRECTIVES

COMMISSION DIRECTIVE 2008/4/EC

of 9 January 2008

amending Directive 94/39/EC as regards feedingstuffs intended for the reduction of the risk of milk fever

(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:

(1) By Directive 94/39/EC [2], the Commission established a list of intended uses of animal feedingstuffs for particular nutritional purposes.

(2) In its opinion of 8 December 2004 the European Food Safety Authority (the Authority) concluded that zeolite (synthetic sodium aluminium silicate) has the potential of reducing the risk of milk fever in dairy cows [3]. However, it could not fully assess the risk for animal and human health due to missing data. Taking into account the additional information received, the Authority concluded in its opinion of 11 July 2007 that adding zeolite to feedingstuffs for dairy cows for a period of about two weeks before calving does not pose a risk to animal or human health or to the environment [4]. Zeolite should therefore be included in the line 'reduction of the risk of milk fever' in the list of intended uses in Part B of the Annex to Directive 94/39/EC.

(3) In its opinion of 12 June 2007 the Authority concluded that feedingstuffs with high calcium content administered around parturition can be very effective in treating mild cases of milk fever and in preventing relapses in dairy cattle and therefore that a new entry should be added to the list concerning the prevention of the risk of milk fever [5]. The Authority further concluded that a marginal risk for animal health cannot be completely excluded making it necessary to balance the individual risk against the overall benefits of the administration. In order to allow the dairy herd manager such assessment, the different sources of calcium should be indicated on the label together with their quantity. Further, the label should include a recommendation to seek advice of a nutritional expert. The Authority neither expects a risk for the consumer nor an additional risk for the environment. Feedingstuffs with high calcium content should therefore be included in the line 'reduction of the risk of milk fever' in the list of intended uses in Part B of the Annex to Directive 94/39/EC.

(4) Directive 94/39/EC should therefore be amended accordingly.

(5) 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:

Article 1

The Annex to Directive 94/39/EC is amended in accordance with the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 24 June 2008 at the latest. They shall forthwith inform the Commission thereof.

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[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 207, 10.8.1994, p. 20. Directive as last amended by Directive 2002/1/EC (OJ L 5, 9.1.2002, p. 8).

[3] Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the request from the Commission on the use of synthetic sodium aluminium silicate (zeolite) for the reduction of risk of milk fever in dairy cows. Adopted on 8 December 2004. *The EFSA Journal* (2004) 160, 1-11.

[4] Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety of zeolite (sodium aluminosilicate, synthetic) for the reduction of risk of milk fever in dairy cows. Adopted on 11 July 2007. *The EFSA Journal* (2007) 523, 1-11.

[5] Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety of feedingstuffs with high calcium content for the reduction of milk fever in dairy cows. Adopted on 12 June 2007. *The EFSA Journal* (2007) 504, 1-10.

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 its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 9 January 2008.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

In Part B of the Annex to Directive 94/39/EC, the line of the particular nutritional purpose 'Reduction of the risk of milk fever' is replaced by the following:

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provision
'Reduction of the risk of milk fever	— Low level of calcium	Dairy cows	— Calcium — Phosphorus — Magnesium	1 to 4 weeks before calving	Indicate in the instructions for use: "Stop feeding after calving"
	and/or				
	— Low cations/anions ratio		— Calcium — Phosphorus — Sodium — Potassium — Chlorides — Sulphur	1 to 4 weeks before calving	Indicate in the instructions for use: "Stop feeding after calving"
	or				
	— High level of zeolite (synthetic sodium aluminium silicate)		Content of synthetic sodium aluminium silicate	The 2 weeks before calving	Indicate in the instructions for use: — "The amount of feed shall be restricted to ensure that a daily intake of 500 g sodium aluminium-silicate per animal is not exceeded." — "Stop feeding after calving"
	or				
	— High level of calcium in the form of highly available calcium salts		Total calcium content, sources and respective quantity of calcium	Start at first signs of parturition to two days subsequent to parturition	Indicate on the package, container or label: — The instruction of use i.e. the number of applications and the time before and after calving. — The text "It is recommended that a nutritional expert's opinion be sought before use".'