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EUROPEAN COMMISSION

Brussels,

Draft

COMMISSION REGULATION (EU) No .../..

of [...]

**on the status of certain products with regard to feed additives within the scope of
Regulation (EC) No 1831/2003**

(Text with EEA relevance)

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**on the status of certain products with regard to feed additives within the scope of
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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Article 2(3) thereof,

Whereas:

- (1) For certain substances, micro-organisms or preparations, all together hereinafter referred to as products, there is uncertainty whether they are feed additives. This uncertainty concerns some products which are authorised as feed additives included in the Register of feed additives and also included in the Catalogue of feed materials provided for in Article 24 of Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC², some products which are neither authorised as feed additives nor included in the Catalogue of feed materials and some products which are authorised as feed additives, could be included in the Catalogue of feed materials in accordance with the conditions laid down in Regulation (EC) No 767/2009.
- (2) To avoid inconsistencies in the treatment of such products, to facilitate the work of the national competent control authorities and to lighten the burden of the interested parties, as regards certain products it is necessary to adopt a Regulation determining that those products are no feed additives.
- (3) For that determination all the characteristics of the products concerned have to be taken into account.

¹ OJ L 268, 18.10.2003, p. 29.

² OJ L 229, 1.9.2009, p. 1.

- (4) For the comparison between the characteristics of the products included in the Register of feed additives on the one hand and of the products mentioned in the Catalogue of feed materials on the other hand, several criteria may be derived for the classification of products as feed material, feed additive or other products. Useful criteria for this differentiation are the production and processing method, the level of standardisation, the homogenisation, the purity, the chemical definition and the mode of use of the products. For the sake of consistency, products with similar properties should be considered by analogy for their classification. For products for which there were doubts whether they were feed additives, an examination has been carried out taking into account these criteria.
- (5) Based on that examination, the products set out in the Annex should not be considered as feed additives within the scope of Regulation (EC) No 1831/2003.
- (6) As regards the labelling of the products which were authorised as feed additives and the labelling of feed materials and compound feed containing those products, a transitional period should be provided for to allow manufacturers to adapt. Furthermore those products should be deleted from the Register of feed additives.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The substances, micro-organisms and preparations (all together hereinafter referred to as 'products'), as set out in the Annex, are no feed additives within the scope of Regulation (EC) No 1831/2003.

Article 2

The products listed under point 1 of the Annex, shall no more be authorised feed additives within the scope of Regulation (EC) No 1831/2003.

Article 3

Products set out in Part 1 of the Annex which are labelled as feed additives in accordance with Regulation (EC) No 1831/2003 may continue to be placed on the market until [... *Office of publications please insert date [one year] after date of publication of this Regulation*] and remain on the market until stocks are exhausted. The same applies to feed materials or compound feed which refer to these products in their labelling as feed additives in accordance with Regulation (EC) No 767/2009.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, [...]

*For the Commission
The President
Jose Manuel Barroso*

ANNEX

Products which are no feed additives within the scope of Regulation (EC) No 1831/2003

PART 1. PRODUCTS WHICH WERE AUTHORISED AS FEED ADDITIVES

- 1.1 Calcium carbonate
- 1.2 Calcium sulphate dihydrate
- 1.3 Sodium carbonate
- 1.4 Sodium hydrogen carbonate
- 1.5 Sodium sulphate
- 1.6 Calcium tetrahydrogen diorthophosphate
- 1.7 Calcium hydrogen orthophosphate
- 1.8 Pentasodium-triphosphate
- 1.9 Sodium, potassium and calcium salts of edible fatty acids / stearates
- 1.10 Mono- and di-glycerides of fatty acids
- 1.11 Sorbitol
- 1.12 Mannitol
- 1.13 Glycerol
- 1.14 Propane-1,2-diol
- 1.15 Pectic substances

PART 2. PRODUCTS WHICH WERE NOT AUTHORISED AS FEED ADDITIVES

- 2.1 Potassium chloride
- 2.2 Calcium chloride
- 2.3 Calcium sodium phosphate
- 2.4 Sodium magnesium phosphate
- 2.5 Methyl sulfonyl methane (MSM)
- 2.6 Plain caramel

- 2.7 Glucosamine, Chitosamine (amino sugar (monosaccharide) being part of the structure of the polysaccharides chitosan and chitin, produced by the hydrolysis of crustacean and other arthropods exoskeletons or by fermentation of a grain such as maize or wheat)
- 2.8 Chondroitin sulphate (polysaccharide with repeating unit consisting of an amino sugar and D-glucuronic acid, sulphate esters of chondroitin are major structural components of cartilage, tendons and bones)
- 2.9 Hyaluronic acid (glucosamineglucan (polysaccharide) with repeating unit consisting of an amino sugar (N-acetyl-D-glucosamin) and D-glucuronic acid present in the skin, synovial fluid and the umbilical cord, produced from animal tissue or by bacterial fermentation)
- 2.10 Egg powder (dried eggs without shells or a mixture of dried albumen and dried egg yolk)
- 2.11 Fructo-Oligosaccharide, Mannan-Oligosaccharide, Galacto-Oligosaccharide, Xylo-Oligosaccharide, Inulin (saccharide polymers containing typically three to ten component sugars. Derived from plants such as artichoke, chicory and asparagus or obtained from cell walls of micro-organisms or by chemical or microbial synthesis)
- 2.12 Lactulose (disaccharide (4-O-D-galactopyranosyl-D-fructose) obtained from lactose through the isomerisation of glucose to fructose. Naturally present in heat treated milk and milk products)
- 2.13 Plant sterols (phytosterols are a group of steroid alcohols, naturally occurring in plants in small quantities and presented as free sterols or esterified with fatty acids)
- 2.14 Tagetes flower meal (ground meal of dried flowers of *Tagetes sp*)
- 2.15 Paprika meal (ground meal of dried fruits of *Capsicum sp*)
- 2.16 Chlorella suspension or meal (suspension of the living micro-algae *Chlorella sp* in water or dried and ground meal of *Chlorella sp*)
- 2.17 Algae meal (dried and ground meal of micro-algae such as *Schizochytrium sp.*, cells of which have been inactivated)
- 2.18 Solid-State-Fermentation by-product (dried and ground residue of solid state fermentation after enzyme extraction, micro-organism cells such as *Aspergillus niger* have been inactivated)
- 2.19 Lysine fermentation broth (Fermentation residue after lysine-extraction micro-organism cells have been inactivated)
- 2.20 Fermented wheat germ (product of fermentation of wheat grains, less than 10^8 colony forming units micro-organisms/kg or inactivated)
- 2.21 Fermented plants (fermentation products based on merely physically processed plant materials).