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**COMMISSION REGULATION (EC) No 2439/1999
of 17 November 1999**

on the conditions for the authorisation of additives belonging to the group ‘binders, anti-caking agents and coagulants’ in feedingstuffs

(OJ L 297, 18.11.1999, p. 8)

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on the conditions for the authorisation of additives belonging to the group 'binders, anti-caking agents and coagulants' in feedingstuffs

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 Regulation (EC) No 1636/1999 ⁽²⁾, and in particular Article 11 thereof,

Whereas:

- (1) kaolinitic clays originating from certain mines situated in the Federal Republic of Germany have been found to contain extremely high levels of dioxins. According to available information, this could be a contamination of geological origin;
- (2) under 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, finds 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;
- (3) several Member States have prohibited the use of contaminated kaolinitic clays in pre-mixtures and feedingstuffs;
- (4) under Article 3a(b) of Directive 70/524/EEC, authorisation of an additive is to be given only if, taking account of the conditions of use, it does not adversely affect human or animal health or the environment;
- (5) the use of feedingstuffs contaminated with dioxins may contaminate foodstuffs of animal origin. Dioxins are classified as a human carcinogen by recognised international organisations. These organisations recommend that measures are taken to reduce the ingestion of dioxins through food as much as possible;
- (6) contaminated additives should be avoided as much as possible;
- (7) a complete risk assessment cannot be carried out for lack of adequate scientific data. In view of the need for urgent measures to prevent an unacceptable degree of contamination of feedingstuffs and pending the results of the monitoring programme on clays and the risk assessment, the acceptable level of dioxins in kaolinitic clays should be restricted by way of precaution to the analytical limit of determination. This limit may be reviewed in the light of the results of any investigations carried out and of the monitoring programme;
- (8) the contamination of kaolin found in Germany could in fact also concern other additives authorised for use as binders, anti-caking agents and coagulants under Directive 70/524/EEC, as indicated by the fact that ball clay, sedimentary clays containing other minerals besides kaolin, originating from a mine in the United States has also been shown to be heavily naturally contaminated by dioxins of geological origin. It is appropriate to examine in the frame of the monitoring programme the possible presence of dioxins in all these authorised additives. It is foreseen for the time being to apply a provisional maximum limit only for the kaolinitic clays, the analytical limit of determination will apply as

⁽¹⁾ OJ L 270, 14.12.1970, p. 1.

⁽²⁾ OJ L 194, 27.7.1999, p. 17.

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the maximum limit after a well-defined period of time for the additives other than the kaolinitic clays in the absence of the establishment, if required, of a specific maximum limit based on sufficient data concerning the presence of dioxins;

- (9) the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

The conditions for the authorisation of additives belonging to the group 'binders, anti-caking agents and coagulants' referred to in the Annex to this Regulation are hereby replaced by those set out in the Annex hereto in accordance with Directive 70/524/EEC.

The Commission shall re-examine the provisions of this Regulation before ►**M1** 15 October 2000 ◀ in the light of any investigations carried out and of the results of the monitoring programme.

Article 2

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

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

ANNEX

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					mg/kg of complete feedingsstuff			
Binders, anti-caking agents and coagulants								
E 330	Citric acid	$C_6H_8O_7$	All species or categories of animals	—	—	—	All feedingsstuffs. Compliance with the provisions of Article 16(1)(g)	Without a time limit
E 470	Sodium, potassium and calcium stearates	$C_{18}H_{35}O_2Na$ $C_{18}H_{35}O_2K$ $C_{18}H_{35}O_2Ca$ Maximum dioxin content: (1)	All species or categories of animals	—	—	—	All feedingsstuffs	Without a time limit
E 516	Calcium sulphate, dihydrate	$CaSO_4 \cdot 2H_2O$ Maximum dioxin content: (1)	All species or categories of animals	—	—	30 000	All feedingsstuffs	Without a time limit
E 551a	Silicic acid, precipitated and dried	— Maximum dioxin content: (1)	All species or categories of animals	—	—	—	All feedingsstuffs	Without a time limit
E 551b	Colloidal silica	— Maximum dioxin content: (1)	All species or categories of animals	—	—	—	All feedingsstuffs	Without a time limit
E 551c	<i>Kieselgur</i> (diatomaceous earth, purified)	— Maximum dioxin content: (1)	All species or categories of animals	—	—	—	All feedingsstuffs	Without a time limit
E 552	Calcium silicate, synthetic	— Maximum dioxin content: (1)	All species or categories of animals	—	—	—	All feedingsstuffs	Without a time limit
E 554	Sodium aluminosilicate, synthetic	— Maximum dioxin content: (1)	All species or categories of animals	—	—	—	All feedingsstuffs	Without a time limit
E 558	Bentonite-montmorillonite	— Maximum dioxin content: (1)	All species or categories of animals	—	—	20 000	All feedingsstuffs Mixing with additives from the antibiotics, growth promoters, coccidiostats and other medical substances groups is prohibited,	Without a time limit

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					mg/kg of complete feedstuff	mg/kg of complete feedstuff			
E 559	Kaolinitic clays, free of asbestos	Naturally occurring mixtures of minerals containing at least 65 % complex hydrated aluminium silicates whose main constituent is kaolinite. Maximum dioxin content: 500 pg WHO-PCDD/F-TEQ/kg (2)	All species or categories of animals	—	—	—	—	except in the case of: narasin, monensin-sodium, lasalocid-sodium, pholipol, salinomycin sodium, nicarbazin and robenidine Indication on the label of the specific name of the additive	Without a time limit
E 560	Natural mixtures of steatites and chlorite	Natural mixtures of steatite and chlorite, free of asbestos: minimum purity of the mixtures 85 %.	All species or categories of animals	—	—	—	—	All feedings	Without a time limit
E 561	Vermiculite	Natural silicate of magnesium, aluminium and iron, expanded by heating, free of asbestos. Maximum fluorine content: 0,3 % Maximum dioxin content: (1)	All species or categories of animals	—	—	—	—	All feedings	Without a time limit
E 562	Sepiolite	Hydrated magnesium silicate of sedimentary origin, containing at least 60 % sepiolite and maximum 30 % montmorillonite, free of asbestos	All species or categories of animals	—	—	20 000	—	All feedings	Without a time limit

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					mg/kg of complete feedingstuff	mg/kg of complete feedingstuff			
E 563	Sepiolitic clay	Hydrated magnesium silicate of sedimentary origin, containing at least 40 % sepiolite and 25 % illite, free of asbestos.	All species or categories of animals	—	—	—	20 000	All feedingstuffs	Without a time limit
E 565	Lignosulphonates	— Maximum dioxin content: (1)	All species or categories of animals	—	—	—	—	All feedingstuffs	Without a time limit
E 566	Natrolite-phonolite	Natural mixture of aluminium silicates, alkalines and alkaline-earth and aluminium hydrosilicates, natrolite (43 to 46,5 %) and feldspar. Maximum dioxin content: (1)	All species or categories of animals	—	—	—	25 000	All feedingstuffs	Without a time limit
E 598	Synthetic calcium aluminates	Mixture of calcium aluminates containing between 35 and 51 % of Al ₂ O ₃ . Maximum molybdenum content: 20 mg/kg Maximum dioxin content: (1)	Poultry	—	—	—	20 000	All feedingstuffs	Without a time limit
			Rabbits	—	—	—	20 000	All feedingstuffs	Without a time limit
			Pigs	—	—	—	20 000	All feedingstuffs	Without a time limit
			Dairy cows	—	—	—	8 000	All feedingstuffs	Without a time limit
			Cattle for fattening	—	—	—	8 000	All feedingstuffs	Without a time limit
			Calves	—	—	—	8 000	All feedingstuffs	Without a time limit
			Lambs	—	—	—	8 000	All feedingstuffs	Without a time limit
			Kids	—	—	—	8 000	All feedingstuffs	Without a time limit
E 599	Perlite	Natural silicate of sodium and aluminium, expanded by heating, free of asbestos. Maximum dioxin content: (1)	All species or categories of animals	—	—	—	—	All feedingstuffs	Without a time limit



No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					mg/kg of complete feedingstuff			
3	Clinoptilolite of volcanic origin	Calcium hydrated aluminosilicate of volcanic origin containing a minimum of 85 % of clinoptilolite and a maximum of 15 % of feldspar, micas and clays free of fibres and quartz Maximum lead content: 80 mg/kg Maximum dioxin content: (1)	Pigs	—	—	20 000	All feedingstuffs	30.9.2000 (2)
			Rabbits	—	—	20 000	All feedingstuffs	30.9.2000 (2)
			Poultry	—	—	20 000	All feedingstuffs	30.9.2000 (2)

(1) In the absence of the establishment, if required, of a specific maximum limit based on sufficient data on the presence of dioxins, the maximum limit of 500 pg WHO-PCCD/F-TEQ/kg will apply from 15 October 2000.

(2) The dioxin content is the sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, applying WHO TEFs (toxic equivalence factors, 1997).
The content must be expressed as upperbound, i.e. it is calculated assuming that all the values of the different congener elements below the limit of detection are equal to the limit of detection.

(3) First authorisation Commission Regulation (EC) No 1245/1999 (OJ L 150, 17.6.1999, p. 15).