

Report of the Scientific Committee for Animal Nutrition on the use of Propane-1,2-diol (Propylene glycol; 1,2-Propanediol), as a feed additive in the feedstuffs for cats. Provisional opinion expressed: 15 January 1991.

Terms of reference (November 1990)

1. May Propane-1,2-diol (E-490), at the level permitted in the feeding-stuffs (see background), adversely affect the health of the cats?
2. Is the level permitted in feeding-stuffs such that an usage distinct from that of heading G ("preservatives") of Council Directive 70/524/EEC is excluded?
3. Can the maximum level be reduced from its permitted level (see background) without affecting the desired "preservative" properties in feedingstuffs for cats?
4. Can other additives listed under the same heading G ("preservatives") satisfactorily replace Propane-1,2-diol?

Background

Additive E-490 is included in Annex I of Directive 85/520/EEC of 11 November 1985 amending the Annexes to Council Directive 70/524/EEC concerning additives in feeding-stuffs¹ under heading G (Preservatives) at a maximum level of 75 000 mg/kg (equivalent to 7.5 % w/w fresh matter basis). It is claimed that when the additive is fed to cats over a prolonged period of time, erythrocytes may develop oxidative damage to the haemoglobin, Heinz body formation and, possibly, reduced resistance to oxidative stress. Therefore the Commission Services would like to know if the permitted amount will lead in practice to significant higher levels when expressed per unit dry matter basis, and whether it presents a danger to the wellbeing of cats.

The Government of the Federal Republic of Germany, wrote to the Commission in the following terms:

In the Annex to this letter, a report by Hickman et al. shows an increased presence of Heinz body formation within erythrocytes in kittens fed on a diet of a feedingstuffs containing Propane-1,2-diol. From the results of the experimental survey, it is manifestly clear that Propane-1,2-diol increases the occurrence of Heinz bodies. This was already known from the data presented before authorising the product and it was also clear it could be caused by other factors in this species of animal. It was not, however, known that relevant physiological parameters are changed. However, in the survey by Hickman et al., it has been proven that feeding with Propane-1,2-diol significantly shortens the life-span of erythrocytes. This state of affairs sheds new light on the question of absence of danger to health in feedingstuffs for cats containing Propane-1,2-diol because, as indicated in the survey, the shortened life-span of the erythrocytes could, when the animals are specifically stressed (illnesses, intoxication) have negative consequences on animal health. The Government of the Federal Republic of Germany is therefore urging the Commission to put the use of Propane-1,2-diol for cats on the agenda of the next meeting of the Committee of Experts on Additives which will be held on

¹ O.J. No. L319, 08.12.84,p.13.

19 September 1990. On this occasion, a decision needs to be taken to suspend the use of the aforesaid additive until the damaging suspicions have been eliminated through further experimentation.

Opinion of the Committee

The SCAN considered the communication received from the Federal Republic of Germany on the production of Heinz bodies by large doses of 1,2-Propanediol in the food for cats and considered, provisionally that there was no immediate need to suspend the use of this substance.

New references were distributed among members of the Toxicology group. The experts also examined a dossier that has not been examined before by SCAN presented by FEDIAF in 1983². On the basis of which admission was granted by Commission Directive 87/552/EEC of 17 November 1987³ amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs⁴. This dossier addressed the issues of whether Heinz body formation should be interpreted as a significant adverse effect in the cat, and justification for the level of inclusion.

The SCAN experts agreed that this information should be examined, together with that provided by the Federal Republic of Germany before seeking to answer the questions mentioned in Annex VII and before seeking further data from industry. In the meantime, the declaration made at the 71 meeting (see below), is still valid.

"Before coming to any decision on the continued use of this substance in pet-food the Committee required the provision of adequate data on the toxicology of 1,2-Propanediol. SCAN did not consider that there was an immediate need to suspend the use of this substance before it had an opportunity to assess its safety-in-use as an ingredient of pet-food."

References.

Bibliography accompanying the communication of the Federal Republic of Germany

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- Further references added by Commission Services
- Christopher Mary M. Eckfeldt J.H. & Eaton J.W. (1990) "Propylene glycol ingestion causes D-lactic acidosis". *Lab. Invest.*, 62:114-118.

² Fédération Européenne de l'Industrie des Aliments pour Animaux Familiars (F.E.D.I.A.F.) 1983. "**1,2-Propylene Glycol (Propylene Glycol) in Soft-Moist Cat Foods, Part 1 (250 pp) and Part II (Appendix I to XI, 293 pp)**". Brussels (Belgium): Square Marie-Louise, 18.

³ OJ No L 336, 26.11.87, p. 34

⁴ OJ No L 270, 14.12.1970, p. 1.

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