REPORT OF THE SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION ON THE USE OF POLYETHYLENE GLYCOL 6000 AND OF A POLYOXYPROPYLENE-POLYOXYETHYLENE POLYMER IN FEEDINGSTUFFS

Opinion delivered on 15 January 1980

TERMS OF REFERENCE (March 1979)

The Scientific Committee for Animal Nutrition is requested to give its opinion on the following questions :

Could the use of polyethylene glycol 6000 and of a polymer of polyoxypropylene-polyoxyethylene (M.W. 6800 - 9000) for coating vitamins intended for incorporation into feedingstuffs under the conditions proposed (cf. Background)

- be harmful for productive livestock and/or pets ?
- result in undesirable effects on the quality of animal products ?

BACKGROUND

The autorization of the use in the Community of the products concerned as additives in feedingstuffs (group of emulsifiers, stabilizers, thickeners and gelling agents) was requested by a Member State. The proposed conditions of use are the following :

- Feedingstuffs intended for all animal species
- Maximum content :
  polyethylene glycol 6000 : 300 mg/kg of complete feedingstuffs
  polyoxypropylene-polyoxyethylene polymer (M.W. 6800 - 9000) : 50 mg/kg complete feedingstuffs.

OPINION OF THE COMMITTEE

1. Polyethylene glycols of high molecular weight (4000 - 6000) are used in pharmacy in the preparation of ointments, suppositories and tablets and they are also used in the preparation of cosmetics. They are water-soluble substances which act essentially as dispersants or binding agents.
   They are described in many pharmacopoeias.

   Polyoxypropylene-polyoxyethylene polymers are non-ionic surfactants used in pharmaceutical preparations and cosmetics either as emulsifiers or to facilitate gastro-intestinal absorption of certain active substances.

Polyoxypropylene-polyoxyethylene polymer (M.W. 6800 - 9000) as an emulsifying agent, in combination with polyethylene glycol 6000 as a dispersant, has been found suitable for the preparation of premixes of liposoluble vitamins for incorporation into feedingstuffs, particularly milk powders and milk replacer feeds.

The biologicial and toxicological properties of these products have been thoroughly investigated. Polyethylene glycols with a molecular weight ranging from 300 - 9000 are biologically inert when administered orally or applied dermally. Their oral LD 50 ranges from 40 to over 50 g/kg body weight for rat and from 20 to over 50 g/kg body weight for guinea pig. Long-term administration of polyethylene glycols (M.W. 1500 and 4000) at levels of 2 % in the diet of dogs and 4 % in the diet of rats had no adverse effects. Polyethylene glycol 6000 is not absorbed from the digestive tract and is not affected by the action of intestinal microorganisms. It is recovered quantitatively unchanged from the faeces. For these reasons, it is also used as a "marker" in studies of the process of digestibility and gastrointestinal absorption of certain nutrient principles.

The biological and toxicological properties of polyoxypropylene-polyoxyethylene polymers vary with their molecular weight and the weight ratio between the chains of polyoxypropylene and polyoxyethylene. The polymer of molecular weight 6800 - 9000, having about 80 % by weight of polyoxyethylene chains and 20 % by weight of polyoxypropylene chains, has little toxicity for rats, mice, guinea pigs, dogs or rabbits. The oral LD 50 for these species is above 15 g/kg body weight. The administration of the product for six months at levels of 0.1 and 0.05 mg/kg body weight in the diet of dogs and for two years at the levels of 3 % and 5 % in the diet of rats produced no adverse biochemical, haematological or histopathological changes and dit not affect growth or rate of survival. A marked reduction of growth was observed in the rat only at a concentration of 7.5 % in the diet. Orally administered, the product is not metabolized and is recovered quantitatively unchanged from the faeces.

No sensitization or irritant effects were found on repeated dermal application to dog, rabbit, guinea pig and man.

2. Since orally administered polyethylene glycol 6000 and polyoxypropylene-polyoxyethylene polymer are neither absorbed from the digestive tract nor metabolized in the organism, they are unlikely to influence the quality of animal products.

3. In view of the data presented, the Committee is of the opinion that the use of polyethylene glycol 6000 and of polyoxypropylene-polyoxyethylene polymer (M.W. 6800 - 9000), under the conditions proposed for the preparation of vitamin premixes intended for incorporation into feedingstuffs, has no harmful effects on animal or human health, nor will it affect the quality of animal products.

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