

REPORT OF THE SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION
ON THE USE OF FLAVOPHOSPHOLIPOL IN FEEDINGSTUFFS FOR RABBITS

Opinion expressed 22 January 1986

TERMS OF REFERENCE (April 1982)

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

1. Does the use of the antibiotic flavophospholipol under the conditions proposed for feedingstuffs for rabbits (see Background) result in the presence of residues in tissues and organs of the animal ? If so, what is the qualitative and quantitative composition of these residues ? Could these residues be harmful to the consumer ?
2. Could the excreted products, derived from the additive, be prejudicial to the environment ? If so, what is the nature of the risks ?
3. In the light of the answers to the above questions, are the proposed conditions of use acceptable ?

BACKGROUND

In accordance with the provisions of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (1), as last amended by the thirty-ninth Commission Directive of 15 January 1982 (2), the use of flavophospholipol is authorized at Community level under the conditions set out as follows in Annex I, Section A of the Directive :

(1) OJ No L 270, 14.12.1970, p. 1

(2) OJ No L 42, 13.02.1981, p. 16

Species of animal	Maximum age	Minimum content	Maximum content
		ppm (mg/kg) of complete feedingstuffs:	
Turkeys	26 weeks	5	20
Other poultry, with the exception of ducks, geese, laying hens and pigeons	16 weeks	1	20
Swine	6 months	1	20
	3 months	10 *	25 *
Calves	6 months	6	16
	6 months	8 *	16 *
Animals bred for fur		2	4
Laying hens		2	5
Cattle for fattening		2 **	10 **

* Milk replacers

** The following statements must be notified in the instructions for use :
 "For supplementary feedingstuffs the maximum dose in the daily ration must not exceed
 - for 100 kg bodyweight : 40 mg,
 - above 100 kg : add 1,5 mg for each additional 10 kg bodyweight."

It is proposed to complete the authorization of use of this additive by the following provisions :

Species of animal : rabbits

Minimum and maximum content of complete feedingstuffs : 2-4 ppm (mg/kg).

OPINION OF THE COMMITTEE

The dossiers available to the Committee are those relating to a 4 % preparation of flavophospholipol manufactured by Hoechst A.G.

Since the questions raised by the Commission could not be answered on the basis of the data available in 1982 relating specifically to rabbits, the

Committee requested that studies be carried out on the possible effects of caecotrophy on the balance of the flavophospholipol ingested by rabbits and on the metabolism of the product in question. In this respect, additional information has been provided by Hoechst A.G. over the past 3 years. The opinion set out below is based on an assessment of the information available as of November 1985.

1. The first studies carried out on the flavophospholipol balance in rabbits showed that the product is not excreted quantitatively. The recovery rates observed on the basis of the determination of the antimicrobial activity of the faeces and of the gut contents collected for a period of 6 to 7 days following ingestion of the product varied between 69 and 104 % in individual instances (limit of determination of the method expressed as flavophospholipol : 0.1 mg/kg). In a later study, carried out on rabbits the caecotrophy of which was hampered, the recovery rates obtained by the same method, using faeces and gut contents collected for a period of 5 days following ingestion of the product, varied between 85 and 113 %. These results show that caecotrophy does not significantly alter the amount of flavophospholipol excreted but slightly prolonged the period of elimination of the product.

The tissue residues were determined microbiologically (limit of determination expressed as flavophospholipol : 0.8 mg/kg) in two groups of rabbits that had received complete feedingstuffs with 4 and 40 mg of flavophospholipol/kg respectively over a period of 7 weeks. Immediately after treatment and following a withdrawal period of 2 days, no residues were detected in the muscles, liver, kidneys and perirenal fat of animals that had received the feedingstuffs containing 4 mg flavophospholipol/kg. Traces of flavophospholipol were detected in the liver and kidneys of animals that had received feedingstuffs with 40 mg/kg without withdrawal period. In a later trial on two groups of rabbits in similiar

experimental conditions (4.2 and 41.2 mg flavophospholipol/kg of complete feedingstuff respectively), no residues were detected in the tissues, although the method of determination was 10 times more sensitive (microbiological assay with a determination limit of 0.08 mg, expressed as flavophospholipol, per kg).

The methods of analysis used to study the balance and the residues did not enable metabolites possessing no antibiotic activity to be determined.

2. Under the conditions of use proposed, the antibiotic activity of the faeces is slowly reduced by the microorganisms. After being stored in soil for 22 days, the microbiological activity was reduced to 33 % of its initial value. Moreover, partial analyses of the gut flora of rabbits that had received feedingstuffs supplemented with flavophospholipol did not reveal any significant change in the number of Coliforms or Clostridiae. The use of flavophospholipol in feedingstuffs for rabbits does not, therefore, seem likely to increase the risks to the environment that are inherent in the excretion of pathogens.

3. In the light of the available data the Committee is of the opinion that the use of flavophospholipol under the conditions proposed (complete feedingstuffs for rabbits containing 2-4 mg of flavophospholipol/kg) could be admitted provisionally. A reassessment of this use is envisaged when additional studies on metabolism of flavophospholipol and tissue residues become available.

REFERENCES

Dossiers Hoechst A.G. (1980 to 1985)