Report of the Scientific Committee for Animal Nutrition on Question 65 by the Commission on the extension of use of robenidine in the feedingstuffs for rabbits for breeding purposes
(Opinion expressed on 7 July 1995)

Terms of reference (January 1993)

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

1. Has the use of Robenidine (1,3bis[(4-chlorobenzilidene))-amino] guanidine hydrochloride), under the conditions proposed for its use as an additive for the feedingstuffs for Rabbits for breeding purposes significant effects on the prevention of coccidiosis in this animal species?

2. Is this use safe to the rabbit for breeding?

3. Can it be monitored in animal feedingstuffs?

4. Can it result in development of resistance in bacteria to prophylactic or therapeutic preparations?

5. What is the metabolic fate of Robenidine in rabbits for breeding purposes? Does this use result in the presence of residues in meat?, If so, what is the qualitative and quantitative composition of these residues? Could these residues be harmful to the consumer?

6. Do the toxicology studies allow the conclusion that the proposed use does not present unacceptable risks
   - for the consumer?
   - for the user?

7. What are the nature and the persistence of the excreted products derived from Robenidine? Can these products be prejudicial to the environment?

8. In the light of the answer 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 amended by Council Directive 84/587/EEC of 29 November 1984[2], the use of Robenidine (E 758, 1,3–bis[(4-chlorobenzilidene)-amino] guanidine hydrochloride) is authorised at Community level

1 O.J. No. L270, 14.12.70 p.1
2 O.J. No. L319, 08.12.84, p.13

under the conditions set out in Annex II, Section D (Coccidiostats) of Commission Directive 91/248/EEC[3] at last amended by Commission Directive 92/99/EEC[4].

D. Coccidiostats

Species or category of animals	Maximum Age	Minimum content mg/kg of complete feedingstuff	Maximum content mg/kg of complete feedingstuff	Other provisions
Chickens for fattening	-	-	-	-
Turkeys	-	30	36	Use prohibited at least 5 days before slaughter
Rabbits for fattening	-	50	56	Use prohibited at least 5 days before slaughter

The Scientific Committee for Animal Nutrition (SCAN) expressed his favourable opinion on the use of robenidine for rabbits, in its report of 10 February 1982[5].

In October 1992 request has been made to include a new usage as follows:

D. Coccidiostats

Species or category of animals	Maximum Age	Minimum content mg/kg of complete feedingstuff	Maximum content mg/kg of complete feedingstuff	Other provisions
Rabbits for breeding	-	50	66	Use prohibited at least 5 days before slaughter

The firm has submitted a complementary dossier, supporting this extension of use.

3 O.J. No. L124, 18.05.91, p.1
4 O.J. No. L350, 01.10.92, p.83
5 Reports of the Scientific Committee for Animal Nutrition Fourth Series, 1984 Report EUR 8769, Catalogue CD-NK-83-010-EN-C. Luxembourg: Office for EC Publications. (p.31)

OPINION OF THE COMMITTEE

Recently, (February 1995) a supplementary dossier has been provided by the firm in further support of its request. In this dossier is contained information already known by the SCAN but which emphasises relevant evidence. Also present was a new study designed to investigate the effect on breeding of Robenidine fed to males at 66 ppm.

Because the request is for an extension to a different category of animals belonging to the same species (rabbits), many of the Commission questions were already satisfactorily answered in the previous opinion expressed by this Committee (4th Series) when robenidine was approved for the use in rabbits for fattening.

Among the questions posed by the Commission the SCAN has therefore focused its attention on the safety of use of robenidine for the rabbits for breeding, in order to evaluate the effects of this use on the reproductive performance in treated animals.

When compared with positive control groups of does (treated with a 200 ppm bifuran in the feed), the does fed with a 50 ppm robenidine diet showed only minor reductions in reproductive indices:

- 1.7 % prolonged interval between litters;
- 12 % reductions of number of matings;
- 5 % reduction of rabbits born for litter;
- 3 % reductions in viable rabbits born per litter;
- 2 % reduction in rabbits weaned per litter.

These slight untoward effects are commercially offset by a reduced total mortality of the animals. (5%).

Similar conclusions were obtained through different research stations and field experiments performed with robenidine supplemented feedingstuffs (60 and 50-60 ppm respectively) compared with negative control diets (without any anticoccidial substance).

In each case the marginal and inconsistent reductions in reproductive performance of does treated even for long periods (up to 4-5 months) have been compensated by remarkable reductions immortality. From the zootechnical point of view, the rabbits for breeding behaved as did rabbits for fattening, both being positively affected by the introduction of robenidine into their diet.

The data on the use of robenidine in rabbits for breeding support the view that this anticoccidial may be used during the whole reproductive cycle of rabbits since the few slight negative effects are not sufficient to abolish the advantages coming from its use.

The conclusion agrees with the previous opinion of the SCAN on the use of robenidine for rabbits for fattening, on account of the absence of toxic effects on reproductive performance even when fed ten times the admitted levels of this additive.

Based on the new data and the positive opinion previously expressed by the SCAN on the use of robenidine in rabbits for fattening (in which any concern for consumers, users and the environment was excluded provided five days withdrawal time was observed) the Committee is of the opinion that the use of robenidine for rabbits for breeding is acceptable under the conditions and provisions already admitted to Annex 1 of Directive 70/524/CEE for rabbits for fattening.