REPORT OF THE SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION ON THE USE OF LASALOCID SODIUM IN FEEDINGSTUFFS FOR CATTLE FOR FATTENING

(Opinion expressed September 1993)

TERMS OF REFERENCE (January 1993):

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

1. Do the toxicology studies allow the conclusion that the proposed use does not present risks for the consumer?

2. In the light of the answer to the above question, are the proposed conditions of use acceptable?

BACKGROUND:

In its report of 27 July 1990[1], the Scientific Committee for Animal Nutrition (SCAN) expressed his favourable opinion regarding the inscription in the annex to Dir. 70/524/EEC[2] as amended by Council Directive 84/587/EEC[3] concerning additives in animal feedingstuffs, of lasalocid sodium (E 763, $C_{34}H_{53}O_8Na$, sodium salt of a polyether monocarboxylic acid produced by *Streptomyces lasaliensis*) as a feed additive in the feedingstuffs for cattle for fattening. On that occasion the firm requested an inscription in which under the column "Other provisions" is was mentioned: "Use prohibited at least 5 days before slaughter".

The Scientific Committee for Animal Nutrition has also expressed a favourable opinion for the use of lasalocid as a coccidiostat for chickens[4] and more recently, the 1st July 1991, for turkeys[5].

In October 1992, complementary data were provided by the firm, supporting an inscription as follows:

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1 Reports of the Scientific Committee for Animal Nutrition. Eighth Series, 1992 (In preparation) Luxemburg: Office for EC Publications (p.3)

2 O.J. No. L270 (14.12.70) p. 1

3 O.J. No. L319 (08.12.84) p. 13

4 Reports of Scientific Committee for Animal Nutrition. Fourth series, 1984 , Report EUR 8769, p. 106-110, Catalogue No. CD-NK-83-010-EN-C

5 Reports of the Scientific Committee for Animal Nutrition. Eighth Series, 1992 (In preparation) Luxemburg: Office for EC Publications (p.19)

A. Antibiotics				
Species or category of animal	Maximum age	Minimum content mg/kg of complete feedingstuff	Maximum content mg/kg of complete feedingstuff	Other provisions
Cattle for fattening	-	10	33	Indicate in the instructions for use: "For complementary feedingstuffs, the quantity of lasalocid sodium must not exceed : - 105 mg for 100 kg body weight, and 5.5 mg for each additional 10 kg of body weight". This feedingstuff contains an ionophore, simultaneous use with certain medicinal substances can be contraindicated"

OPINION OF THE COMMITTEE:

1. In its report of 27 July 1990 the Committee agreed with the request made by the company to maintain the provision in the annex to the amended Council directive 84/587/EEC "use prohibited at least 5 days before slaughter". An application has now been received to vary this provision to permit a zero withdrawal period for lasalocid sodium when used in the feedingstuffs of cattle for fattening.

   No additional toxicological data have been submitted nor would these have been required, because the 1990 report of the Committee had already established the safety of the proposed use of lasalocid sodium for the target species and the absence of any risk to the consumer from residues in animal produce even in the absence of a withdrawal period. From the toxicological data an ADI of 0.005 mg/kg b.w. equivalent to an intake of 0.3 mg/person/day was calculated. Residues were found essentially only in the liver at an approximate levels of 0.25 mg/kg tissue.

   There are therefore no reasons for the Committee to change its earlier opinion that the proposed use of lasalocid sodium in feedingstuffs for cattle does not present a risk for the consumer.

2. The bioavailability of the liver residues has been shown to be about 25%, so that only 0.062 mg/kg would be available for ingestion. If, in addition, the calculated daily consumption of liver by the consumer is taken to be 223 g then the daily exposure of the consumer would amount to no more than 0.223 x 0.062 = 0.014 mg/person per day. This is about 1/20th of the ADI which already includes a safety factor of 100.

   In this case the Committee had to consider the acceptability of residues which were non-genotoxic and non-carcinogenic and for which an adequate toxicological profile and safety margin existed. The Committee had also to

consider whether a correction for bioavailability of the residue rather than the parent compound was admissible. A third consideration was the acceptability of the proposed figure for the daily consumption of liver.

On the basis of the above considerations as well as the above calculations, the available evidence on bioavailability of the liver residues and on the exposure of the consumer through ingestion of liver, the Committee considers acceptable the proposal to change the provisions in the annex to the Directive by substituting a zero withdrawal period for the former 5 days withdrawal period for the use of lasalocid sodium in feedingstuffs for fattening cattle.