SECOND REPORT OF THE SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION ON THE USE OF OLAQUINDOX IN FEEDINGSTUFFS FOR PIGS

Opinion expressed 3 May 1984

TERMS OF REFERENCE (July 1978)

In reply to questions put by the Commission on the safety of use of olaquindox in feedingstuffs for pigs, the Committee, in its report of 8 July 1981 (*), considered that the proposed use could be admitted provisionally and that a reassessment would be necessary once additional data on mutagenicity become available. The Committee noted that the mutagenicity studies then available appeared to be insufficient and requested further extensive studies using a battery of tests covering not only bacterial test systems but also those investigating other genetic endpoints in relation to chromosomal and DNA changes.

As the studies requested have been carried out and are now available, the Committee expressed the following opinion.

OPINION OF THE COMMITTEE

1. The Committee reviewed a total of 15 mutagenicity tests covering the following genetic endpoints : point mutations in prokaryotes and eukaryotes in vitro and in vivo, cytogenetic changes in vitro and in vivo, the latter by several routes of administration, and reaction with DNA. Practically all in vitro and in vivo tests were positive but only at near toxic doses. Covalent binding to DNA and those tests in mice, where the dosage used was low, were negative. The mouse appears to be comparatively insensitive to olaquindox yet most of the mutagenicity tests were performed in this species.

(*) Reports of the Scientific Committee for Animal Nutrition, fourth series (1984), No EUR 8769, p. 1

However, a test for clastogenic potential in the Chinese hamster, a sensitive species, was positive. These findings show that olaquindox is genotoxic. It has no carcinogenic potential as determined in long-term studies.

2. Possible risks from dust inhalation were also studied. Feedingstuffs containing 50 mg olaquindox/kg feed were tested both in meal and pellet form under normal feeding conditions, the process of preparing the feed from premix containing olaquindox not having been examined for dust development. Feeding proceeded by distributing either 2 batches of meal or 1 batch of pellets to 5 pens over a period of 3 minutes. Air was sampled throughout the whole feeding period at the height and in the neighbourhood of the operator using an Andersen-Mark II-Cascade impactor. No olaquindox was detected on the filters or in the 24-hour urine sample of the operator. These findings confirm the opinion of the Committee stated earlier, that the risk to health incurred by farm workers is negligible under practical conditions of distribution of animal feed containing olaquindox.

3. The Committee recalls that residues resulting from the use of olaquindox in pig feed are below the detection limits after 48 hours withdrawal (limit of detection 0.1 mg/kg).

4. In the light of these data, the Committee is of the opinion that olaquindox fulfilling the specifications of the preparation investigated can be used without risks in feedingstuffs for pigs up to four months at the levels provisionally authorized (15-50 mg/kg of complete feedingstuffs; 50-100 mg/kg of milk replacers) and with a withdrawal period of at least four weeks before slaughter.

REFERENCES

Supplementary Dossiers Bayer A.G. (1983, 1984)