

THIRD REPORT OF THE SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION ON  
THE USE OF HALOFUGINONE IN FEEDINGSTUFFS FOR POULTRY

Opinion expressed 8 February 1984

TERMS OF REFERENCE (November 1977 and October 1981)

In reply to questions put by the Commission on the safety of use of halofuginone in feedingstuffs for chickens and turkeys, the Committee, in its reports of 25 April 1979 (\*) and 17 November 1982 (\*\*), considered that the proposed uses could be admitted provisionally with a withdrawal period of at least seven days before slaughter and that further information was necessary to issue a final opinion.

As the additional studies requested on the biodegradation of the product in the environment had been carried out, and assessed by the Committee in 1982 (\*\*), alone some toxicological aspects of halofuginone needed to be clarified. As new experimental data on this topic are now available, the Committee expressed the following opinion.

OPINION OF THE COMMITTEE

The Committee has reviewed the results of four additional mutagenicity tests requested to clarify whether or not halofuginone had any genotoxic potential.

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- (\*) Reports of the Scientific Committee for Animal Nutrition, second series (1980), No EUR 6918, p. 11  
(\*\*) Reports of the Scientific Committee for Animal Nutrition, fourth series (1984), No EUR 8769, p. 94

The in vitro point mutation test in cultured mouse lymphoma cells strain L 51784 Y was negative both in the presence and absence of S 9 mix for metabolic activation. The in vivo bone marrow cytogenetics test in the rat showed no clastogenic effects in this species. An in vitro test for DNA repair synthesis in HeLa 53 epithelioid cells, using radiolabelled thymidine incorporation and autoradiography, gave erratic results which were not repeatable. Because of a vague indication that halofuginone might induce some DNA repair synthesis directly in the absence of S 9 mix, a test for covalent binding of halofuginone to the hepatic DNA of rats was carried out. Practically no covalent binding was detected.

In the light of these findings, the Committee considered that halofuginone had no genotoxic activity nor any mutagenic potential. This compound can be admitted without risks in feedingstuffs for chickens and turkeys at the levels provisionally authorized (2-3 mg/kg) and with a withdrawal period of at least five days before slaughter.

#### REFERENCES

HRC Reports PSL 563/83976, 564/82723, 64/83730

IBMC Report 0333-83