

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

Opinion expressed 5 October 1977

TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition was requested to give an opinion on the following questions concerning furazolidone, nitrofurazone and bifuran (furazolidone + nitrofurazone):

1. Have carcinogenic or mutagenic effects been noted in experiments with these products ?
2. Does the use of these products as additives in feedingstuffs result in the presence of residues in products of animal origin ? If so, what are the nature and quantities of such residues ? Could these residues be harmful to the consumer ?
3. Are there any differences in purity of marketed products ?
4. Are data available to make it possible to establish that use of the products as coccidiostats is no longer economic in livestock production ?
5. In view of the answers to the abovementioned questions should
 - use of the products concerned as additives in feedingstuffs be prohibited in Member States ?
 - use be restricted to certain animal species under specific conditions ?

BACKGROUND

In accordance with the provisions of Council Directive 70/524/EEC (1), of 23 November 1970, concerning additives in feedingstuffs, as last amended by the nineteenth Commission Directive of 26 July 1977 (2), Member States are authorized to use, by way of derogation up to 31 December 1977, furazolidone, nitrofurazone and bifuran (furazolidone + nitrofurazone) as additives in feedingstuffs. These products are listed in Annex II, Section B, of the directive without specific conditions of use.

A recent examination of the use of these products has revealed numerous uncertainties as regards compliance with the fundamental principles governing Community approval of additives, as laid down in Article 6 of the Directive. The Commission, therefore, considered it as necessary to seek the Opinion of the Scientific Committee for Animal Nutrition on the unresolved questions relating to these products.

(1) OJ Nr L 270 of 14.12.1970, p. 1
(2) OJ nr L 207 of 13.8.1977, p. 53

OPINION OF THE COMMITTEE

The Committee has examined the available data on the use of furazolidone, nitrofurazone and bifuran in animal nutrition and has identified numerous gaps in knowledge concerning methods of analysis, metabolism, carcinogenicity and mutagenicity. The information on nitrofurazone and bifuran appeared particularly deficient. The replies to the Commission's questions are set out below :

1. Carcinogenic, mutagenic and teratogenic activity has been observed in laboratory animals. Additional data on these effects is necessary, particularly "dose/effect" relationships.
2. These products, whose molecules are unstable, give rise to residues which are difficult to assess qualitatively and quantitatively given the lack of specificity and sensitivity of the existing methods. It is likely that certain of the metabolites formed are not detected by analysis. It would be desirable to study the effects of these residues by the method of relay toxicity.
3. In addition to the substances originally authorized, products of various origins are being marketed without any guarantee as to purity criteria required by national pharmacopeas. These constitute a further risk factor. In this regard the Committee wishes, as a general rule, that marketed additives be warranted with respect to purity and amount of impurities.
4. It has been established that the nitrofurans concerned have favourable coccidiostatic effects in some instances.
5. In view of these considerations, the Committee feels that, in the absence of additional data, the use of furazolidone, nitrofurazone and bifuran as additives in feedingstuffs should be prohibited in the Community.