

FIRST REPORT OF THE SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION
ON THE CONDITIONS OF USE OF CERTAIN ANTIBIOTICS IN FEEDINGSTUFFS

Opinion expressed 21 February 1978

TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition was requested to examine the conditions of use of zinc bacitracin and flavophospholipol, authorized by Community Directives, and to give an opinion on the following questions.

A. Use of zinc bacitracin and flavophospholipol in feedingstuffs for laying hens

1. Has use of these antibiotics in feedingstuffs for laying hens a significant effect on egg production ?
2. If so, is it to be considered as a nutritional, prophylactic or therapeutic action at the dose levels authorized (15-100 ppm (mg/kg) in complete feedingstuffs for zinc bacitracin ; 2-5 ppm (mg/kg) for flavophospholipol) ?
3. Does the use of these antibiotics, under the conditions authorized, result in the presence of residues in eggs ? If so, what is the nature and the amount of these residues ?
4. In the light of the answers to the abovementioned questions and the requirements of Article 6(2) of Council Directive 70/524/EEC concerning additives in feedingstuffs (1), should
 - the use of zinc bacitracin and/or flavophospholipol in feedingstuffs for laying hens be prohibited in Member States ?
 - the permitted conditions of use be modified ?

B. Use of zinc bacitracin in feedingstuffs for young animals

1. Do increased nutritional effects, free of prophylactic or therapeutic effects, result from the addition to complete feedingstuffs of dose levels of zinc bacitracin higher than 20 ppm (mg/kg) and not exceeding 50 ppm (mg/kg) (with the exception of milk replacers where a maximum content of 80 ppm (mg/kg) is permitted), when feeding
 - poultry, excluding ducks and geese, up to the age of 4 weeks,
 - swine up to the age of 10 weeks,
 - calves, lambs and kids up to the age of 16 weeks,
 - animals bred for fur ?
2. Do these conditions of use result in the presence of residues in animal products ? If so, what is the nature and the amount of these residues ?

(1) OJ N° L 270 of 14.12.1970, p. 1

3. Can they give rise to problems of bacterial resistance ?
4. Are they acceptable for the environment ?
5. Would a modification of the conditions of use indicated under item 1 to increase up to 100 ppm (mg/kg) the maximum content of zinc bacitracin in complete feedingstuffs
 - for turkeys and chickens for fattening up to the age of 8 weeks,
 - for pullets up to point of laying,
 - for swine during the growing periodresult in a significant increase of nutritional effects, free of prophylactic or therapeutic effects, and/or result in modifying the answers to questions posed under items 2, 3 or 4 ?
6. In the light of the answers to the abovementioned questions and the requirements of Article 6(2) of Council Directive 70/524/EEC concerning additives in feedingstuffs (1), should
 - 6.1 conditions of use of zinc bacitracin indicated under item 1 for
 - poultry, excluding ducks and geese,
 - swine,
 - calves, lambs and kids,
 - animals bred for furbe maintained ?
 - 6.2 conditions of use for poultry, insofar as turkeys, chickens for fattening and pullets are concerned, and for swine be modified according to the conditions indicated under item 5 ?

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 twenty first Commission Directive of 23 December 1977 (2), the use of zinc bacitracin and flavophospholipol is authorized at Community level under the following conditions set out in Annex I, Section A, of the Directive :

(1) OJ N° L 270 of 14.12.1970, p. 1

(2) OJ N° L 40 of 10. 2.1978, p. 19

| Additive/Species of animal | Maximum age | Minimum content | Maximum content |
|--|-------------|---------------------------------------|-----------------|
| | | ppm (mg/kg) of complete feedingstuffs | |
| <u>Zinc bacitracin</u> | | | |
| Turkeys | 26 weeks | 5 | 20 |
| Other poultry, with the exception of ducks, geese, laying hens and pigeons | 16 weeks | 5 | 20 |
| Swine, calves, lambs and kids | 6 months | 5 | 20 |
| Animals bred for fur | - | 5 | 80 (*) |
| <u>Flavophospholipol</u> | | | |
| Turkeys | 26 weeks | 1 | 20 |
| Other poultry, with the exception of ducks, geese, laying hens and pigeons | 16 weeks | 1 | 20 |
| Swine | 6 months | 1 | 20 |
| | | 10 (*) | 25 (*) |
| Calves | 6 months | 6 | 16 |
| | | 8 (*) | 16 (*) |
| Animals bred for fur | - | 2 | 4 |
| (*) Milk replacers | | | |

Furthermore, Member States are authorized to use, by way of derogation up to 31 December 1978,

- zinc bacitracin and flavophospholipol in feedingstuffs for laying hens,
- dose levels of zinc bacitracin exceeding the maximum permitted levels stated in Annex I, under the following conditions stated in Annex II, Section A, of the Directive :

| Additive/Species of animal | Maximum age | Minimum content | Maximum content |
|---|----------------------|---------------------------------------|-----------------|
| | | ppm (mg/kg) of complete feedingstuffs | |
| <u>Zinc bacitracin</u> | | | |
| Laying hens | | 15 | 100 |
| Poultry, with the exception of ducks, geese and laying hens | end of the 4th week | > 20 | 50 |
| Swine | end of the 10th week | > 20 | 50 |
| Calves, lambs and kids | end of the 16th week | > 20 | 50 |
| Animals bred for fur | - | > 20 | 50 |
| <u>Flavophospholipol</u> | | | |
| Laying hens | | 2 | 5 |
| Cattle for fattening | | 5 | 15 |

Besides, the Commission was asked by a Member State to amend as follows the conditions of use of zinc bacitracin stated in Annex II, Section A :

| Species of animal | Maximum age | Minimum content | Maximum content |
|---|-----------------|---------------------------------------|-----------------|
| | | ppm (mg/kg) of complete feedingstuffs | |
| Turkeys, chickens for fattening | 8 weeks | > 20 | 100 |
| Pullets | point of laying | > 20 | 100 |
| Other poultry | unchanged | unchanged | unchanged |
| Swine | growing period | > 20 | 100 |
| Calves, lambs, kids, animals bred for fur | unchanged | unchanged | unchanged |

OPINION OF THE COMMITTEE

A. Use of zinc bacitracin and flavophospholipol in feedingstuffs for laying hens

1. The addition of zinc bacitracin or flavophospholipol to feedingstuffs for laying hens can, under certain conditions, increase the output of eggs, particularly in the case of hens with a low level of egg production. It remains to be proved, however, that significant results are obtained from strains with high levels of production and that the use of zinc bacitracin in concentrations exceeding 80 mg/kg feedingstuff is justified. Nevertheless, it has been established that these additives have a favourable effect on the animal organism and that they reduce mortality.
2. At authorized dose-levels, both zinc bacitracin and flavophospholipol give improved utilization of dietary constituents and beneficial effects on the intestinal flora. For zinc bacitracin however, a concomitant bactericidal effect on some micro-organisms of the animal alimentary tract cannot be ruled out at concentrations higher than 80 mg/kg feedingstuff.

These additives have a limited antibacterial spectrum with no systemic action and no known effects on specific diseases of laying hens.

3. Under the authorized conditions of use, zinc bacitracin and flavophospholipol are not absorbed in measurable amounts by the alimentary tract and, at the lower limit of analytical determination (*), no residues have been found in eggs.
4. The Committee is of the opinion that there is no reason to prohibit the use in Member States of zinc bacitracin and/or flavophospholipol in feedingstuffs for laying hens. However, for the reasons mentioned in points 1 and 2, it is recommended
 - that the maximum content of zinc bacitracin in complete feedingstuffs be limited to 80 mg/kg, and
 - that the manufacturers of these additives be required to continue to carry out studies with the view to determine both for flavophospholipol and zinc bacitracin the variation of egg production in relation to the dose-level of additive, the composition of the diet and the mode of feeding, the genetic quality of the breeds and strains of laying hens as well as the conditions under which they are reared. The results obtained should be presented with all details of the experimental procedures applied.

A reassessment could subsequently be made in the light of the results of this work.

B. Use of zinc bacitracin in feedingstuffs for young animals

1. Improved growth can result when zinc bacitracin at levels between 20 and 50 mg/kg of complete feedingstuffs (or between 20 and 80 mg/kg in milk replacers) is given to :
 - poultry (excluding ducks and geese) up to the age of 4 weeks,
 - swine up to the age of 10 weeks,
 - calves, lambs and kids up to the age of 16 weeks,
 - animals bred for fur.

This response to the antibiotic is considered to be nutritional and without prophylactic or therapeutic effects.

(*) zinc bacitracin : 0.1 mg/kg for egg yolk
 0.05 mg/kg for albumen
flavophospholipol : 0.07 mg/kg for egg yolk
 0.01 mg/kg for albumen

2. Zinc bacitracin is not absorbed in measurable quantities from the alimentary tract and, at the lower limit of analytical determination (0.05 - 0.1 mg/kg), no residues have been found in food products of animal origin when the antibiotic is given in feeding-stuffs at authorized levels.
3. At these levels there have been no indications of problems of bacterial resistances.
4. The use of zinc bacitracin at authorized levels is not considered detrimental to the environment. When excreted in animal faeces the product is degraded in dung and soil within a few weeks and, if much water is present, within a few days.
5. For
 - turkeys and chickens for fattening up to the age of 8 weeks,
 - pullets up to the point of laying,
 - swine during the growing period,

experimental evidence is lacking that an increase of zinc bacitracin up to a level of 100 mg/kg in complete feedingstuffs results in a significant increase in nutritional effects. Furthermore, there is little information on the effects of these levels on the gut flora and on the bacterial resistances.

6. The Committee is of the opinion that the permitted conditions of use of zinc bacitracin indicated under item 1 should be maintained.

An increase of the dose-levels, as indicated in the Commission's question N° B 5, could be envisaged only if statistically controlled data were available on the effects of these levels on

- animal production, and
- bacterial resistances after long-term feeding,

as well as information on the degradation in dung and soil of the amounts excreted.