European Food Safety Authority

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SCIENTIFIC OPINION

Compatibility of the microbial product BioPlus 2B (*Bacillus licheniformis* and *Bacillus subtilis*) with lasalocid sodium[1]

Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed

(Question No EFSA-Q-2008-332)

Adopted on 22 October 2008

PANEL MEMBERS

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SUMMARY

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the compatibility of the microbial product BioPlus 2B (*Bacillus licheniformis* and *Bacillus subtilis*) with lasalocid sodium.

A 42-day trial on 300 one-day-old male turkeys was performed. For the trial, the birds were divided into control and treatment groups of 150 animals each. Both groups received a standard of 1.3 x 10^9 CFU kg^{-1} as confirmed by microbiological analysis. The test group received also lasalocid sodium at the maximum recommended level (125 mg active substance kg^{-1} feed). During the trial the birds were followed for zootechnical parameters and for morbidity and mortality. At the end of the trial, the caecal *Bacillus* counts were recorded from 15 birds per treatment group.

No differences in the mortality or morbidity between the groups were observed during the trial. The results indicate a significant improvement in average weight gain and the feed conversion ratio of the birds in the lasalocid sodium group. Therefore, no signs of incompatibility of both strains composing BioPlus 2B with lasalocid sodium at the authorised level have been observed, which allows concluding to the compatibility of both products.

This conclusion could be applied to either strain used individually.

[1] For citation purposes: Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on the compatibility of the microbial product BioPlus 2B (*Bacillus licheniformis* and *Bacillus subtilis*) with lasalocid sodium. *The EFSA Journal* (2008) 841, 1-7

Key words: zootechnical additive, micro-organism, BioPlus 2B, *Bacillus subtilis*, *Bacillus licheniformis*, turkeys for fattening, compatibility, lasalocid sodium

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BACKGROUND AS PROVIDED BY EC

Regulation (EC) No 1831/2003 establishes rules governing the Community authorisation of additives for animal nutrition and in particular defines the conditions that a substance/product should meet to be granted the authorisation. This Regulation replaces Council Directive 70/524/EEC. Regulation foresees also the possibility to modify authorisations already given in its Article 13.

The company Chr. Hansen A/S is seeking to modify the current Community authorisations of their product Bioplus 2B, a microbial preparation of *Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750. Notably, the Company is asking to assess the compatibility of Bioplus 2B with lasalocid A sodium (Table 1).

Table1 **Description of the additive Bioplus 2B**

Product category	Micro-organisms
Trade name	-
Description	*Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750 (in ratio 1/1) containing a minimum $3.2x10^9$ CFU/g ($1.6x10^9$ of each bacterium).
Target animal category	Turkeys for fattening
Applicant	Chr. Hansen A/S
Type of request	Modification of authorisation

EFSA, in its opinions adopted on 22 September 2005 (Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the modification of terms of authorisation of the micro-organism product *Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750 (BioPlus 2B) authorised as feed additive in accordance with Council Directive 70/524/EEC) and on 18 October 2007 (Compatibility of the microbial preparation of *Bacillus licheniformis* and *Bacillus subtilis* (BioPlus 2B) with the coccidiostat lasalocid A sodium in feed for turkeys), was not able to give a conclusive opinion on the compatibility with lasalocid sodium because of lack of data provided by the company.

Therefore, the Commission gave the possibility to the company to submit complementary information to complete these assessments.

The Commission has received a supplementary dossier from the applicant company Chr. Hansen A/S containing new data to support the compatibility of BioPlus 2B with lasalocid A sodium. The data generated by the company and complied in the above-mentioned supplementary dossier have been sent directly to the Authority.[2]

TERMS OF REFERENCE AS PROVIDED BY EC

In view of the above, the Commission asks to the European Food Safety Authority to deliver an opinion on the compatibility of the microbial BioPlus 2B (*Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750) with lasalocid A sodium, under the requested conditions of use.

[2] Dossier reference: FAD-2008-0018

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Group on Micro-organisms for the preparation of this opinion.

ASSESSMENT

1. Introduction

BioPlus 2B is a mixture of two species (*B. licheniformis* DSM 5749 and *B. subtilis* DSM 5750). The product has been previously assessed by the FEEDAP Panel regarding the compatibility with the coccidiostat lasalocid A sodium. In its previous opinion, the FEEDAP Panel was unable to reach a conclusion on the compatibility of this microbial product with the coccidiostat in question due to the low number of birds analysed (two birds per treatment).

2. Compatibility trial

A 42-day trial on 300 one-day-old male turkeys was performed. The birds were divided into control and treatment groups of 150 animals each. The number of pens was ten, giving a total of five replicates per group. Both groups received a standard dose of 1.3×10^9 CFU kg^{-1}. The dose was confirmed by microbiological analysis. The test group received also lasalocid sodium at the maximum recommended level (125 mg active agent kg^{-1} feed). The dose was confirmed by chemical analysis. During the trial, the birds were followed for zootechnical parameters and for morbidity and mortality. At the end of the trial, the caecal *Bacillus* counts were recorded from 15 birds per treatment group. No heat treatment was applied to differentiate between the vegetative cells and spores.

No differences in the mortality or morbidity between the groups were observed during the trial. The average weight gain and the feed to gain ratio of the birds in the treatment groups are given in Table 2. The results indicate a significant improvement in these parameters in the lasalocid sodium group. The statistical evaluation was done using analysis of variance.

Table 2. **Weight gain, feed to gain ratio and caecal *Bacillus* counts of turkeys (42 days)**

	Weight gain (kg)	Feed /gain (kg kg^{-1})	Caecal counts (log CFU g^{-1} ± SD)	
			B. subtilis	*B. licheniformis*
Control	2.20[a]	1.76[a]	4.00 ± 0.36	4.94 ± 0.21
Lasalocid sodium	2.35[b]	1.68[b]	4.01 ± 0.36	4.99 ± 0.17

[a, b]: Values with different superscript within the column differ statistically significantly ($P < 0.05$)

The caecal counts of bacilli at the end of the trial are given in Table 2. According to the results, there were no statistically significant differences in the CFU counts of either of the *Bacillus* species between the controls and the animals treated with lasalocid sodium.

CONCLUSIONS

The treatment with lasalocid sodium did not affect the total caecal CFU counts of either of the *Bacillus* species of BioPlus 2B. Therefore, no signs of incompatibility of both strains composing BioPlus 2B with lasalocid sodium at the authorised level have been observed, which allows concluding to the compatibility of both products.

This conclusion could be applied to either strain used individually.

DOCUMENTATION PROVIDED TO EFSA

1. Compatibility study with BioPlus 2B and the coccidiostat lasalocid A sodium for turkeys. June 2008. Submitted by Chr. Hansen A/S.