European Food Safety Authority

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SCIENTIFIC OPINION

Compatibility of the microbial product 035 (*Bacillus subtilis*) with lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, salinomycin sodium and semduramicin sodium[1]

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

(Questions No EFSA-Q-2008-331)

Adopted on 14 May 2009

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 035 (*Bacillus subtilis*) with lasalocid sodium, maduramicin ammomium, monensin sodium, narasin, salinomycin sodium and semduramicin sodium. Compatibility with lasalocid sodium has been previously established.

The applicant provided a 35-day study carried out with 600 chickens, all of which received 035 at the recommended inclusion rate in the presence or absence of the following coccidiostats: salinomycin (70 mg kg^{-1}), narasin (70 mg kg^{-1}), monensin (125 mg kg^{-1}) and maduramycin (5 mg kg^{-1}). At the end of the experiment, caecal samples were randomly collected and analysed for *Bacillus.* No significant differences in caecal total *Bacillus* counts were observed between control and coccidiostat-supplemented groups.

However, since no treatment was applied to distinguish between spores and vegetative cells, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) is unable to conclude on the compatibility between 035 and maduramicin ammomium, monensin sodium, narasin and salinomycin sodium. Moreover, in the absence of experimental data, no statement can be made regarding semduramicin sodium.

[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 products 035 (*Bacillus subtilis*) with lasalocid sodium, maduramicin ammomium, monensin sodium, narasin, salinomycin sodium and semduramicin sodium. *The EFSA Journal* (2009) 1096, 1-7

Key words: zootechnical additive, 035, *Bacillus subtilis*, chickens for fattening, compatibility, coccidiostats, maduramicin ammomium, monensin sodium, narasin, salinomycin 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 its product 035, a microbial preparation of *Bacillus subtilis* DSM 17299, as regards its compatibility with some coccidiostats. Notably, the Company is asking to assess the compatibility of 035 with lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, salinomycin sodium and semduramicin sodium (Table 1)

Table 1 **Description of the additive 035**

Product category	Zootechnical: gut flora stabilisers
Trade name	035
Description	*Bacillus subtilis* DSM 17299 containing a minimum of 1.6 x10^9 CFU/g
Target animal category	Chickens for fattening
Applicant	Chr. Hansen A/S
Type of request	Authorisation

The EFSA in its opinion adopted on 17 October 2006 (Opinion of the Scientific Panel on Additive and Products or Substance used in Animal Feed on the microbiological product "035", a preparation of *Bacillus subtilis* DSM 17299 as a feed additive for chickens for fattening in accordance with Regulation (EC) 1831/2003) and on 18 October 2007 (Opinion of the Scientific Panel on Additive and Products or Substance used in Animal Feed on compatibility of microbiological product 035, a preparation of *Bacillus subtilis* DSM 17299 with lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, salinomycin sodium semduramicin sodium), was not able to give a conclusive opinion on the compatibility of the product with some coccidiostats 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 035 with lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, salinomycin sodium and semduramicin 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 preparation 035 (*Bacillus subtilis* DSM 17299)

[2] Dossier reference: FAD-2008-0017

with the coccidiostats: lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, salinomycin sodium, and semduramicin sodium, under the requested conditions of use.

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

The additive 035 is a microbial feed additive based on *Bacillus subtilis* (DSM 17299). The compatibility of 035 with the coccidiostats decoquinate, narasin/nicarbazin, robenidine and diclazuril when added to chickens' diets has been established in a previous opinion (EFSA, 2008a). In other opinions, however, the FEEDAP Panel was unable to reach a conclusion on the compatibility of this microbial product with the coccidiostats lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, salinomycin sodium and semduramicin sodium, based on the data available (EFSA, 2006 and 2007). However, the compatibility of DSM 17299[3] with lasalocid sodium has been established in connection with a compatibility study with the product BioPlus 2B from the same company and containing this strain (EFSA, 2008b).

The applicant has now provided new data to support the compatibility of 035 with salinomycin narasin, monensin, and maduramicin.

2. Compatibility of 035 with coccidiostats

The applicant provided a 35-day study carried out with 600 one-day-old chickens, all of which received 035 at the recommended inclusion rate (8 x 10^8 CFU kg^{-1} feedingstuff, confirmed by analysis). The birds were divided into six treatment groups, each consisting of three replicates (pens) of 40 birds. One group served as the control while each of the other groups received one of the following coccidiostats at the maximum authorised level: salinomycin (70 mg kg^{-1}), narasin (70 mg kg^{-1}), monensin (125 mg kg^{-1}), and maduramicin (5 mg kg^{-1}) . No experiments with semduramicin sodium have been reported. The birds were followed for performance throughout the starter, grower and finisher phase. At the end of the grower phase (day 28), caecal samples were randomly collected (six birds per pen) and analysed for *Bacillus.*The medium contained colistine sulphate to reduce the background growth. However, the analysis did not involve the heat treatment necessary to distinguish between spores and vegetative cells. The performance parameters were analysed using ANOVA (Duncan test) and the microbiological data using the Students' t-test.

There were no significant differences in the total caecal *Bacillus* CFU counts between the treatment groups and the control, values were as follows: control 5.23, salinomycin 5.17, narasin 5.11, monensin 5.10, maduramicin 5.19 log CFU g^{-1}

CONCLUSIONS

Since no treatment was applied to distinguish between spores and vegetative cells in the caecal samples, as it is likely that the vegetative forms would be more susceptible to coccidiostats, no conclusion can be drawn on the compatibility between 035 and maduramicin ammomium, monensin sodium, narasin and salinomycin sodium. Moreover, due to the lack of experimental data, no statement can be made regarding semduramicin sodium.

DOCUMENTATION PROVIDED TO EFSA

1. Study on the compatibility between the microbial feed additive 035/GalliPro® and four coccidiostats in feed for chickens for fattening. January 2008. Submitted by Chr. Hansen A/S.

[3] Also registered with the deposition number DSM 5750

2. Supplementary dossier on the microbiological product 035/GalliPro® (*Bacillus subtilis* DSM 17299) for use with coccidiostats in chickens for fattening-ADDENDUM. January 2009. Submitted by Chr. Hansen A/S.

REFERENCES

EFSA (European Food Safety Authority), 2006. Opinion of the Scientific Panel on Additive and Products or Substance used in Animal Feed on the microbiological product "035", a preparation of *Bacillus subtilis* DSM 17299 as a feed additive for chickens for fattening in accordance with Regulation (EC) 1831/2003. http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej406_035_cff_en.pdf?ssbinary=true

EFSA (European Food Safety Authority), 2007. Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the compatibility of the microbial product 035, a preparation of Bacillus subtilis with lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, salinomycin sodium and semduramycin sodium. http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej575_035_coccid_en.pdf?ssbinary=true

EFSA (European Food Safety Authority), 2008a. Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the compatibility of the microbial product 035 (*Bacillus subtilis*) with decoquinate and narasin/nicarbazin. http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej840_035_en.pdf?ssbinary=true

EFSA (European Food Safety Authority), 2008b. Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the compatibility of the microbial product BioPlus 2B (*Bacillus licheniformins* and *Bacillus subtilis*) with lasalocid sodium http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej841_bioplus2b_en.pdf?ssbinary=true