

Newsletter

Vol. 5, No. 48, March 2007

≡ Biomin ≡

> EDITORIAL

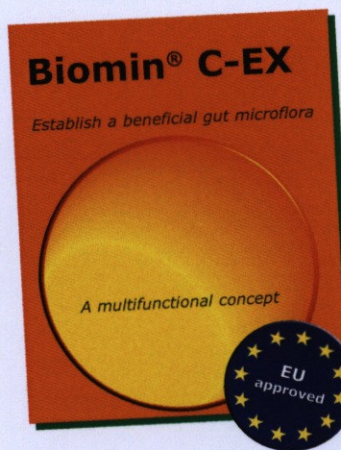
Today probiotics are used in modern animal nutrition world wide because of their beneficial effect on the animal. They improve the intestinal microbial balance in the gut of the animals which results in a better health status and improved performance. Most commonly used probiotic bacteria in animal feeding are species like *Enterococcus*, *Pediococcus*, *Lactobacillus*, *Bifidobacterium* and *Bacillus*. In Europe the use of probiotics in animal feeds is strictly regulated by a European Commission Directive. According to the European law probiotic feed additives may not be put on the market unless authorization has been given following a scientific evaluation demonstrating that the additive has no harmful effects on human and animal health and on the environment. Besides safety for target species, humans and environment, also the efficacy has to be proven. In the US the use of probiotics in animal feed is regulated by the Food and Drug Administration (FDA). Since 1989 manufacturers in the US are required to use the term "direct-fed microbials" (DFMs) instead of probiotics. The FDA defines DFMs as products that are purported to contain live (viable) microorganisms (bacteria and/or yeast). Microorganism that are approved by the FDA are listed in the Association of American Feed Control Officials (AAFCO) official publication. The listed organisms are considered as generally recognized as safe (GRAS) for the intended use. That means that they are not subjected to the premarket review and approval requirement by the FDA. However European legislation has global implications since companies wishing to supply the EU market must comply with the laws. In order to obtain the approval for a probiotic feed additive in the EU companies need to provide substantial financial and human resources. However, these efforts ensure optimum safety for both the consumer and the environment and also prove the efficacy of the relevant probiotic product. This newsletter gives a short overview about the registration process for probiotics for animal nutrition in Europe. Furthermore some trial results for our probiotic strain *Enterococcus faecium* Biomin® IMB 52, which recently obtained the EU authorization as feed additive for chickens for fattening are presented.

Enjoy reading.

Michaela Mohnl



Biomin® C-EX and Biomin® IMBO product line



The probiotics used in animal nutrition in the European Union must be registered as microbial feed additives. Only additives that have gone through an authorisation procedure may be placed on the European market. Authorisations are granted for specific animal species, specific conditions of use and for ten years periods. The feed additive registration process requires a dossier to be submitted to the European Food Safety Authority (EFSA). EFSA is responsible for conducting the evaluation of the data submitted requesting authorisations. After a favourable opinion of the EFSA, the Commission prepares a draft regulation to grant authorization.

Enterococcus faecium Biomin® IMB 52 obtained EU authorization as a feed additive for chickens for fattening

According to the regulation (EC) No 1831/2003 probiotics are categorized in the class "zootechnical additives" as gut flora stabilisers. SCAN (Scientific Committee on Animal Nutrition) has published guidelines for the assessment of additives in feeding stuff. The manufacturers have to prepare a dossier, which demonstrates the safety, efficacy and stability of their products. The dossier essentially provides a guarantee to

the customer that the feed using the probiotic is safe for the target animal and the final consumer. Further the animal producer can be assured that the probiotic is effective for improving performance and stable within quoted shelf life.

The dossier contains following sections:

- I. Summary of the data
- II. Identity, characterisation and conditions of use
- III. Studies concerning efficacy of additive
- IV. Studies concerning safety of additive
- V. Monograph
- VI. Identification note

Studies conducted in the laboratory and under practical conditions follow the requirements of the European Community for registration (Regulation 1831/2003 on additives in animal). These documents contain detailed information on the data required for identity, compatibility with other additives, and efficacy.

In addition, comprehensive studies are requested to ensure that toxicity and transfer of resistance, which could endanger the effective treatment of diseases with antibiotic substances, are excluded. Registration comes into effect only after the EFSA Panel on Feed Additives have positively assessed the quality and efficacy of the probiotic as well as its safety in humans, animals and the environment.



Enterococcus faecium Biomin® IMB 52

Biomin® IMB 52 is a microbial feed additive based on a single strain of *Enterococcus faecium* DSM 3530. This additive has been assessed for its safety and its efficacy for chickens for fattening by the EFSA. The results of three growth trials provided evidence that the inclusion of *Enterococcus faecium* Biomin® IMB 52 in complete feed improves weight gain of chickens for fattening. The FEEDAP Panel considered Biomin® IMB 52 safe for the target animals, the consumer, user and the environment. MIC values for the tested antibiotics were below the FEEDAP breakpoints indicating the absence of resistance against antibiotics of human and veterinary importance. The *E. faecium* DSM 3530 was shown free from known virulence determinants. Different experiments contributed to demonstrate the additive efficacy in chickens for fattening.

Trial results

Trial 1

A 42-day feeding trial was performed with 500 one day-old chickens (Ross 308) which were randomly allocated to five groups: a control group (CG) without additive and four treated groups with different inclusion levels of Biomin® IMB 52. Results showed that the live weight of birds which received Biomin® IMB 52 with an inclusion rate of 2.5×10^8 cfu kg⁻¹ feed (TG A) and 5×10^8 cfu kg⁻¹ feed (TG B) was significantly improved ($P \leq 0.05$) by 4.9 to 5.1 % when compared to the control animals. Mortality could be reduced in all trial groups (CG: 9.26%, TG A: 4.95%, TG B: 3.92%). Through the addition of *Enterococcus faecium* Biomin® IMB 52 efficiency of fattening was improved which resulted in an increased PI (Productivity Index) in the treatment groups. Results are presented in Figure 1.

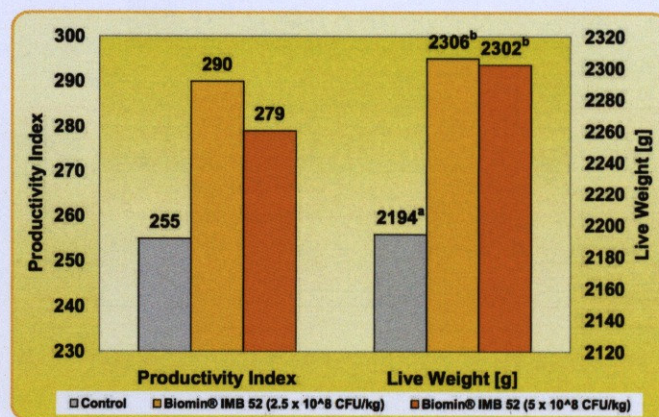


Figure 1: Productivity index and live weight of chickens for fattening fed with Biomin® IMB 52 in comparison to control animals (42 days)

Trial 2

A 42-day feeding trial was performed using 400 one day-old chickens. The chickens were divided into two groups of 200 birds (Control group and Biomin® IMB 52 treated group). Results indicated a significant higher body weight for Biomin® IMB 52 treated animals when compared to control animals (2418 vs. 2321 g, $P \leq 0.05$).

Trial 3

A 42-day feeding trial was performed using 400 one day-old chickens. The chickens were divided into two groups of 200 birds (Control group and Biomin® IMB 52 treated group). Results indicated a significant higher body weight and average weight gain for Biomin® IMB 52 treated animals when compared to control animals (2576 vs. 2540 g, $P \leq 0.05$). Mortality was found to be at a lower level in the treated group (1.5 vs. 5.5%). Improved livability, weight gain and FCR resulted in a remarkably increased value regarding efficiency of fattening. Birds in the trial group showed a PI value of 353 compared to 319 in the control group. Results are presented in Table 1.

Table 1: Performance data of chickens for fattening fed with Biomin® IMB 52 in comparison to control animals (42 days)

	Control	Biomin® IMB 52
Live weight (g)	2540 ^a	2576 ^b
Daily weight gain (g)	59.48 ^a	60.29 ^b
Feed consumption (g)	4453	4321
FCR	1.79	1.71
Mortality (%)	5.5	1.5
PI*	319	353

a,b: Means not sharing a common superscript are significantly different ($P \leq 0.05$)

* PI (Productivity Index) = Livability [%] x live weight [kg]/age [d] x FCR x 100

Table 2: Digestibility of feed nutrients of chickens for fattening fed with Biomin® IMB 52 in comparison to control animals (42 days)

Coefficient of digestibility (%)	Control group	Biomin® IMB 52
Organic matter	72.80	75.42
Crude fat	76.72	78.36
Crude protein	81.24 ^a	83.04 ^b
Crude fiber	9.28	12.58

a,b: Means not sharing a common superscript are significantly different ($P \leq 0.05$)

Trial 4

In addition, a digestibility experiment was conducted with ten chickens (21 day old) divided into two groups: control group and a group supplemented with Biomin® IMB 52 feed. The birds were individually kept in cages with individual watering systems. Compared to the control group *Enterococcus faecium* Biomin® IMB 52 increased digestibility of feed nutrients like organic matter (+ 2.6 %), crude fat (+ 1.6 %), crude protein (+ 1.8 %) and crude fiber (+ 3.3 %). Furthermore the ammonia concentration in blind bags was reduced by 8 % compared to the control group. Results are presented in Table 2 and Figure 2.

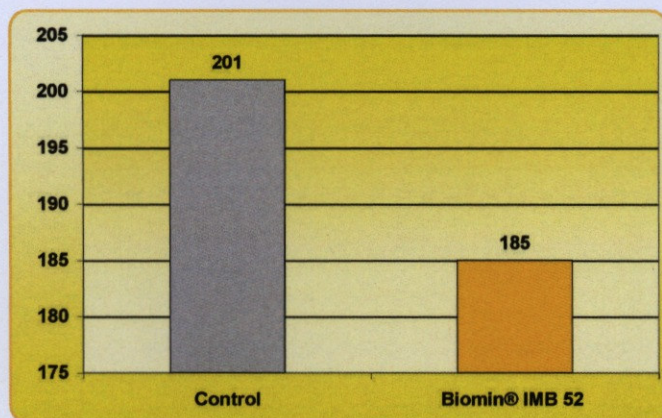


Figure 2: Amount of ammonia in blind bags, [mg %] of chickens for fattening fed with Biomin® IMB 52 in comparison to control animals (42 days)

Biomin® C-EX and Biomin® IMBO

The probiotic strain *Enterococcus faecium* Biomin® IMB 52 is part of BIOMIN probiotic products Biomin® C-EX and Biomin® IMBO. The probiotic product line is based on natural raw materials combining the beneficial effects of probiotics, prebiotics and immune-modulating substances and is used particularly in the diets of young animals to establish a healthy gut and support the unspecific immune-system. The probiotic strain *Enterococcus faecium* Biomin® IMB 52 helps to establish

and stabilise a beneficial gut microflora and to prevent pathogen colonization due to fast proliferation, colonization and acidification in the gut. The immune-modulating components enhance the innate immune system and thus improve the resistance to infections. The beneficial gut microflora is additionally supported by the prebiotic component in the products. Young animals will be more resistant against invading pathogenic bacteria and thus to enteric disease.

The natural way.

Biomin®

Natural Growth Promoters

from BIOMIN have been proven to be effective in scientific trials as well as in practical use.

- Significant Improvement of health status in broilers, FCAV Universidade Est. Paulista, Brazil, 2006
- 2 % Increase in Broiler Productivity Index compared to AGPs Kasetsart University, Thailand, 2006
- Improvement of Broiler Productivity Index by 8.4 % Texas A&M University, USA, 2006

New trial results available

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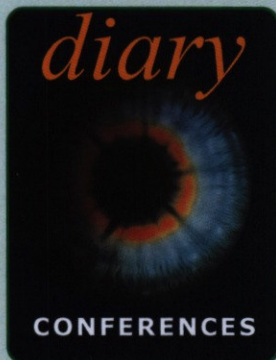
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 Master thesis: Medium design and Optimization of the fermentation process for a Ochratoxin A detoxifying yeast
 Since 2003 Doctoral thesis: Development of the fermentation process for the production of a competitive exclusion product for poultry meeting the regulatory requirements for registration in the EC



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VIV Asia

March 7th - 9th, 2007, Bangkok, Thailand

AFMA Forum

March 13th - 16th, 2007, Sun City, South Africa

BSAS Annual Conference

April 2nd - 4th, 2007, Southport, UK

Conference on Gastrointestinal Function (CGIF)

April 16th - 18th, 2007, Chigago, US

2nd International Gut Flora Workshop "Gut Microbiota in health and disease"

April 27th - 28th, 2007, Amsterdam, Netherlands

> LITERATURE:

ANADON et al. (2005). Legislation of probiotics for animal nutrition in the European Union, 3rd Probiotics & Prebiotics & New Foods, EPA session, 6th of Sept. 2005, Rome, Proceeding book, page 11-15

EFSA (2005). Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the updating of the criteria used in the assessment of bacteria for resistance to antibiotics of human or veterinary importance. The EFSA Journal (2005) 223, 1-12.

FEFANA booklet on probiotics in animal nutrition. www.fefana.org/publications.aspx

> IMPRESSUM

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