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Safety and efficacy of fumonisin esterase (FUMzyme®) as a technological feed additive for all avian species

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Abstract

FUMzyme® is an enzyme-based feed additive intended to degrade fumonisin mycotoxins found as contaminants in feeds for avian species. It is produced from a genetically modified strain of *Komagataella pastoris*. The additive is already authorised for use with pigs. During the course of this assessment, it was shown that the production strain and its recombinant genes are not present in the final product. Safety for the consumer, the user and the environment were also established. The extension of its use to all avian species is not expected to alter these conclusions. Chickens and turkeys for fattening and laying hens showed no adverse effect when given feed containing 100 times the maximum recommended dose. Consequently, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concludes that the additive is safe for poultry when used within the dose range proposed (15–300 U/kg feed) and extends this conclusion to all other avian species. Five short-term feeding studies were made in which poultry were given feed contaminated with fumonisins with or without the additive. Each included a measure of the concentration of fumonisin B1 and its breakdown products and showed that the enzyme was able to significantly reduce the concentration of fumonisin in faeces and various points in the digestive tract and increase the concentration of the degradation products. In addition, ratio of sphinganine/sphingosine, considered the most sensitive endpoint for fumonisin toxicosis, was significantly reduced by the addition of FUMzyme® at the minimum proposed dose, when added to diets contaminated with fumonisins. FUMzyme® has the capacity to degrade fumonisins in feed, at concentrations below the Guidance limits operating in the EU in chickens and turkeys for fattening and laying hens at the minimum recommended dose of 15 U/kg complete feed. This conclusion can be extrapolated to all avian species.

Keywords: fumonisin esterase, *Komagataella pastoris*, poultry, fumonisin mycotoxins, sphinganine/sphingosine, safety, efficacy

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Biomin GmbH[2] for authorisation of the product fumonisin esterase (FUMzyme®), when used as a feed additive for all avian species (category: technological additives; functional group: substances for reduction of the contamination of feed by mycotoxins).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 19 February 2015.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product fumonisin esterase (FUMzyme®), when used under the proposed conditions of use (see Section 3.2).

1.2. Additional information

FUMzyme is an enzyme-based additive intended to degrade fumonisin mycotoxins found as contaminants of feed. The safety and efficacy of the additive when used in feed to pigs was the subject of an opinion published in 2014 (EFSA FEEDAP Panel, 2014). This opinion considered the fact that the enzyme is produced by a genetically modified (GMM) strain of *Komagataella pastoris*. However, since the production organism and its recombinant DNA could not be detected in the final product, it was concluded that the additive did not give rise to any safety concern with regard to the genetic modification of the production strain. Evidence was also available showing that the additive was safe for use with pigs at the proposed dose and that its use in animal production did not give rise to concerns for the consumer of animal products, for users of the additive or for the environment. It was also shown that metabolites of fumonisin produced by the action of the enzyme have a lower toxicity than the parent mycotoxin. Subsequent to this opinion, the additive was authorised for use in feed for pigs and is included in the European Union (EU) Register of Feed Additives (1m03).[3] The applicant is now seeking authorisation for use of the same additive with all avian species.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[4] in support of the authorisation request for the use of FUMzyme® as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008[5], and the applicable EFSA guidance documents.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies.

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Biomin GmbH, Industriestraβe 21, 3130 Herzogenburg, Austria.
[3] Commission implementing Regulation (EU) No 1115/2014 of 21 October 2014 concerning the authorisation of a preparation of fumonisin esterase produced by *Komagataella pastoris* (DSM 26643) as a feed additive for pigs. OJ L 302, 22.10.2014, p. 51.
[4] FEED dossier reference: FAD-2014-0040.
[5] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[6]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of FUMzyme® is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012a) and Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

3. Assessment

The use of a GMM for the production of the additive has been previously assessed and safety for consumers, users and the environment established. Extension of use to the additional species under application is not expected to alter these conclusions. Consequently, this opinion focuses on the safety and efficacy of the additive when used in feed for the additional target species.

3.1. Characterisation

The additive which is the subject of the present application has the same formulation and method of manufacture as that considered in the previous opinion for pigs (EFSA FEEDAP Panel, 2014). Thus, the data pertaining to impurities, physical properties and shelf life still apply. The data on stability in vitamin–mineral premixes and feed for pigs for fattening and evidence that the additive is capable of homogeneous mixing in feed are considered applicable to poultry given the similarity in feed formulation.

3.2. Conditions of use

FUMzyme® is intended for use in feed for all avian species at a minimum dose of 15 units of enzyme activity (U)/kg complete feed and a maximum of 300 U/kg complete feed. It can be added directly to feed or via premixtures. No withdrawal period is proposed.

3.3. Safety

3.3.1. Safety for the target species

3.3.1.1. Chickens for fattening

A tolerance trial was made with 600 mixed-sex 1-day old Ross 308 birds distributed to one of three treatment groups.[7] These were a control group given a maize–soybean mash diet, a group given the same diet supplemented with FUMzyme at 300 U/kg complete feed (1× maximum recommended dose) and an overdose group given the same diet supplemented with 30,000 U/kg complete feed (100×). The concentration of enzyme in the diets was confirmed by analysis and fumonisin B1 and B2 were absent (limit of detection (LOD) 25 μg/kg).[8] The duration of the trial was 35 days. The study followed a randomised complete block design with 10 pens of 20 birds used for each treatment group. Daily observations were made of health and mortality was recorded. Individual weight was measured at the start, on days 14 and 28, and at the end of the trial at 35 days. Feed intake per pen was recorded. From this data, weight gain, daily weight gain and the feed to gain ratio of each pen were calculated.

Data were first checked for normal distribution by the Shapiro–Wilk test. Where data was not normally distributed, data were compared by a Kruskal–Wallis test (non-parametric analysis of variance (ANOVA) for more than two samples) including pairwise comparisons. Otherwise, data were compared by ANOVA including tests for homogeneity of variances (Levene's test). Where variances were homogeneous, ANOVA was followed up with Bonferroni test for multiple comparisons. Where variances were not homogeneous, ANOVA was substituted by Welch Test and followed up by Tamhane's T2 test for multiple comparisons. A power calculation was made. Pen was considered the experimental unit for the statistical analysis.

[6] The full report is available on the EURL website: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2013-0002?search&form-return

[7] Technical dossier/Supplementary Information March 2016/Section III/Annex (i) 01.

[8] Technical dossier/Supplementary Information March 2016/Section III/Annex (i) 06.

Overall mortality was around 5% with no significant differences between groups. Feed to gain ratio (between 1.75 and 1.82) and feed intake (between 3.0 and 3.2 kg/bird) also did not differ significantly between groups. There was a significant increase in final body weight in the group treated with 300 U/kg FUMzyme (1.87 kg) compared to either the control group (1.77 kg) or the 100× overdose group (1.75 kg). However, the difference between the control and 100× overdose groups was not significant.

3.3.1.2. Turkeys for fattening

A total of 720 one-day-old female BUT 10 turkey pullets were assigned to either a control group, a group given FUMzyme at an intended dose of 300 U/kg (1×) or an overdose group given an intended dose of 30,000 U/kg (100×).[9] However, analysis of the diets showed that the enzyme addition was higher than intended (490 and 560 for the lower dose group and 40,000 and 50,000 U/kg for the overdose group). Each treatment consisted of 16 replicates of 15 animals. Animals were given a basal diet based on wheat and soybean meal in mash form and were fed for a total of 42 days. Diets were free from fumonisin B1 and B2 (LOD 20 μg/kg feed).

Birds were monitored for health and mortality was recorded. Weights were taken on days 0, 21 and 42, and intake recorded on days 21 and 42. From this data, daily weight gain and feed to gain ratio were calculated. Results obtained were subjected to ANOVA and the Tukey's test was used to compare means between treatments. Pen means were the units for statistical analysis.

Overall mortality was low (1.8%). No significant differences in final body weight (~2.1 kg) or total feed intake (3.5 kg/bird) were found between treatments. The calculated feed to gain ratio did not differ between the control and 300 U/kg group (1.79–1.78) but a significant improvement in feed to gain ratio was recorded for the overdose group compared to the control group (1.68 vs 1.79).

3.3.1.3. Laying hens

In this trial, 780 laying hens (Novobrown) at the start of their laying period were assigned to the same three treatment groups as in the trials above.[10] The start of the experiment, when hens were 140 days of age, was preceded by a 7-day acclimatisation period. Eggs produced during this period were discarded. The intended dose of FUMzyme was confirmed by analysis of the feed. Birds were housed in pens of 13 birds with each pair of pens representing one replicate. In total, there were 10 replicates per treatment. Birds were fed a basal diet of wheat/sunflower cake and soybean meal in mash form and the duration of the trial was 58 days.

Mortality, feed consumption and egg production was monitored throughout the study, average egg size measured at two-week intervals and body weight recorded at the start and end of the experiment and when birds were 168 days of age. Feed intake to egg mass was calculated. Egg quality parameters (individual egg weights, shell strength and Haugh units) were determined for all eggs produced when birds were 140, 168 and 198 days of age. Results were subjected to ANOVA after normality of data and evenness of variance confirmed (Shapiro and Bartlett tests). The experimental unit was either the paired pens or the eggs depending on the parameters evaluated.

Mortality over the experimental period was low (0.3%). The overall laying rate was 91.7%, average egg weight 54.7 g, egg mass/hen 2.9 kg and the feed to egg mass ratio was 2.08. No significant differences between treatments were recorded for any parameter after the start of the experiment.

3.3.2. Conclusions on safety for the target species

Chickens for fattening, turkeys for fattening and laying hens showed no adverse effects when FUMzyme was included in diets at a 100-fold higher inclusion rate than the maximum recommended dose. Consequently, the FEEDAP Panel concludes that FUMzyme is safe for chickens, turkeys and laying hens at the maximum recommended dose of 300 U/kg complete feed.

Since a wide margin of safety has been demonstrated in two poultry species covering both growth and reproduction, this conclusion can be extended to all avian species when given diets containing FUMzyme containing a maximum of 300 U/kg complete feed without a need for further studies.

3.3.3. Safety for the consumer

Toxicological studies, including tests for genotoxicity and a subchronic oral toxicity study, were assessed in the context of the previous application for the use of FUMzyme with pigs. No concerns

[9] Technical dossier/Supplementary Information March 2016/Section III/Annex (ii) 07-11.
[10] Technical dossier/Supplementary Information March 2016/Section III/Annex (ii) 01-06.

about the toxicity of the enzyme or any residual material carried over from its production were identified. Similarly, the metabolites resulting from the complete or partial de-esterification of fumonisins were also assessed for safety and found to be less toxic than the parent mycotoxin. Since the action of FUMzyme on any contaminating fumonisins will be essentially the same in the pig and avian digestive tracts, the conclusion on safety for the consumer following the use of the additive with pigs also applies to its use with avian species.

3.4. Efficacy

3.4.1. Enzyme specificity

A number of *in vitro* studies made with fumonisin B1 considered in the previous opinion (EFSA FEEDAP Panel, 2014) showed that the action of FUMzyme resulted in partial or complete de-esterification, releasing tricarballylic acid (TCA) and the fully or partially de-esterified aminopentol backbone. Although fumonisin B1 and B2 are the most prevalent fumonisins, a total of eight are recognised (Soriano and Dragacci, 2004). These differ by the number and position of hydroxyl groups on the aminopentol backbone. However, since all fumonisins possess tricarballylic substituents on carbons 6 and 7 and since the presence of the hydroxyls are insufficiently bulky to affect enzyme binding or catalytic activity, FUMzyme is considered equally effective in its action against all recognised fumonisins.

3.4.2. Efficacy in poultry

A total of five short-term (14 days) *in vivo* studies made with chickens, turkeys for fattening or laying hens were provided in support of the efficacy of FUMzyme® in poultry.

Each study consisted of a group of birds given a basal diet essentially free of fumonisin, a group given feed artificially contaminated with fumonisin B1 and a third group given the contaminated feed supplemented with FUMzyme. Artificial contamination resulted in concentrations of fumonisin of 10–20 mg/kg feed, at or below the maximum level given by Commission Recommendation 2006/576/EC (20 mg/kg complete feed for poultry).

In all five studies, the concentration of fumonisin B1 (FB1) and its metabolites (hydrolysed fumonisin B1 (HFB1) and partially hydrolysed fumonisin B1 (pHFB1)) were analysed in excreta. Additionally, in two of the chicken studies (studies 1 and 2), FB1 and its metabolites were monitored at various points in the digestive tract. Excreta and digesta samples were taken on the last day of the trial. In the second study with chicken and in the study with turkeys, the ratio of sphinganine/sphingosine (Sa/So) in plasma and/or liver was also monitored.

Studies 1[11] and 2[12] were done at the same location with a similar design. The first involved 96 and the second 108 one-day-old male Ross 708 chicks; both given 7 days acclimatisation before the start of the trial. In study 1, each treatment was replicated eight times with four birds per replicate, and in study 2, six replicates of six birds were used. FUMzyme was applied at 250 U/kg feed in study 1 and 75 U/kg in study 2. Concentration of FB1 and its metabolites in excreta and the digestive tract were analysed by ANOVA after a normal distribution was confirmed followed by a post-hoc Tukey's test.

The third study[13] involving chickens for fattening used 75 mixed-sex 1-day-old Ross 308 birds, 10 days of age at the start of the trial. There were five replicates of five birds per treatment. FUMzyme was applied at the minimum recommended dose of 15 U/kg feed. Comparisons of values for analysed parameters were made using a Student's t-test or Mann–Whitney test depending on the normality of distribution.

Study 4[14] was made with 15 individually housed female turkeys (Hybrid Converter), 10-week-old at the start of the study. Five birds were allocated to each treatment and FUMzyme was applied to feed at the minimum recommended dose of 15 U/kg feed. In this study, in addition to the concentration of fumonisin B1 and its metabolites in excreta and the digestive tract, the analyses of Sa/So in serum was done by ANOVA preceded by Kolmogorov–Smirnov test for normal distribution and Levene's test for homogeneity of variances. ANOVA was followed up with post-hoc Bonferroni test. When

[11] Technical dossier/Section IV/Annex IV_03-08.
[12] Technical dossier/Section IV/Annex IV_09-16.
[13] Technical dossier/Section IV/Annex IV_28-38.
[14] Technical dossier/Section IV/Annex IV_17-27.

comparisons of only two groups were carried out, Student's t-test (normally distributed) or Mann–Whitney test (not normally distributed) were used.

The fifth study[15] was made with 120 laying hens (Lohmann Brown), 22 weeks of age at the start of the study. There were 10 replicates of four birds per pen allocated to each treatment and faeces were collected at the start and on days 7 and 14. FUMzyme was added at the minimum recommended dose of 15 U/kg feed. FB1 (day 7 and day 14) and pHFB1a (day 7) were compared by Kruskal–Wallis test (all groups), followed by pairwise comparison, for the rest of the parameters the contaminated diet was compared to the contaminated diet plus FUMzyme by Student's t-Test.

Results of the analysis of FB1 and its degradation products in faecal samples collected at the end of each study are shown in Table 1.

Table 1: Average concentration of fumonisin B1 (FB1) and its degradation products (HFB1: hydrolysed fumonisin B1; pHFB1a and b: partially hydrolysed fumonisin B1) in faeces of poultry (μg/g faeces) after 14 days

Study No, animal (dose)	Parameters	Treatment group			p value
		Uncontaminated diet	Contaminated diet (x)	Contaminated diet + Fumzyme (y)	x vs y
Study 1 chickens (250 U/kg)	FB1	0.35	4.27	1.32	< 0.001
	pHFB1a	0.06	0.06	0.06	–
	pHFB1b	0.05	0.13	0.67	0.003
	HFB1	0.05	0.09	0.49	0.007
Study 2 chickens (75 U/kg)	FB1	0.19	5.75	2.23	< 0.001
	pHFB1a	0.08	0.10	0.29	0.006
	pHFB1b	0.08	0.12	1.32	< 0.001
	HFB1	0.05	0.05	1.24	0.002
Study 3 chickens (15 U/kg)	FB1	0.20	4.87	2.34	0.001
	pHFB1a	0.05	0.17	0.20	ns
	pHFB1b	0.05	0.20	1.13	0.008
	HFB1	0.05	0.05	1.29	0.008
Study 4 turkeys (15 U/kg)	FB1	0.20	5.24	1.19	0.002
	pHFB1a	0.02	0.02	0.02	–
	pHFB1b	0.02	0.02	0.41	0.054
	HFB1	0.06	0.06	1.65	0.005
Study 5 hens (15 U/kg)	FB1	0.11	8.05	3.45	ns
	pHFB1a	0.01	1.19	0.75	ns
	pHFB1b	0.01	2.35	1.89	ns
	HFB1	0.02	0.57	4.44	< 0.001

—: Values < limit of detection (LOD), statistics no calculated.

The results of all five studies show a common pattern in which > 50% of fumonisin B1 seen in the faeces of birds given the contaminated diet is degraded to the partially or fully de-esterified hydrocarbon backbone. The results also suggest that the hydrolysis of the TCA linked to carbon 6 is favoured over that linked to carbon 7. In studies 1 and 2, where samples were also taken from the gizzard, upper small intestine (duodenum/mid-jejunum) and lower small intestine (mid-jejunum/ileum), the pattern of degradation was also the same and the differences between the contaminated feed with and without FUMzyme addition significant. The relatively high values seen for the partially hydrolysed fumonisin seen in laying hens given the contaminated feed implies some natural capacity for degradation.

The ratio of sphinganine/sphingosine (Sa/So) is the most sensitive endpoint for fumonisin toxicosis. Two of the four studies (study 2 in chickens for fattening and study 4 in turkeys for fattening) included this biomarker. In study 2, both the liver and serum taken at the end of the trial were analysed, while in study 4, only serum samples were taken. The Sa/So ratios found in the two studies are shown in Table 2.

[15] Technical dossier/Supplementary Information March 2016/Annex (iii) 01-11.

Table 2: Sphinganine/sphingosine (Sa/So) ratio in serum and liver samples

Study No and animal	Tissue	Sa/So ratio			P value
		Uncontaminated diet	Contaminated diet (x)	Contaminated diet + Fumzyme (y)	x vs y
Study 2 chickens	Serum	0.11	0.20	0.16	0.003
	Liver	0.11	0.28	0.18	0.037
Study 4 turkeys	Serum	0.16	0.24	0.19	0.016

As it can be seen, in both studies, poultry receiving the contaminated feed had a significantly higher Sa/So ratio compared to birds given the feed free from fumonisins. Addition of FUMzyme® to contaminated feed significantly reduced the Sa/So values, but not to the level seen in the uncontaminated control.

3.4.3. Conclusions on efficacy for the target species

FUMzyme® has the capacity to degrade fumonisins in feed. This was shown at fumonisins concentrations in feed below the Guidance limits operating in the EU in chickens and turkeys for fattening and laying hens at the minimum recommended dose of 15 U/kg complete feed. This conclusion can be extrapolated to all avian species without the need for further studies.

4. Conclusions

The use of the additive in feed for pigs has been previously assessed and safety for consumers, users and the environment established. Extension of use to all avian species is not expected to alter these conclusions.

FUMzyme is safe for chickens, turkeys and laying hens at the maximum recommended dose of 300 U/kg complete feed. Since a wide margin of safety has been demonstrated in two poultry species covering both growth and reproduction, this conclusion can be extended to all avian species when fed diets containing FUMzyme containing a maximum of 300 U/kg complete feed.

FUMzyme® has the capacity to degrade fumonisins in feed. This was shown at fumonisins concentrations in feed below the Guidance limits operating in the EU in chickens and turkeys for fattening and laying hens at the minimum recommended dose of 15 U/kg complete feed. This conclusion can be extrapolated to all avian species.

Documentation provided to EFSA

1) FUMzyme® (fumonisin esterase). December 2014. Submitted by Biomin GmbH.
2) FUMzyme® (fumonisin esterase). Supplementary information March 2016. Submitted by Biomin GmbH.
3) Comments from the Member States.

References

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Abbreviations

ANOVA analysis of variance
EURL European Union Reference Laboratory
FEEDAP EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed

GMM	Genetically modified microorganism
LOD	limit of detection
Sa	sphinganine
So	sphingosine
TCA	tricarballylic acid
U	units of enzyme activity