

SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* LMG S-15136 (Belfeed B MP/ML) for gestating sows (Puratos NV)

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The declarations of interest of all scientific experts active in EFSA's work are available at <https://open.efsa.europa.eu/experts>

Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Belfeed B MP/ML as a feed additive for gestating sows when used at 10 IU/kg feed. The additive contains endo-1,4-b-xylanase produced by a genetically modified strain of *Bacillus subtilis* (LMG S-15136). The FEEDAP Panel concluded that the additive is safe for the target species at the proposed use level and that there are no concerns regarding the use of Belfeed B MP/ML for the consumers and for the environment. The two formulations of the additive were considered skin and eye irritants and respiratory sensitizers. The Panel concluded that the additive has the potential to be efficacious as a zootechnical additive in sows during the gestation period at 10 IU/kg feed.

KEY WORDS

digestibility enhancers, efficacy, safety, sows, xylanase, zootechnical additives

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003¹ 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 feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Puratos NV² for the authorisation of the additive consisting of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* LMG S-15136 (Belfeed B), when used as a feed additive for gestating sows (category: zootechnical additives; functional group: digestibility enhancers).

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). The dossier was received on 18 April 2024 and the general information and supporting documentation are available at <https://open.efsa.europa.eu/questions/EFSA-Q-2024-00263>. The particulars and documents in support of the application were considered valid by EFSA as of 24 July 2024.

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 feed additive consisting of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* LMG S-15136 (Belfeed B), when used under the proposed conditions of use (see Section 3.1.4).

1.2 | Additional information

The additive is a preparation containing endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* LMG S-15136. The additive is currently authorised for use in feed for lactating sows and minor porcine species other than reproductive animals, weaned and suckling piglets, pigs for fattening and poultry (4a1606i).³ EFSA issued three opinion(s) on the safety and efficacy of this product (EFSA FEEDAP Panel, 2016, 2019, 2021).

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁴ in support of the authorisation request for the use of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *B. subtilis* LMG S-15136 (Belfeed B) as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002⁵ and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,⁶ a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 21 March to 11 April 2025 for which no comments were received. The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 26 July 2024 to 26 October 2024; the comments received were considered for the assessment.

¹Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

²Puratos NV; Industrialaan 25 - Zone Maalbeek 1702 Groot-Bijgaarden – Belgium.

³COMMISSION IMPLEMENTING REGULATION (EU) 2017/211 of 7 February 2017 concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* (LMG-S 15136) as a feed additive for poultry, weaned piglets and pigs for fattening, and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 322/2009 and repealing Regulation (EC) No 516/2007 (holder of authorisation Beldem, a division of Puratos NV); COMMISSION IMPLEMENTING REGULATION (EU) 2020/1377 of 1 October 2020 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) as a feed additive for suckling piglets, all minor porcine species other than reproductive animals (holder of authorisation Beldem, a division of Puratos NV) and COMMISSION IMPLEMENTING REGULATION (EU) 2021/1413 of 27 August 2021 concerning the authorisation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG-S 15136 as a feed additive for lactating sows (holder of the authorisation Beldem, division of Puratos NV).

⁴Dossier reference: FEED-2022-7531.

⁵Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

⁶Decision available at: <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>.

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, peer-reviewed scientific papers, other scientific reports and experts' (elicitation) knowledge, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the enzyme activity in animal feed are valid and applicable for the current application.⁷

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of preparation containing endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* LMG S-15136 (Belfeed B MP/ML) is in line with the principles laid down in Regulation (EC) No 429/2008⁸ and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024), EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2024).

3 | ASSESSMENT

The product Belfeed B MP/ML is a feed additive that contains an endo-1,4-β-xylanase (EC 3.2.1.8; xylanase) produced by fermentation with *B. subtilis* LMG S-15136 and is intended to be used in gestating sows as a zootechnical additive (functional group: digestibility enhancers). The additive was characterised in previous opinions (EFSA FEEDAP Panel, 2016, 2019, 2021). The applicant provided new information on the characterisation, which is described below.

3.1 | Characterisation

3.1.1 | Characterisation of the production organism

The xylanase present in the additive is produced with a genetically modified strain of *B. subtilis* deposited at the Belgian Coordinated Collections of Microorganisms with accession number LMG S-15136.⁹

The taxonomic identification of the production strain LMG S-15136 was confirmed by average nucleotide identity (ANI) analysis of the whole genome sequence (WGS) data of the production strain, which showed an ANI value of 99.95% when compared with the well-known *B. subtilis* 168.¹⁰

The antimicrobial susceptibility of the production strain was tested using a broth microdilution method against the battery of antibiotics recommended by the EFSA (EFSA FEEDAP Panel, 2018).¹¹ All the minimum inhibitory concentration (MIC) values fell below the corresponding cut-off values, except for [REDACTED]. Therefore, the strain is considered susceptible to all relevant antibiotics [REDACTED].

The WGS data of the production strain were interrogated for the presence of acquired antimicrobial resistance (AMR) genes by a search against CARD, Resfinder and NCBI databases.¹² A total of 12 hits exceeding the threshold recommended by EFSA (EFSA, 2024) were found. Further analysis of these hits following EFSA's criteria (EFSA BIOHAZ Panel, 2023) did not reveal any acquired AMR genes. Therefore, the FEEDAP Panel concludes that the strain harbours no acquired AMR genes and raises no safety concerns. Although the strain was shown to be resistant to [REDACTED], since no acquired AMR genes were found in the WGS, the resistance to [REDACTED] does not raise safety concerns.

The WGS data were also interrogated for the presence of known toxins and virulence factors genes against the UniProt database.¹³ No genes of concern were identified.

⁷Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en (The EURL-FA Evaluation Report issued on 03-11-2016 related to the dossier FAD-2010-0285 is considered valid and applicable for the current application).

⁸Commission 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.

⁹Annex 2.2.1 Certificate of deposition.

¹⁰Annex 2.2.6 - WGS analysis report_new.

¹¹Annex 2.2.6A Antimicrobial susceptibility New Study.

¹²Annex 2.2.6 - WGS analysis report_new.

¹³Annex 2.2.6 - WGS analysis report_new.

The capacity of the production strain to produce antimicrobials was investigated in three batches of an intermediate enzyme concentrate.²³ The strains tested were *Staphylococcus aureus* ATCC 6538, *E. coli* ATCC 11229, *Bacillus cereus* ATCC 2, *Nallia circulans* ATCC 4516, *Streptococcus pyogenes* ATCC 12344 and *Serratia marcescens* ATCC 14041. No antimicrobial activity was detected.

The presence of viable cells of the production strain was investigated in three batches of an intermediate liquid concentrate (after sterile filtration), used to obtain the final formulations, in triplicate.²⁴ For each sample, 1 mL of the product was analysed by spreading 2 × 0.5 mL sample on non-selective agar plates. The plates were incubated for 3 days at 37°C. A positive control was included. No viable cells of the production strain were detected.

The presence of DNA of the production strain was investigated in the same three batches, in triplicate.²⁵ The starting material was 1 mL. [REDACTED]. The DNA extraction method included a lysis step. Positive and negative controls were used. The limit of detection (LOD) of samples spiked with genomic DNA of the production strain was 10 ng/mL. No DNA of the production strain was detected.

TABLE 1 The data presented are average values and (range) for batch-to-batch variation of the enzyme activities and ranges for all other parameters [#batches analysed].

	Belfeed B MP (solid)	Belfeed B ML (liquid)
Specifications		
Xylanase (IU/g)	400	400
Batch-to-batch variation	[5]	[5]
Xylanase (IU/g)	413 (405–417)	409 (402–422)
Impurities	[3]	[3]
Lead (mg/kg)	<0.05	<0.05
Mercury (mg/kg)	<0.005	<0.005
Cadmium (mg/kg)	0.02–0.02	<0.05
Arsenic (mg/kg)	<0.1	<0.1
Mycotoxins (µg/kg)	<0.1	<0.1
Aflatoxin B1, B2, G1 and G2 (individual)	<0.1	<0.1
Zearalenone	10	10
Ochratoxin A	<0.2	<0.2
Deoxynivalenol	20	20
Microbial contamination	[3]	[3]
<i>Salmonella</i> spp. (per 25 g)	Not detected	Not detected
<i>Escherichia coli</i> (per 25 g)	Not detected	Not detected
<i>Enterobacteriaceae</i> (CFU/g)	<10–120	<10
Yeast (CFU/g)	<100	<100
Moulds (CFU/g)	<100–700	<100
Total coliforms (CFU/g)	60–160	<100
<i>Bacillus cereus</i> (CFU/g)	160–790	<10
Physical properties		
Bulk/Tapped density (kg/m ³)	691/799 [1]	–
Density (kg/m ³)	–	1044 [1]
Viscosity (cP)	–	43.4–45.0 [3]
Dusting potential (Stauber Heubach) (mg/m ³)	575–628 [3]	–
Particle size distribution (laser diffraction) (% of particles below, v/v)		
100 µm	0	–
50 µm	5.1	–
10 µm	79.3 [3]	–

Abbreviations: CFU, colony forming units; DM, dry matter; IU, One international unit is defined as the amount of enzyme which liberates one micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4.5 and 30°C.

[†]Means below the limit of quantification.

[‡]Not analysed.

²³Annex 2.1.8 Analytical reports impurities and Annex 2.1.15 Method of analysis - Antimicrobial activity JECFA.

²⁴Annex 2.1.12 Absence of viable cells of the production organism_v2 and Annex_2.1.14_COAs_Analyses_rDNA_and_viable_cells.

²⁵Annex 2.1.13 Absence of rDNA_v2.

3.1.4 | Conditions of use

The additive is intended for use in feed for gestating sows at a proposed minimum use level of 10 IU per kg complete feed.

3.2 | Safety

3.2.1 | Safety of the production strain

The production strain *B. subtilis* LMG S-15136 is a genetically modified strain developed to increase the production of xylanase. It belongs to a species, *B. subtilis*, which qualifies for the qualified presumption of safety (QPS) approach to safety assessment (EFSA BIOHAZ Panel, 2023). The taxonomic identification of the production strain was unequivocally established, it does not carry acquired AMR genes, and the lack of toxigenic potential was confirmed. The assessment of the genetic modification of the production strain LMG S-15136 was performed in previous evaluations (EFSA FEEDAP Panel, 2016), and the Panel concluded that the genetic modification does not raise any safety concern. The WGS data submitted in the current application confirmed that the production strain has not been subject to any further genetic modification, and no new information has been made available that would lead the Panel to reconsider its previous conclusion. Moreover, no viable cells nor DNA of the production strain were detected in an intermediate enzyme concentrate, representing the additive. Therefore, the FEEDAP Panel concludes that the additive does not pose any safety concern for the target species, consumers, users and the environment regarding the genetically modified production strain.

3.2.2 | Safety for the target species, consumers and environment

In a previous opinion, the Panel already concluded that the additive is safe for porcine species at any developmental stage (including sows and minor reproductive porcine species), the consumers and the environment (EFSA FEEDAP Panel, 2019). There is no new information that would lead the Panel to reconsider the previous conclusion. Therefore, the Panel reiterates its previous conclusion that the additive under the proposed conditions of use is safe for gestating sows, the consumers and the environment.

3.2.3 | Safety for the user

The safety aspects regarding the use of this additive in feed have been previously assessed (EFSA FEEDAP Panel, 2016, 2019, 2021). The Panel concluded that the intermediate fermentation product of the additive is not an irritant for the skin or eyes, but it should be considered a potential respiratory sensitiser. However, owing to the lack of data, the Panel could not conclude on the potential of the additive as a dermal sensitiser.

The Panel notes that the studies previously assessed for skin and eye irritancy potential of the additive were performed with the intermediate fermentation concentrate and not with the final formulations. In the current application, the applicant included a material safety data sheet (SDS) with toxicological information about the final formulations.²⁶ Based on the information present in the SDS, both forms of the additive are irritant to the skin and eyes.

3.2.3.1 | Conclusions on safety for the user

Both forms of the additive are skin and eye irritants, and respiratory sensitisers. Any exposure is considered a risk.

3.3 | Efficacy

The applicant submitted four short-term trials²⁷ aiming at demonstrating the effect of the additive on the dry matter and energy digestibility of gestating sows.

In all trials, sows were balanced by parity and body condition, and randomly distributed to two groups receiving the same basal diet, either not supplemented (control) or supplemented with Belfeed B MP (solid) at 10 IU/kg complete feed (confirmed by analysis; see Tables 2 and 3). In trials 2–4, sows entered the trial in two consecutive batches. During the gestation period, sows were housed in groups and fed individually. One week before farrowing, sows were moved to individual crates in which they remained until weaning (end of the experiment). The experimental feeds included an external marker and were offered following a restricted regime based on the physiological status of the animals.

²⁶Annex 2.3.3 TDS MSDS COA Label.

²⁷Annex 4.3.1–4.3.2 Efficacy trial 1; Annex 4.3.3–4.3.5 Efficacy trial 2; Annex 4.3.6–4.3.10 Efficacy trial 3; Annex 4.3.11–4.3.13 Efficacy trial 4.

TABLE 2 Trial design and use level of the efficacy trials performed in gestating sows.

Trial	Total N (animals/replicate) Replicates/ group	Breed (Parity)	Duration (Adaptation/Collection)	Composition feed (form)	Groups (IU/kg complete feed)	
					Intended	Analysed* (Gestation/Lactation)
1	24 (1) 12	Landrace (1–7)	Day 84 to 102 of gestation (14/4)	Wheat, barley, maize and sunflower meal (mash)	0 10	0.98/– 11.2/–
2	36 (1) 18	Landrace × Large White (1–8)	Day 86 to 104 of gestation (14/4)	Barley, wheat, sunflower and soybean meal (pellet)	0 10	0.3/0.1 10.3/9.9
3	36 (1) 18	Landrace × Large White (1–6)	Day 86 to 104 of gestation (14/4)	Barley, wheat, sunflower and soybean meal (pellet)	0 10	0.4/0.0 10.2/8.8
4	38 (1) 19	Landrace × Large White (2–8)	Day 86 to 104 of gestation (14/4)	Barley, wheat, sunflower and soybean meal (pellet)	0 10	0.0/0.3 10.0/9.9

*In trial 1, the additive was only supplemented during the gestation phase; in trials 2–4, both gestation and lactation diets were supplemented with the additive.

The sows' and litter's health status and mortality were checked daily. The animals were allowed to adapt to the experimental diets supplemented with the additive for 2 weeks (from days 84/86 to 98/100 of gestation), and the faeces were collected during the following 4 days and pooled per sow. Thereafter, in trial 1, all sows received the same basal diet; in trials 2, 3 and 4, the experimental diets were offered to the sows until the weaning of the litters. In all trials, the sows' and litters' performance was monitored until the weaning of the piglets. Feed and faecal samples were analysed for dry matter, external marker and gross energy to calculate the apparent total tract digestibility of the dry matter and energy. The experimental data were analysed with a generalised linear model, including the diet as a fixed effect. The individual sow was considered the experimental unit. The significance level was set at 0.05.

TABLE 3 Effects of Belfeed B on the gross energy digestibility of gestating sows.

Trial	Groups (IU/kg feed)	Dry matter digestibility (%)	Gross energy digestibility (%)	Digestible energy content (kcal/kg)
1	0	73.0 ^b	77.3 ^b	3528 ^b
	10	75.3 ^a	79.3 ^a	3620 ^a
2	0	73.0	73.3 ^b	2862 ^b
	10	74.6	75.2 ^a	2934 ^a
3	0	77.6 ^b	80.1 ^b	3141 ^b
	10	80.2 ^a	81.9 ^a	3230 ^a
4	0	76.8	77.2	3053
	10	76.3	76.6	3031

^{a,b}Mean values within a trial and within a column with a different superscript are significantly different $p < 0.05$.

No sow died during the trials. In trials 1, 2 and 3, the supplementation of the additive in the feed of sows resulted in a significantly higher gross energy digestibility and calculated digestible energy content of the diets compared to the control. Trials 1 and 3 also showed higher dry matter digestibility. No differences were observed in trial 4. No differences were observed in any zootechnical parameter measured.

The additive has the potential to be efficacious in gestating sows when added to feed at 10 U/kg feed.

3.4 | Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation²⁸ and Good Manufacturing Practice.

4 | CONCLUSIONS

The additive is safe for gestating sows at the proposed conditions of use.

²⁸Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

The use of Belfeed B ML/MP in the feed of gestating sows under the conditions of use proposed is of no concern for consumer safety and no risks for the environment are expected.

The two formulations of the additive are considered skin and eye irritants, and respiratory sensitisers.

The Panel concludes that the additive has the potential to be efficacious as a zootechnical additive in sows during the gestation period at 10 IU/kg feed.

ABBREVIATIONS

AMR	antimicrobial resistance
ANI	average nucleotide identity
BIOHAZ	EFSA Panel on Biological Hazards
BW	body weight
CFU	colony forming unit
CV	coefficient of variation
DM	dry matter
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
IU	International unit
LOD	limit of detection
LOQ	limit of quantification
MIC	minimum inhibitory concentration
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
ORF	open reading frames
QPS	qualified presumption of safety
SDS	safety data sheet
WGS	whole genome sequence

REQUESTOR

European Commission

QUESTION NUMBER

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