REGULATED PRODUCTS SAFETY ASSESSMENT

Safety Assessment on the Safety and Efficacy of a Feed Additive Containing Endo-1,4-Beta-Xylanase Produced by *Aspergillus Niger* CBS 109.713, and Endo-1,4-Beta-Glucanase Produced by *Aspergillus Niger* DSM 18404 for Its Use in All Pigs (RP1880)

Food Standards Agency[1], Food Standards Scotland[2]

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FSA Research and Evidence

An application was submitted to the Food Standards Agency and Food Standards Scotland in January 2023 from BASF SE ('the applicant') for an extension of use of an additive containing endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713, and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404, under the category of 'zootechnical additives' and functional group 'digestibility enhancers'. The additive is proposed to be used at a minimum inclusion rate of 560 TXU/kg and 250 TGU/kg of complete feed (12% moisture) for all pigs.

Under assimilated Regulations (EU) No 1404/2013, 2020/1371, 271/2009 and 1068/2011, the additive is currently authorised in GB for its use for pigs for fattening (EU 2013), lactating sows (EU 2020), weaned piglets; chickens for fattening; laying hens; turkeys for fattening; ducks for fattening (EC 2009) and chickens reared for laying, turkeys for breeding purposes, turkeys reared for breeding, other minor avian species (other than ducks for fattening) and ornamental birds (EU 2011). This application requested an extension of use in feed for all pigs.

The FSA/FSS carried out an assessment of the dossier, taking previous evaluations into consideration, and concluded that the additive was correctly identified and characterised as there were no changes from the previous assessment. No significant concerns were raised for the identity, characterisation and condition of use section of the dossier.

FSA/FSS concluded the additive is safe for consumers, the environment and the target species up to the maximum inclusion level of 840 TXU/kg xylanase and 375 TGU/kg glucanase of complete feed. Both formulations of the additive are considered to be non-irritant to the skin and eyes but should be considered respiratory sensitisers and potential skin sensitisers.

FSA/FSS concluded the additive is efficacious in weaned piglets and has the potential to be efficacious in pigs for fattening and lactating sows. This demonstrates that the additive favourably affects animal production by affecting the digestibility of feedingstuffs. No conclusion could be drawn on the efficacy of the additive in gestating sows.

This safety assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication.

1. Introduction

The FSA and FSS have undertaken an assessment for a feed additive containing endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713, and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 (Natugrain®, BASF SE, 67056, Ludwigshafen, Deutschland), under assimilated Regulation (EC) No 1831/2003 (EC, 2003) in the category of 'zootechnical additives' and functional group 'digestibility enhancers' for its extension of use to all pigs (from pigs for fattening, weaned piglets and lactating sows).

In line with Article 8 of Assimilated Regulation No 1831/2003, the assessment has considered and concluded that the feed additive complies with the conditions laid down in Article 5, including: safety considerations for human, animal and environmental health; efficacy of the additive for its intended effect; potential impairment of the distinctive features of animal products. This, and the FSA/FSS guidance for the evaluation of feed additive applications, has formed the basis and structure for the assessment.

This safety assessment represents the opinion of the FSA and FSS.

Table 1. Table showing products included in this assessment

Title	Product type	Intended use/s	Intended species or categories of animals
Endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404	Feed additive	Zootechnical additive	All pigs

2. Assessment

2.1. Previous assessments and authorisations

Under assimilated Regulations (EU) No 1404/2013, 2020/1371, 271/2009 and 1068/2011, the additive is currently authorised in GB for its use for pigs for fattening (EU, 2013), lactating sows (EU, 2020), weaned piglets; chickens for fattening; laying hens; turkeys for fattening; ducks for fattening (EC, 2009) chickens reared for laying, turkeys for breeding purposes, turkeys reared for breeding, other minor avian species (other than ducks for fattening) and ornamental birds (EU, 2011).

In addition, the additive is authorised in the EU under the equivalent Commission Implementing Regulations 1404/2013 for pigs for fattening and 2020/1371 lactating sows, and under Commission Implementing Regulation (EU) No 2021/981 for all poultry, ornamental birds and weaned piglets. This application requested an extension of use for all pigs.

The European Food Safety Authority (EFSA) published several opinions reviewing the safety and efficacy of the additive for pigs for fattening (EFSA, 2013), lactating sows (EFSA, 2020b) and weaned piglets (EFSA, 2008; 2020a). The additive was found to be safe for the target species, consumers, workers and the environment. Efficacy was demonstrated for pigs for fattening, weaned piglets and lactating sows. These conclusions were published at the time when GB was still part of the EU.

2.2. Section II: Identity, characterisation and conditions of use

The additive is an enzyme preparation containing endo-1,4-beta-xylanase produced by genetically modified *A. niger* CBS 109.713, and endo-1,4-beta-glucanase produced by genetically modified *A. niger* DSM 18404, from this point on referred to as 'Natugrain'. The additive is proposed to be authorised both as:

- Dry formulation (Natugrain TS): a yellowish-brown powder meant for inclusion in premixture and compound feed with a minimum activity of 5,600 TXU (xylanase activity units) and 2,500 TGU (glucanase activity units) per gram of product.
- Liquid formulation (Natugrain TS L): a liquid product meant for direct inclusion in compound feed, via post-pelleting application, with a minimum activity of 5,600 TXU (xylanase activity units) and 2,500 TGU (glucanase activity units) per gram of product.

The taxonomic identity of the production strains *A. niger* CBS 109.713 and *A. niger* DSM 18404 was confirmed by an updated sequence analysis submitted by the applicant. The genetic modifications of the production strain do not raise any safety concerns, and both strains have a long history of safe use (EFSA, 2008). The production process and conditions of use have not been modified since the previous authorisation; therefore, the conclusions that the production strain is safe remain relevant to this assessment.

No changes to the formulation from the previous authorisation were proposed. The applicant provided new certificates of analysis from several batches for the composition and impurities of the additive. No new data was provided for the physico-chemical properties of the additive, which are expected to remain the same as those of previous authorisations, given there are no changes to the composition or the production process. Tables 2 and 3 show identification values for the solid and liquid formulations of the product, respectively.

Table 2. Identity table for solid formulation of Natugrain TS

Composition
Xylanase
Glucanase
Other organic solids
Water

Chemical-physical properties	
Appearance	Yellowish-brown powder
Dusting potential	> 100 mg/m^3
Particle size distribution	> 10 µm – 99.5 % < 10 µm - 0.5 % < 1 µm – 0%
Bulk density	0.35 g/cm^3

Impurities	
Arsenic	No safety concerns
Lead	No safety concerns
Cadmium	No safety concerns
Mercury	No safety concerns
E. coli	No safety concerns
Salmonella spp.	No safety concerns
Enterobacteriaceae	No safety concerns
Yeasts and filamentous fungi	No safety concerns
Aflatoxin B1	No safety concerns
Deoxynivalenol	No safety concerns
Zearalenone	No safety concerns
Ochratoxin A	No safety concerns
Sum of Fumonisin B1/B2	No safety concerns

Table 3. Identity table for liquid formulation of Natugrain TS L

Composition
Xylanase
Glucanase
Other organic solids
Water

Appearance
Light brown to brown liquid

Chemical-physical properties	
Density	1.4 g/ml
Viscosity at 25^{o}C	7 mPa.s

Impurities	
Arsenic	No safety concerns
Lead	No safety concerns
Cadmium	No safety concerns
Mercury	No safety concerns
E. coli	No safety concerns
Salmonella spp.	No safety concerns
Enterobacteriaceae	No safety concerns
Yeasts and filamentous fungi	No safety concerns
Aflatoxin B1	No safety concerns
Deoxynivalenol	No safety concerns
Zearalenone	No safety concerns
Ochratoxin A	No safety concerns
Sum of Fumonisin B1/B2	No safety concerns

FSA/FSS reviewed the new data and noted enzymatic activity varied from batch to batch, showing an overage compared to the minimum activities of 5,600 TXU and 2,500 TGU that were specified by the applicant. This is expected and no concern was raised.

Analysis of three production batches of the additive showed the production microorganisms and recombinant DNA were absent. No gene coding for antibiotic production has been added in the construction of the production strains *A. niger* CBS 109.713 and *A. niger* DSM 18404 according to the applicant. The applicant confirmed that no antibiotic is intentionally added along the manufacturing process of the enzyme.

For both formulations, the levels of heavy metals, microbial contaminants and mycotoxins tested in three batches were below the limit of detection.

The applicant presented data on the shelf life of the additive tested for the solid form for 18 months at three different temperature points (6^{o}C, 20^{o}C, and 35^{o}C) and for the liquid form for 24 months at two different temperature points (20^{o}C and 30^{o}C). Both enzymes showed good retention values in the solid form at 6^{o}C and 20^{o}C and in the liquid form at 20^{o}C and 30^{o}C. The proposed shelf life for both products is therefore 18 months at 20^{o}C for the solid formulation and 24 months at 20^{o}C for the liquid formulation.

In feed, the additive showed good stability in mash and pelleted feed (mixed or sprayed after pelleting) at 20^{o}C for up to 16 weeks. Data from several batches also showed stability in premixtures for up to 12 weeks when stored at 20^{o}C. In water, the additive was shown to be stable. Stability during the pelleting process was tested in three batches for temperatures of 75^{o}C, 80^{o}C and 85^{o}C for 5 seconds. It is recommended to take the short time of exposure into consideration, as some of the uses may require longer conditioning times.

The applicant provided certificates of analysis demonstrating the additive's homogeneity in feed and in vitamin-mineral premixes. No homogeneity data in water for the additive's specific formulation under evaluation was provided; therefore FSA/FSS cannot conclude on the homogeneity of Natugrain TS L in water.

Table 4. Conditions of use of Natugrain (solid and liquid) proposed by the applicant

Natugrain TS and Natugrain TS L			
Species or category of animal	Min content in complete feed	Max content in complete feed	Withdrawal period
All pigs (xylanase)	560 TXU/kg	840 TXU/kg	-
All pigs (glucanase)	250 TGU/kg	375 TGU/kg	-

Other provisions and additional labelling considerations	
Specific conditions for use	The dry powder preparation shall be mixed into the feed directly with the other feed materials or after incorporation in a premixture. The liquid preparation is for post-pelleting application, to be sprayed directly onto the compound feed using appropriate spraying equipment. It is possible to dilute it with water to meet the required dose.
Stability	The additive was shown to be stable at 20^{O}C but not at 35^{O}C. Stability during pelleting could not be evaluated for more than 85^{O}C or for more than 5 seconds.

The FSA/FSS evaluated the proposed conditions of use by the applicant in the context of extrapolation of previous conclusions to all pigs. As described in the efficacy section of this safety assessment, no conclusion could be reached regarding the efficacy of the additive in gestating sows.

2.2.1. Conclusions on Section II: Identity, characterisation and conditions of use

The FSA/FSS concluded that the additive was fully identified and characterised. No changes to the formulation from the previous authorisation were proposed, and the submitted information did not raise any new concerns. It was concluded that the additive Natugrain did not raise any safety concerns regarding the genetic modification of the production strain. The impurity testing did not raise safety concerns. The production strain and its recombinant DNA were not detected in the additive. It was noted that the pelleting stability for the additive was only tested for 5 seconds, and therefore this should be made clear on the label as some of the uses may require longer conditioning times. No further concerns were raised for the identity, characterisation and conditions of use section of the dossier.

2.3. Section III: Safety

The FSA/FSS evaluated the safety of the additive in the context of authorisation requested by the applicant for an extension to all pigs. The data supporting existing authorisations was reviewed by EFSA (EFSA, 2008; 2013, 2020a, 2020b) prior to the UK's exit from the EU; thus, these conclusions are applicable to GB. These studies formed part of the assessment leading to the current authorisation of the additive in GB. EFSA concluded that the additive is safe for the target species, consumers, workers and the environment.

The applicant referenced these previous conclusions and provided an updated literature review to support the safety of the additive for the target species, consumers, workers and the environment. Upon request, the original studies underpinning the aforementioned EFSA conclusions were provided and reviewed by the FSA/FSS assessors to conclude on the

safety of this application. The following subsections summarise data from the original studies and the updated literature review to draw a conclusion on safety.

2.3.1. Safety for the target species

Safety for piglets was evaluated through a tolerance study in 300 weaned piglets for 6 weeks under veterinary supervision, in line with guidance recommendations. Three groups were fed a control feed, and two test feeds supplemented with the maximum proposed dose of Natugrain of 150 mg/kg (equivalent to 840 TXU/kg and 375 TGU/kg) and 100 times the maximum recommended dose (equivalent to 84,000 TXU/kg and 37,500 TGU/kg). No adverse effects were observed on animal health or performance parameters (weight gain, feed intake, feed conversion ratio) at the highest dose tested (EFSA, 2008).

Safety for pigs for fattening was evaluated through the tolerance study in piglets. Following guidance principles, safety data can be extrapolated between developmental stages within species when there is a similarity in purpose, digestive system and metabolism. As pigs for fattening and piglets are growing Suidae, and given the margin of safety of 100 from the piglet tolerance trial, conclusions from this trial can be extrapolated to determine the additive is safe for pigs for fattening. This is the approach that EFSA also followed in their 2013 opinion (EFSA, 2013).

Safety for sows was evaluated through a tolerance study in lactating sows during the lactation phase. No adverse effects were shown on the sows or the piglets during this phase.

Evidence from the safety for the consumer section of the first evaluation of the additive was also used to support its safety for sows, specifically a sub-chronic oral toxicity study in rats which identified a NOAEL of 200,000 TXU and 90,000 TGU/kg body weight/day. Using default feed intake values set in Guidance on the assessment of the safety of feed additives for the target species (EFSA, 2017) and an uncertainty factor of 100 applied to the NOAEL derived from the sub-chronic toxicity study, the daily maximum safe concentration of the additive for sows was calculated to be 58,000 TXU and 26,000 TGU/kg of feed. This is approximately 70 times the maximum recommended dose (EFSA, 2020b).

The applicant provided an updated literature review as part of the application, which was carried out following guidance principles. Only one relevant study was identified for xylanase (Wang et al., 2020), which did not raise any safety concerns.

The FSA/FSS conclude that, based on the weight of evidence presented through previous tolerance and toxicological studies, as well as previous and updated literature reviews, the additive has been shown to be safe in piglets and lactating sows, which can be extrapolated to all pigs and minor porcine species.

2.3.2. Safety for the consumer

Safety for the consumer has been fully evaluated or reviewed in previous EFSA opinions, which did not identify any safety concerns for consumers (EFSA, 2008; 2020a, 2020b). To support the assessment of safety for consumers, the applicant presented three studies which were also submitted as part of the original application for authorisation:

- Bacterial reverse mutation assay (OECD TG 471)
- *In vivo* mouse micronucleus assay (OECD TG 474)
- 90-day oral toxicity study (OECD TG 408)

The 90-day study was carried out in rats, with Natugrain applied at concentrations of 0, 1,000, 4,000 and 16,000 mg/kg of diet. No adverse effects were reported at the highest dose tested, equivalent to approximately 1200 mg/kg bw/day. The NOAEL of the study, expressed in enzymatic activity, was identified to be 200,000 TXU and 90,000 TGU/kg bw/day, equivalent to 1,200 mg of Natugrain/kg bw/day (EFSA, 2008; 2020b).

No evidence of genotoxicity or chromosome damage was detected in the bacterial reverse mutation and *in vivo* micronucleus assays (EFSA, 2008).

As part of this application, a new *in vitro* mammalian micronucleus test in human peripheral blood lymphocytes was submitted to evaluate the genotoxic potential of the additive. The test was performed following OECD TG 487 and was claimed to be GLP compliant. The additive was tested at concentrations which were based upon the results of a preliminary cytotoxicity assay. The additive did not induce a significant increase in the frequency of binucleated micronucleated cells compared to a vehicle control. Therefore, the FSA/FSS concludes that the test item did not induce structural and numerical chromosome aberrations *in vitro* in human peripheral blood lymphocytes under the experimental conditions employed in this study.

The applicant provided an updated literature review as part of the application, which was carried out following guidance principles. Only one relevant study was identified for xylanase (Wang et al., 2020), which looked at the effect of an acidic thermostable xylanase in the gut microbiota of piglets and its impact in growth performance. This study did not raise any safety concerns.

Considering the lack of findings in the literature review, and the lack of changes to the formulation of the product or its production process, the FSA/FSS conclude that the additive remains safe for the consumer.

2.3.3. Safety for the user/worker

The applicant provided the following studies from the original authorisation to evaluate the safety of the additive for the user/ worker:

- Acute dermal irritation study in rabbit (OECD 404)
- Acute eye irritation study in rabbit (OECD 405)

When these studies were assessed by the EFSA in 2008, it was determined that the additive was shown to not be a skin or eye irritant. No skin sensitisation test was provided. It was therefore concluded that the additive would be considered a potential skin sensitiser (EFSA, 2008).

No new data has been provided by the applicant since the original authorisation; therefore, and in the absence of changes to dosage, composition or conditions of use, previous conclusions apply to this request for authorisation.

The solid formulation of the product showed a low-to-moderate dusting potential and a very low number of particles under the respirable fraction. This poses a low risk of respiratory exposure; however, the proteinaceous nature of the additive means it will be regarded as a potential respiratory sensitiser, requiring protective equipment to handle the additive.

The applicant provided an updated literature review as part of the application, which was carried out following guidance principles. Only one relevant study was identified for xylanase (Wang et al., 2020), which did not raise any safety concerns.

The FSA/FSS concluded that both formulations of the additive are considered to be non-irritant to the skin and eyes. Both formulations should be considered respiratory sensitisers and potential skin sensitisers. The use of protective equipment is recommended to minimise respiratory exposure.

2.3.4. Safety for the environment

Safety for the environment has been assessed in a previous FEEDAP opinion (EFSA, 2008), and ratified by later opinions (EFSA, 2013, 2020a, 2020b) when the UK was an EU member state, and therefore these assessments remain applicable to GB. They concluded there was no environmental risk as the active component is proteins and these are degraded through the digestive tract. The applicant has not provided any new information for the FSA/FSS to reconsider these conclusions. The

FSA/FSS concluded that the proposed extension of use to all pigs does not impact the environmental safety of the additive which have been previously evaluated. The additive, under the proposed conditions of use, is considered safe for the environment.

2.3.5. Conclusions on safety

The FSA/FSS concludes that the use of the additive, under the proposed conditions of use, is safe for consumers and the environment. Both formulations of the additive are considered to be non-irritant to the skin and eyes but should be considered to be respiratory sensitisers and potential skin sensitisers. Based on data from safety for piglets and sows, the proposed extension of use to all pigs did not raise any further safety concerns. The FSA/FSS concluded that the additive is safe for all pigs up to the maximum inclusion level of 840 TXU/kg xylanase and 375 TGU/kg glucanase of complete feed.

2.4. Section IV: Efficacy

The FSA/FSS evaluated the efficacy of the additive in the context of authorisation requested by the applicant for an extension to all pigs. The data was reviewed by EFSA (EFSA, 2008; 2013, 2020a, 2020b) prior to the UK's exit from the EU; thus, these conclusions are applicable to GB. These studies formed part of the assessment leading to the current authorisation of the additive in GB. EFSA concluded that the additive is efficacious in weaned piglets and has the potential to be efficacious in pigs for fattening and lactating sows. No conclusion could be drawn on the efficacy of Natugrain in gestating sows.

The applicant referenced these previous conclusions to support the efficacy of the additive for favourably affecting animal production by affecting the digestibility of feedingstuffs. Upon request, the original studies underpinning the aforementioned EFSA conclusions were provided and reviewed by the FSA/FSS assessors to conclude on the efficacy of this application.

2.4.1. Efficacy in all pigs

As part of the original application, EFSA evaluated three efficacy trials in weaned piglets using the minimum proposed dose of 560 TXU and 250 TGU/kg feed (EFSA, 2008), and concluded that the additive could be considered efficacious for piglets at the minimum recommended dose. These conclusions were extrapolated to pigs for fattening in the EFSA 2013 opinion (EFSA, 2013). In 2020, as part of the evaluation of the additive for its use in feed for sows, the FEEDAP panel evaluated four trials in lactating sows and concluded that the additive had the potential to be efficacious for sows at the lactating phase at the minimum recommended

dose (EFSA, 2020b). These conclusions were not extended to gestating sows. These conclusions were drawn at the time when the UK was part of the EU, and given that no changes are proposed to the composition or conditions of use of the additive, remain relevant for GB in the context of this authorisation.

No new efficacy data has been provided by the applicant as part of this dossier for authorisation, including no new data in gestating sows. The FSA/FSS recognises that gestating sows are a significantly different production stage to lactating sows, and therefore conclusions from lactating sows cannot be extrapolated to gestating sows. Therefore, the FSA/FSS conclude that the additive can be considered to be efficacious in weaned piglets, and to have the potential to be efficacious in pigs for fattening and lactating sows, but not gestating sows. These conclusions can be extrapolated to minor porcine species at the corresponding developmental stage. A summary of these conclusions can be found in Table 5.

Table 5. FSA/FSS conclusions on efficacy of Natugrain for all pigs.

Species/Developmental stage	Efficacy conclusion
Weaned piglets (including minor species)	Efficacious
Pigs for fattening (including minor species)	Potential to be efficacious
Lactating sows (including minor species)	Potential to be efficacious
Gestating sows (including minor species)	Efficacy not demonstrated

2.4.2. Conclusions on efficacy

Based on the three trials provided, the FSA/FSS concluded that Natugrain is efficacious in weaned piglets and has the potential to be efficacious in pigs for fattening and lactating sows. This demonstrates that the additive favourably affects animal production by affecting the digestibility of feedingstuffs. No conclusion could be drawn on the efficacy of Natugrain in gestating sows.

3. Analytical methods evaluation

Conclusions on the analytical methods are presented here as an extract from the Evaluation Report of the European Union Reference Laboratory (EURL) for Feed Additives on the Method(s) of the Analysis for Natugrain TS and Natugrain TS L (EURL, 2011).

> "For the determination of endo-1,4-β-xylanase in the feed additive, premixtures and feedingstuffs, the Applicant proposes a single-laboratory validated viscosimetric method, further verified by an independent laboratory. Endo-1,4-β-xylanase catalyses the hydrolysis of glycosidic bonds in the

substrate standard wheat arabinoxylan to yield xylose and reduces consequently the viscosity. The decrease in viscosity of the substrate enzyme solution, expressed in terms of a drop time, is a measure for the endo-1,4-β-xylanase activity and is determined using a falling ball viscosimeter at pH = 3.5 and 55^{o}C. The quantification is performed using an endo-1,4-β-xylanase standard curve based on reference enzyme provided by the Applicant. The following performance characteristics, determined for the feed additive, premixtures and feedingstuffs were reported:

- a relative standard deviation for repeatability (RSDr) ranging from 2.5 to 9.9 %;

- a relative intermediate precision (RSDip) ranging from 4.2 to 9.9 %;

- a recovery rate (Rrec) ranging from 82 to 115 %; and

- a limit of detection (LOD) and quantification (LOQ) of 11 and 36 TXU/kg feedingstuffs, respectively.

For the determination of endo-1,4-β-glucanase in the feed additive, premixtures and feedingstuffs, the Applicant proposes a single laboratory validated viscosimetric method, further verified by an independent laboratory. Endo-1,4-β-glucanase catalyses the hydrolysis of glycosidic bonds in the substrate standard barley betaglucan to yield glucose and reduces consequently the viscosity. The decrease in viscosity of the substrate enzyme solution, expressed in terms of a drop time, is a measure for the endo-1,4-β-glucanase activity and is determined using a falling ball viscosimeter at pH = 3.5 and 40^{o}C. The quantification is performed using an endo-1,4-β-glucanase standard curve based on reference enzyme provided by the Applicant. The following performance characteristics, determined for the feed additive, premixtures and feedingstuffs, were reported:

- RSDr ranging from 4.1 to 10.4 %;

- RSDip ranging from 7.5 to 12.3 %;

- Rrec from 85 to 115%; and

- LOD and LOQ of 16 and 49 TGU/kg feedingstuffs, respectively.

> Based on the performance characteristics presented, the EURL recommends for official control the two viscosimetric methods submitted by the Applicant for the determination of endo-1,4-β-xylanase and endo-1,4-β-glucanase in the feed additive, premixtures and feedingstuffs, within the concentration range covered by the experimental data."

The FSA/FSS accepts the EURL analytical method evaluation reports. The FSA/FSS determined the analytical methods proposed as appropriate for official controls for this feed additive. The analytical methods were approved in 2011, at the time in which the UK was still an EU member.

4. Conclusions

The additive is presently authorised as a zootechnical (digestibility enhancer) for use in feed for weaned piglets, pigs for fattening, lactating sows and all poultry and ornamental birds. This new application requested an extension of use for all pigs. The manufacturing process and the composition of the additive have not been modified since the previous assessments. The data was reviewed by EFSA in 2008, 2013 and 2020. The opinions were prepared prior to the UK's exit from the EU; thus, these conclusions are applicable to GB. The additional data provided in the current assessment was evaluated by the FSA and FSS in the context of the extension of use to all pigs. The additive was correctly identified and characterised. It was noted that the pelleting stability for the additive was only tested for 5 seconds. The production strains can be considered safe for the production of the enzymes.

The FSA/FSS concluded that the additive is safe for all pigs up to the maximum inclusion level of 840 TXU/kg xylanase and 375 TGU/kg glucanase of complete feed. The FSA/FSS concluded that the additive under the proposed conditions of use is safe for consumers and the environment. Both formulations of the additive are considered to be non-irritant to the skin and eyes but should be considered respiratory sensitisers and potential skin sensitisers. The proposed extension to all pigs requested for this authorisation did not raise any further safety concerns.

Based on the data from previous trials provided, the FSA/FSS concluded that the additive is efficacious in weaned piglets and has the potential to be efficacious in pigs for fattening and lactating sows. This demonstrates that the additive favourably affects animal production by affecting the digestibility of feedingstuffs. No conclusion could be drawn on the efficacy of the additive in gestating sows.

The FSA/FSS accepts the EURL analytical method evaluation reports. The FSA/FSS determined the analytical methods proposed as appropriate for official controls for this feed additive.

This safety assessment represents the opinion of the FSA and FSS.

Abbreviations

Abbreviation	Definition
CFU	Colony forming units
EC	European Commission
EFSA	European Food Safety Authority
EURL	European Union Reference Laboratory
FEEDAP	Scientific Panel on Feed Additives and Products or Substances Used in Animal Feed
FSA	Food Standards Agency
FSS	Food Standards Scotland
LOD	Limit of detection
LOQ	Limit of quantification
Rrec	Recovery rate
RSDip	Relative standard deviation for intermediate precision
RSDr	Relative standard deviation for repeatability
TXU	Xylanase activity units
TGU	Glucanase activity units
NOAEL	No observed adverse effect level
OECD	Organisation for Economic Co-operation and Development

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