SCIENTIFIC OPINION

ADOPTED: 3 December 2015 PUBLISHED: 5 January 2016

doi:10.2903/j.efsa.2016.4350

Safety and efficacy of Axtra® XB 201 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a feed additive for lactating sows and minor porcine species

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

Abstract

Axtra® XB 201 is a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase to be used as a feed additive for lactating sows (major and minor species) and minor porcine species for meat production at the recommended dose of 1,220 U xylanase and 152 U glucanase per kg feed and 610 U xylanase and 76 U glucanase, respectively. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) adopted a scientific opinion on the safety and efficacy of this product as a zootechnical additive for poultry, piglets and pigs for fattening. Since aspects other than the safety and efficacy for the new target species/categories have been addressed previously, the current assessment addressed the safety and efficacy for the new target species only. Based on the results obtained in a tolerance trial in sows, the FEEDAP Panel concluded that the additive is safe for lactating sows at the recommended dose. The safety for piglets was previously established in a trial where piglets tolerated a 60-fold the recommended dose for minor porcine species for meat production. The Panel extrapolated the conclusions on the safety reached in major porcine species to minor porcine species. Seven efficacy trials in sows were submitted. In two short-term trials, the additive improved the apparent faecal digestibility of the dietary gross energy by the sows at the recommended dose. The same dose permitted to reduce the body weight loss of the sow during lactation in two long-term trials. Therefore, the Panel concluded that the additive has the potential to be efficacious in lactating sows at the recommended dose. In the previous opinion, the efficacy in piglets and pigs for fattening was established at the dose recommended for minor porcine species for meat production. The Panel extrapolated the conclusions reached in major porcine species to minor porcine species.

Keywords: Xylanase, glucanase, safety, efficacy, lactating sows, minor porcine species

Requestor: European Commission

Question number: EFSA-Q-2014-00574

Correspondence: feedap@efsa.europa.eu

Panel members: Gabriele Aquilina, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Secundino López Puente, Marta López-Alonso, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

Acknowledgements: The Panel wishes to thank the members of the Working Group on Enzymes: Paul Brantom, Noël Dierick and Ingrid Halle for the preparatory work on this scientific output.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opionion on the safety and efficacy of Axtra® XB 201 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a feed additive for lactating sows and minor porcine species [. EFSA Journal 2016;14(1):4350, 11 pp. doi:10.2903/j.efsa.2016.4350

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) was asked to deliver a scientific opinion on the safety and efficacy of Axtra® XB 201 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a feed additive for sows for reproduction (lactating), minor porcine species for meat production and minor porcine species during lactation.

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted a scientific opinion on the safety and efficacy of the product as a zootechnical additive (functional group of digestibility enhancers) for poultry, piglets and pigs for fattening. That opinion considered the safety aspects of the additive regarding the target species, the consumer, the user, the environment and the genetic modification of one of the production strains as well as its efficacy for the target species. Axtra® XB 201 is now proposed for use in lactating sows (including minor porcine species) at the minimum dose of 1,220 U xylanase and 152 U glucanase per kg feed and in minor porcine species for meat production at the minimum dose of 610 U xylanase and 76 U glucanase per kg feed. The Panel considered that aspects other than the safety and efficacy for the new target species/categories have been addressed in the previous opinion and is not aware of any new information that would lead it to reconsider the previous conclusions. Therefore, the present assessment addressed the safety and efficacy for the new target categories/species only.

A tolerance trial showed that sows tolerated well a 10-fold overdose of the recommended dose and therefore the FEEDAP Panel concluded that the additive is safe for lactating sows at that dose. The safety of the product in piglets was previously established in a trial where piglets tolerated well a 60-fold the dose that is now recommended for minor porcine species for meat production. Based on the margin of safety shown by the product in the trials performed in sows and piglets, the Panel considered that the conclusion can be extrapolated to minor porcine species at the corresponding dose.

Seven efficacy trials were assessed, three short-term trials and four long-term trials. In two short-term trials, the additive improved the apparent faecal digestibility of the dietary gross energy in lactating sows at the recommended dose. The same dose permitted to reduce the body weight loss of the sow during lactation in two long-term trials, without having a negative impact on the litter performance. Consequently, the FEEDAP Panel considered that the additive has the potential to be efficacious at that dose. The efficacy of the product in piglets and pigs for fattening was established previously at the dose that is now recommended for minor porcine species for meat production. Considering that the mode of action of the enzymes is well known and it is assumed to be the same among porcine species the conclusions drawn in the major porcine species were extrapolated to minor porcine species, lactation and fattening phases at the corresponding dose.

Table of contents

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 (EC) received a request from Danisco (UK) Ltd[2] for authorisation of the product Axtra® XB 201, endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase, when used as a feed additive for pigs, sows for reproduction, minor porcine species for meat production and minor porcine species for reproduction[3] (category: zootechnical additive; 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). 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 23 September 2014.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall 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 Axtra® XB 201 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase), when used under the proposed conditions of use (see Section 3).

1.2. Additional information

The additive Axtra® XB 201 is a preparation of endo-1,4-beta-xylanase (xylanase: EC 3.2.1.8) produced by a genetically modified strain of *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase (glucanase: EC 3.2.1.6) produced by a non-genetically modified strain of *Trichoderma reesei* (ATCC SD 2106) available in two forms, solid (TPT) and liquid (L). The additive is authorised for its use in poultry, piglets and pigs for fattening as a zootechnical additive, functional group of digestibility enhancers.

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) adopted a scientific opinion on the safety and efficacy of this product[4] as a feed additive for poultry, piglets and pigs for fattening (EFSA FEEDAP Panel, 2010). That opinion considered the safety aspects of the additive regarding the consumer, the user, the environment and the genetic modification present in one of the production strains. Moreover, the safety and efficacy of the product for poultry, piglets and pigs for fattening was established.

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[5] in support of the authorisation request for the use of Axtra® XB as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003 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.

[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] Danisco (UK) Ltd, PO Box 777, SN8 1XN, Marlborough, Wilshire, UK.
[3] During the assessment the applicant requested to modify the target species as follows, sows for reproduction (lactating sows), minor porcine species for meat production and for reproduction (lactating sows).
[4] Formerly named as Danisco Glycosidase.
[5] FEED dossier reference: FAD-2014-0026.

The European Union Reference Laboratory 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 Axtra® XB is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012)[8] and the Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).[9]

3. Assessment

Axtra® XB 201 is proposed for use in lactating sows (including minor porcine species) in order to increase the digestibility of the diets and reduce the body weight loss of sows during lactation at the minimum dose of 1,220 U xylanase and 152 U glucanase per kg feed and in minor porcine species for meat production at the minimum dose of 610 U xylanase and 76 U glucanase per kg feed. The Panel considers that aspects other than the safety and efficacy for these target species/categories have been addressed in the previous opinion and is not aware of any new information that would lead it to reconsider the previous conclusions. Therefore, the present assessment will address the safety and efficacy for the new target species only.

3.1. Safety for the target species

3.1.1. Safety for lactating sows

A total of 48 sows (Duroc × Landrace) from parity 1 to 8 and with a mean initial weight ~ 260 kg were allocated, according to body weight and parity number, to three dietary treatments (n = 16 sows, initial number).[10] A basal diet based on wheat, barley, sugar beet pulp, wheat middlings and soya bean meal, was supplemented with Axtra® XB 201 (TPT) to provide (xylanase/glucanase) 0/0, 1,220/152 (recommended dose) or 12,200/1,520 (10× recommended dose) U/kg feed. Enzyme recoveries in the experimental diets were confirmed by analysis. The study was performed in six consecutive production runs (involving nine sows in four of the runs and six in the other two runs). The dietary treatment started three weeks before farrowing and finished on the day piglets were weaned (day 28 of life). Feed was offered in mash form twice daily during the gestation period and thereafter ad libitum. Sows were weighed at the start, at the transfer to the farrowing crate, after farrowing and at piglets' weaning and weight gain/loss was calculated. Individual feed intake of the sows was monitored throughout the study. Litter size was recorded at birth and then standardised to 11–12 piglets per sow at 24 h post-farrowing. Piglets were weighed at 24 h of life, 14 days and at weaning. Blood sampling was performed on eight sows in total at allocation to the treatments and on 12 sows per treatment after weaning. Samples were analysed for haematological[11] and biochemical[12] parameters. An analysis of variance (ANOVA) was performed on the data obtained, considering the sow as the experimental unit. The effect of the run, sow's parity number and treatment were considered in the model. Means were compared using the Student–Newman–Keuls test.

No sows died during the study but three sows were excluded from the study, one sow from the control due to an early farrowing and two from the 10-fold dose due to early farrowing and problems

[6] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2010-0007.pdf
[7] 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.
[8] EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance for the preparation of dossiers for zootechnical additives. EFSA Journal 2012;10(1):2536, 19 pp. doi:10.2903/j.efsa.2012.2536
[9] EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: Tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. doi:10.2903/j.efsa.2011.2175
[10] Technical dossier/Section III/Annex III.2 and Supplementary information February 2015 and July 2015.
[11] Including: haematocrit, red blood cells, mean corpuscular volume, anisocytosis index, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, white blood cells (including lymphocytes, segmented neutrophil, monocytes, eosinophils).
[12] Including: total protein, albumin, urea, plasma urea nitrogen, glucose, alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transpeptidase, alkaline phosphatase.

during the lactation. The overall piglet's mortality reached 19%. The mortality was mostly found during the first 24 h (13–16%), probably as a consequence of the high initial number of piglets per sow (13.3 piglets born/sow), but there were no differences between treatments. Mean feed intake of the sows was 4.1 kg/day (for the overall period) and sow's weight loss between farrowing and weaning was ~ 30 kg and no statistically significant differences were found between treatments. Haematological profile and biochemical blood parameters of the sows at weaning were not significantly different between treatments. Mean number of weaned piglets was 11 and piglet's daily body weight gain was 220 g, no statistically significant differences were found between treatments.

Therefore, the FEEDAP Panel considers that the additive AXTRA® XB 201 is safe for lactating sows at the recommended dose.

3.1.2. Safety for minor porcine species

The tolerance study in sows showed that the sows tolerate well a 10-fold the dose of 1,220 U xylanase and 152 U glucanase per kg feed.

The applicant submitted a tolerance trial in weaned piglets that was evaluated by the FEEDAP Panel in 2010 in which the piglets tolerated well 15-fold the dose of 2,440 U xylanase and 304 U glucanase per kg feed (representing 60-fold the recommended dose for minor porcine species for meat production).[13] The FEEDAP Panel concluded based on that trial that the additive is safe for piglets and pigs for fattening at that dose.

Considering the margin of safety shown in major porcine species, the FEEDAP Panel considers that the conclusions on the safety of the product can be extrapolated to minor porcine species for meat production at 610 U xylanase and 76 U glucanase per kg feed and in lactating sows at 1,220 U xylanase and 152 U glucanase per kg feed.

3.2. Efficacy

3.2.1. Efficacy for lactating sows

Short-term trials

Three short-term trials performed with lactating sows were submitted. The details on the design and the relevant results are presented in Table 1. In the three trials, lactating sows were fed with one of the two dietary treatments: diet without additive (control) or diet supplemented with Axtra® XB 201 to provide 1,220 xylanase U and 152 glucanase U/kg feed. Enzyme activities in the diets were confirmed by analyses. In order to study the digestibility of dietary energy and of nutrients, external markers were added to the diets: HCl-insoluble ash in trial 1 and 3 or titanium dioxide in trial 2. Faecal samples were collected at least two weeks after the start of the treatment. The study of the faecal apparent digestibility included, in all trials, gross energy, dry/organic matter, crude protein, crude fibre, neutral detergent fibre (NDF) and acid detergent fibre (ADF). The faecal apparent digestibility of lignin, hemicellulose, cellulose was studied in trial 1, that for non-starch polysaccharides (NSP, as total and individual sugars) was studied in trial 1 and 3 and that for crude fat, P and Ca in trial 3. An ANOVA was performed with the data obtained. Differences were considered significant at a level of at least $P < 0.05$.

[13] Technical dossier/Section III/Annex II.1.

Table 1: Design of the short-term trials performed in lactating sows and results on the digestibility of the energy of the diets

Trial	N per treatment *(body weight)* breed	Start of treatment	Start of collection (duration) methodology	Basal diet	AXTRA® XB 201 xylanase/glucanase (U/kg feed)	Digestibility of the energy (%)
1[14]	16 *295 kg* Duroc x Landrace	Three weeks before farrowing	Day 18 lactation (3 days) Spot sampling	Wheat, barley, sugar beet pulp, wheat middlings and soya bean meal	0/0 1,220/152	73.5 77.2*
2[15]	9 *284kg* Hybrid	Day 108 gestation	Day 12 lactation (3 days) Rectum	Wheat and barley	0/0 1,220/152	80.8 84.0*
3[16]	13 *221 kg* Large White x Landrace	Two weeks before farrowing	Day 28 lactation (1 day) Not reported	Wheat, barley, sugar beet pulp and wheat middlings	0/0 1,220/152	84.3 84.8

* Mean values within one row are different to control ($P < 0.05$)

Supplementation of the diets with Axtra® XB 201 increased significantly the apparent faecal digestibility of energy in trial 1 and 2, but not in trial 3 (Table 1). The results showed also that the additive increased significantly the apparent faecal digestibility of NDF (trial 1: 60.0 vs 66.2%; trial 2: 60.2 vs 67.4%), ADF (trial 1: 44.1 vs 54.0%; trial 2: 44.9 vs 53.9%), crude fibre (trial 2: 41.3 vs 56.6%; trial 3: 28.8 vs 37.0%), lignin (trial 1: 30.0 vs 40.0%), cellulose (trial 1: 49.8 vs 59.4%), NSP (trial 1: 55.7 vs 63.2% for total NSP), crude protein (trial 2: 83.1 vs 86.2%), organic matter (trial 2: 83.5 vs 86.6%) and calcium (trial 3: 56.5 vs 64.1%).

Long-term trials

Four long-term trials were submitted, the details on the design are presented in Table 2. Trials 1, 3 and 4 considered two dietary treatments; diet without additive (control) or diet supplemented with Axtra® XB 201 to provide 1,220 xylanase U and 152 glucanase U/kg feed. Trial 2 followed a 2 x 2 design with two different basal diets differing in the amount of fibre and two levels of additive supplementation, not supplemented or supplemented with Axtra® XB 201 to provide 1,220 xylanase U and 152 glucanase U/kg feed. Enzyme activities in the diets were confirmed by analyses. The start of the treatments was at the end of gestation and followed during lactation. The duration was of at least 39 days. In trials 1 and 2, feed was offered ad libitum throughout the study, and in trials 3 and 4, it was offered restrictively during gestation and then in the lactation, the allowance was set at 6.5 kg per day in trial 3 or offered ad libitum in trial 4. Feed intake of the sows was monitored throughout the experimental period and sows were weighed after farrowing and at weaning of the piglets in all trials. In trials 2 to 4, the back-fat thickness was measured after farrowing and at weaning (P2 position, at 6–8 cm of the dorsal midline at the last rib curve). Weight and back-fat loss during the lactation was calculated, where relevant. In trial 4, the weaning to oestrus interval of the sows was also recorded. Regarding the litters' parameters, number of piglets and weight was recorded at farrowing, after cross-fostering and at weaning. Cross-fostering was performed during the first 24 h of life and within treatment. An ANOVA was performed with the data obtained considering the effect of the diet and parity number of the sows. In trial 2, the two main effects and their interaction was considered in the model. For the sow's body weight loss during lactation, the weight at farrowing was also considered as a covariate in the model. Differences were considered significant at a level of at least $P < 0.05$.

[14] Technical dossier/Section IV/Annex IV.13.
[15] Technical dossier/Section IV/Annex IV.14.
[16] Technical dossier/Section IV/Annex IV.15.

Table 2: Design of the long-term trials performed in lactating sows

Trial	N per treatment	Breed (parity number)	Basal diet	Treatment	
				Start	End
1[17]	15	Duroc x Landrace (1–8)	Wheat, barley, rapeseed meal and soya bean meal	Day 97 of gestation	Day 27 lactation
2[18]	10	Hybrid (1–8)	Low fibre: wheat and barley High fibre: wheat, barley, wheat bran, corn distillers, sunflower meal and soya hulls	Day 108 gestation	Day 27 lactation
3[19]	13	Large White x Landrace (1–7)	Wheat, barley, sugar beet pulp and wheat middlings	Day 100 gestation	Day 28 lactation
4[20]	29	Large White x Landrace (1–8)	Wheat, barley and soya bean meal	Day 93 gestation	Day 18 lactation

No sows died. Table 3 shows the results of the sow's daily feed intake, body weight loss and back-fat loss of the sows during lactation. Average feed intake of the sows was not significantly different between treatments in any of the studies. In trials 1 and 4, sows receiving the additive lost significantly less body weight from farrowing to weaning than those receiving the control. In trial 2, the back-fat loss was significantly lower in the sows receiving the additive compared to those receiving the non-supplemented diet. In trial 4, no differences were found in the weaning to oestrus interval. The number of weaned piglets, piglets' weight at weaning and litter weight (data not shown) were not significantly different between treatments (Table 4).

Table 3: Effect of Axtra® XB 201 on the daily feed intake, body weight and body weight loss of the sows from farrowing to weaning

Trial	Axtra® XB xylanase/glucanase U/kg feed	Daily feed intake (kg)	Body weight (kg)			Back-fat loss (mm)
			Farrowing	Weaning	Loss[(a)]	
1	0/0	4.69	258	225	32.6 (31.0)	Not measured
	1,220/152	4.25	243	217	25.7* (24.2*)	
2	Low Fibre 0/0	5.13	254	231	22.7	4.0
	Low Fibre 1,220/152	5.12	266	248	18.3	2.6*
	High Fibre 0/0	5.38	262	241	20.6	5.0
	High Fibre 1,220/152	5.42	256	239	17.1	3.5*
3	0/0	6.74	205	209	-	0.82
	1,220/152	6.51	202	203	-	0.70
4	0/0	5.36	248	239	8.4 (9.6)	2.56
	1,220/152	5.57	238	237	0.2* (2.9*)	2.51

* Within one trial and within a column, mean value is different to control ($P < 0.05$).
(a): Values within brackets show the body weight loss when the statistical analysis considered the initial body weight of the sows. For trial 2, the values considering the covariate were only made available for the main effect of diet.

[17] Technical dossier/Section IV/Annex IV.9 and Supplementary information July 2015/Annex 2.
[18] Technical dossier/Section IV/Annex IV.10 and Supplementary information July 2015/Annex 3.
[19] Technical dossier/Section IV/Annex IV.11.
[20] Technical dossier/Section IV/Annex IV.12 and Supplementary information July 2015 Annex 4.

Table 4: Effect of Axtra® XB 201 on litter size, piglets' weight and mortality during lactation

Trial	Axtra® XB xylanase/glucanase U/kg feed	Litter Size (n)		Piglets' weight (kg)		Mortality %
		Initial[(a)]	Final[(b)]	Initial[(a)]	Final[(b)]	
1	0/0	11.5	11.0	1.51	7.65	4.6
	1,220/152	11.4	10.6	1.58	7.47	7.6
2	Low Fibre 0/0	13.7	10.8	1.52	7.91	20.9
	Low Fibre 1,220/152	11.5	9.7	1.60	8.63	14.7
	High Fibre 0/0	11.2	9.6	1.62	7.86	12.4
	High Fibre 1,220/152	12.3	10.1	1.48	8.02	17.4
3	0/0	12.9	11.2	1.40	7.45	13.2
	1,220/152	12.9	10.8	1.64*	7.69	16.0
4	0/0	11.4	9.8	1.38	6.56	12.9
	1,220/152	10.4	9.5	1.46	6.44	8.2

* Within one trial and within one column, mean value is different to control ($P < 0.05$).
(a): Initial day for trial 1, 2 and 4 is day 1 and for trial 3 is after birth.
(b): Final day for trial 1, 2 is day 27, for trial 3 is day 28 and for trial 4 is day 18.

Conclusion on efficacy in lactating sows

The additive Axtra® XB 201 improved the apparent faecal digestibility of gross energy of the diets in two out of three short-term trials done in lactating sows. In two out of four long-term trials with lactating sows, Axtra® XB reduced the body weight loss during lactation. The FEEDAP Panel concludes that the additive has the potential to be efficacious in lactating sows at the minimum recommended dose.

3.2.2. Efficacy for minor porcine species

The data in lactating sows show that the additive has the potential to be efficacious at the dose of 1,220 U xylanase and 152 U glucanase per kg feed. The applicant submitted the efficacy studies that supported the efficacy in piglets and pigs for fattening for the previous evaluation.[21] From the studies submitted, the FEEDAP Panel concluded that the efficacy of the additive was demonstrated at the intended minimum recommended dose of 610 U xylanase and 76 U glucanase per kg feed.

The mode of action of the enzymes is well known and it is assumed to be the same among porcine species. Therefore, the Panel considers that the conclusions reached on the efficacy for the major porcine species can be extrapolated to minor porcine species at the dose of 1,220 U xylanase and 152 U glucanase per kg feed in the lactation phase and at 610 U xylanase and 76 U glucanase per kg feed for the weaning–fattening phase.

3.3. 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 Regulation[22] and Good Manufacturing Practice.

4. Conclusion

The additive is safe and efficacious for lactating sows and minor porcine species at the corresponding recommended doses.

[21] Technical dossier/Section IV/Annexes IV.1 to IV.8.
[22] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

Documentation provided to EFSA

1. Axtra® XB for sows and minor porcine species. August 2014. Submitted by Danisco UK Ltd.
2. Axtra® XB for sows and minor porcine species. Supplementary information. February 2015. Submitted by Danisco UK Ltd.
3. Axtra® XB for sows and minor porcine species. Supplementary information. July 2015. Submitted by Danisco UK Ltd.
4. Comments from Member States.

References

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Nutrition), 2010. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal feed on the safety and efficacy of Danisco Glycosidase (and endo-1,3(4)-beta-glucanase) as feed additive for poultry, piglets and pigs for fattening. EFSA Journal 2010;8(12):1916. 22pp. doi:10.2903/j.efsa.2010.1916.

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance for the preparation of dossiers for zootechnical additives. EFSA Journal 2012;10(1):2536, 19 pp. doi:10.2903/j.efsa.2012.2536

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: Tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. doi:10.2903/j.efsa.2011.2175