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# Safety and efficacy of a feed additive consisting of α-galactosidase (produced by *Aspergillus tubingensis* ATCC SD6740) and endo-1,4-β-xylanase (produced by *Trichoderma longibrachiatum* CBS 139997) (Capsozyme SB Plus) for chickens for fattening, chickens reared for laying and minor poultry species (for fattening and reared for laying) (Industrial Técnica Pecuaria S.A.)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Jürgen Gropp, Jaume Galobart, Montserrat Anguita, Fabiola Pizzo and Jordi Ortuño

## Abstract

Following a request from the European Commission, the EFSA 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 Capsozyme SB Plus as a zootechnical feed additive (digestibility enhancers) for chickens for fattening, chickens reared for laying and minor poultry species (for fattening and reared for laying). The additive contains two enzyme ingredients (α-galactosidase, produced by a non-genetically modified strain of *Aspergillus tubingensis*; and endo-1,4-β-xylanase, produced by a non-genetically modified strain of *Trichoderma longibrachiatum*) and is presented in solid form. In 2020, the FEEDAP Panel issued an opinion on this product. In that assessment, the Panel considered the additive safe for the target species and the environment. The Panel concluded that the additive does not raise concern for genotoxicity but could not conclude on consumer safety due to the limitations identified in the 90-day toxicity study. Owing to the lack of data, the Panel could not conclude on the potential of the additive as a skin or eye irritant nor as a skin sensitiser. Moreover, the Panel could not conclude on the efficacy of the additive for chickens for fattening due to the limited evidence provided. The applicant provided supplementary data to support the safety for consumers and the efficacy of the product in chickens for fattening. The FEEDAP Panel concluded that the data provided support the absence of toxicological risk for the consumer. Likewise, according to the new data submitted, the FEEDAP Panel concluded that the additive has the potential to be efficacious in chickens for fattening at the level of 14 GALU (α-galactosidase)/18 AXC (endo-1,4-β-xylanase) per kg feed, and this conclusion was extended to chickens reared for laying and extrapolated to minor poultry species for fattening/reared for laying.



**Keywords:** zootechnical additives, digestibility enhancers, Capsozyme SB Plus, α-galactosidase, endo-1,4-β-xylanase, safety, efficacy

**Requestor:** European Commission

**Question number:** EFSA-Q-2021-00174

**Correspondence:** feedap@efsa.europa.eu

**Panel members:** Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

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# 1. Introduction

## 1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003 establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, Industrial Técnica Pecuaria S.A., is seeking a Community authorisation of endo-1,4-beta-xylanase, alpha-galactosidase as a feed additive to be used as a digestibility enhancer for chickens for fattening, chickens reared for laying, and minor poultry species (for fattening and reared for laying) (Table 1).

**Table 1:** Description of the additive

| | |
|---|---|
| **Category of additive** | Zootechnical additives |
| **Functional group of additive** | Digestibility enhancers |
| **Description** | endo-1,4-beta-xylanase, alpha-galactosidase |
| **Target animal category** | chickens for fattening, chickens reared for laying and minor poultry species (for fattening and reared for laying) |
| **Applicant** | Industrial Técnica Pecuaria S.A. |
| **Type of request** | New opinion |

On 28 April 2020, the Panel on Additives and Products or Substances used in Animal of the European Food Safety Authority ('Authority'), in its opinion on the safety and efficacy of the product, could not conclude on the safety and efficacy of endo-1,4-beta-xylanase, alpha-galactosidase (EFSA FEEDAP Panel, 2020).

After the discussion with the Member States at a meeting of the Standing Committee on Plants, Animals, Food and Feed (Animal Nutrition section), it was suggested to check for the possibility to demonstrate the safety and efficacy of the additive.

The Commission gave the possibility to the applicant to submit complementary information and data in order to complete the assessment and to allow a revision of the Authority's opinion. The new data have been received on 5 March 2021 and were already transmitted to the Authority by the applicant.

In view of the above, the Commission asks the Authority to deliver a new opinion on endo-1,4-beta-xylanase, alpha-galactosidase as a feed additive for chickens reared for laying, chickens for fattening and minor poultry species (for fattening and reared for laying) based on the additional data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

## 1.2. Additional information

Capsozyme SB Plus (endo-1,4-beta-xylanase, alpha-galactosidase) is not authorised in the European Union. The FEEDAP Panel adopted one opinion on the safety and efficacy of the additive (EFSA FEEDAP Panel, 2020) regarding the use for poultry species for fattening or reared for laying and ornamental birds.

# 2. Data and methodologies

## 2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[1] to a previous application[2] of the additive Capsozyme SB Plus (endo-1,4-beta-xylanase, alpha-galactosidase). The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA.

## 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of the additive Capsozyme SB Plus (endo-1,4-beta-xylanase and alpha-galactosidase) is in line with the principles laid

[1] FEED dossier reference: FAD-2020-0105.
[2] FEED dossier reference: FAD-2017-0067.

down in Regulation (EC) No 429/2008[3] and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

# 3. Assessment

The product Capsozyme SB Plus is a feed additive consisting of α-galactosidase and endo-1,4-β-xylanase. The additive is intended to be used in chickens for fattening, chickens reared for laying and minor poultry species (for fattening and reared for laying) as a zootechnical additive (functional group: digestibility enhancers), at a minimum level of 14 GALU[4] and 18 AXC[5] per kg feed and at a maximum of 20 GALU and 25 AXC per kg feed (corresponding to a dose range between 350 and 500 mg Capsozyme SB Plus/kg feed).

The α-galactosidase (Enzyme Commission number, EC, 3.2.1.22; galactosidase) is produced by a non-genetically modified strain of *Aspergillus tubingensis* deposited at the American Type Culture Collection as *Aspergillus niger* with the accession number ATCC SD 6740. The endo-1,4-β-xylanase (EC 3.2.1.8; xylanase) is produced by a non-genetically modified strain of *Trichoderma longibrachiatum*, deposited at the *Centraalbureau voor Schimmelcultures* (CBS) with the accession number CBS 139997. The additive was characterised in full in the EFSA's previous assessment (EFSA FEEDAP Panel, 2020). In that opinion, the FEEDAP Panel could not conclude on the safety for the consumers owing to the limitations identified in the 90-day oral toxicity study. The Panel could also not conclude on the potential of the additive as skin or eye irritant nor as skin sensitiser due to the absence of data. Moreover, the Panel could not conclude on the efficacy of the additive for chickens for fattening due to the limited evidence provided.

The applicant has provided new data to support the safety for consumers and the efficacy of the product in chickens for fattening. No further data have been provided to support the safety for the user.

## 3.1. Safety

## 3.2. Safety for the consumer

In the previous EFSA assessment (EFSA FEEDAP Panel, 2020), the FEEDAP Panel evaluated a set of genotoxicity studies and a 90-day toxicity study in rats, performed with the mixture of the two enzymes used for the formulation of the final additive. Concerning the genotoxicity, the FEEDAP Panel concluded that the test item 'did not show any potential for a genotoxic effect in a bacterial reverse mutation assay and an *in vitro* mammalian cell micronucleus test'.

The 90-day toxicity study, which is fully described in the previous assessment (EFSA FEEDAP Panel, 2020), was claimed by the applicant to follow the OECD test guideline (TG) 408 (1998). In that study, the relative brain weight of female rats of the lowest (1.2 g test item/kg feed, corresponding to 2,136 GALU and 1,710 AXC/kg feed) and the highest level (12 g test item/kg feed, corresponding to 21,360 GALU and 17,100 AXC/kg feed) groups was significantly lower compared to the control (data statistically analysed with ANOVA with treatment as the main effect; two-sided significance level set at 0.05). No similar effects were observed in males. Gross and histopathological examination of organs/tissues (including brain) did not reveal any differences between treated and control groups. However, the FEEDAP Panel considered that 'the reduction in the relative brain weight in the lowest and the highest dose females compared to the control cannot be assessed because of the lack of functional observational battery (FOB) during the study'. The FEEDAP Panel could not conclude on the toxicological potential of the additive, and, consequently, on the safety of the consumer.

In the current dossier, the applicant submitted additional statistical analyses aimed at elucidating the brain weight difference occurring in female rats. Body weight and relative brain weights in the female rats of all groups were compared by the Mood's median test; significance level was set at 0.05.

[3] 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.

[4] One unit of a-galactosidase activity (GALU) is defined as the amount of enzyme which degrades one micromole per minute of para-nitrophenyl-a-D-galactopyranoside at pH 5.5 and 37°C.

[5] One unit of endo-1,4-b-xylanase activity (AXC) is the amount of enzyme, which liberates 0.058 micromoles per minute of reducing sugars, expressed as xylose equivalents, from a wheat arabinoxylan substrate at pH 4.7 and 30°C.

The medians for the body weight and relative brain weight were not statistically different between treated and control groups ($p = 0.361$ and 0.065, respectively).[6]

The applicant also provided an analysis of covariance (ANCOVA) of the absolute brain weight of females (10 animals per group) considering the treatment as the main effect and body weight as covariate (as suggested in Bailey et al., 2004).[7] Two-sided significance level was set at 0.05. There was no significant response of brain weight ($p = 0.054$) to any dose of the test item supplementation in comparison with the control group.

Overall, the new statistical analyses performed showed that the brain weight in females did not significantly differ between control and treated groups.

In addition, the applicant has provided a statement of the study director and an expert report on the suitability of the 90-day study previously submitted, with reference to two publications (Bailey et al., 2004; Sellers et al., 2007).[8]

The FEEDAP Panel reiterates that the previously submitted 90-day toxicity study did not include a proper FOB. Several parameters generally determined in the FOB were indeed not measured (e.g. activity level, increased level of salivation, forelimb/hindlimb/grip strength, sensory function, open field, rectal temperature, excessive or diminished urination). Clinical observations of the animals were done daily. However, as they do not include the typical parameters normally evaluated in a complete FOB, they cannot be considered as an adequate alternative to the FOB. The Panel further considers that, especially in case of slight brain damage, the FOB is a more sensitive and relevant parameter than brain histopathology.

Despite the lack of an appropriate FOB, the FEEDAP Panel considered that the new statistical analyses are sufficient to exclude an adverse effect on the weight brain in rats and, consequently, any toxicological concern related to the additive under assessment can be ruled out.

Therefore, based on the 90-day toxicity study, the FEEDAP Panel identified a no observed adverse effect level (NOAEL) of 12 g test item/kg feed per day (21,360 GALU and 17,100 AXC/kg feed, the highest level tested), corresponding to 1.08 g/kg bw per day (applying a conversion factor of 0.09; EFSA Scientific Committee, 2012).

## 3.3. Conclusions on the safety

The FEEDAP Panel concluded that the additive is not genotoxic and that the 90-day study does not identify any adverse effects in the animals fed with the additive. Consequently, the use of Capsozyme SB Plus in animal nutrition under the conditions of use proposed is safe for the consumer.

The additional information provided by the applicant did not modify the conclusions reached in the previous opinion (EFSA FEEDAP Panel, 2020) regarding the safety of the additive for the target species, users and environment. Therefore, the Panel reiterates that the additive remains safe for the target species and the environment under the proposed conditions of use. Due to the lack of data, the Panel cannot conclude on the skin or eye irritation potential of the additive nor on its skin sensitisation potential. Owing to the proteinaceous nature of the additive, it should be regarded as a potential respiratory sensitiser, but the exposure is presumed to be limited due to the low dusting potential (EFSA FEEDAP Panel, 2020).

## 3.4. Efficacy

### 3.4.1. Efficacy for chickens for fattening

In the previous assessment, the FEEDAP Panel evaluated five trials in chickens for fattening (EFSA FEEDAP Panel, 2020). The results showed significant effects on relevant parameters in only two long-term trials submitted and, consequently, no conclusion could be drawn. Moreover, the Panel noted that the two trials in which significant effects were found might not have been performed independently. Therefore, the data from the two studies should have been analysed as one unique long-term trial.

In the current submission, the applicant has provided one long-term (trial 1 in Tables 2 and 3) and one short-term (trial 3 in Table 2) trials to support the efficacy of the additive in chickens for fattening. In addition, the applicant provided a combined statistical analysis for the two trials (trial 2 in Tables 2

[6] Technical dossier/Section III/Annex 3.
[7] Technical dossier/Supplementary Information (June 2021)/Section III/Annex 1.
[8] Technical dossier/Section III/Annexes 1-2 and 4-5.

and 3) which were considered as non-independent in the previous opinion (EFSA FEEDAP Panel, 2020).

The summary of the experimental design of these three trials is presented in Table 2. One-day-old Ross 308 male birds were used for both long-term trials, while 21-day-old male birds from the same breed were used in the short-term trial. Capsozyme SB Plus was incorporated into diets to provide galactosidase (GALU) and xylanase (AXC) units at the minimum recommended use level (14 GALU/18 AXC per kg of complete feed). The intended enzyme activities were confirmed by analysis (see Table 2).

In the long-term trials, the diets were administered for 35 days (trial 1) or 36 days (trial 2). The health and mortality were monitored throughout the study and the body weight and feed intake were recorded. Feed to gain ratio was calculated. The data were analysed with an analysis of variance (ANOVA), using the pen as the experimental unit. Group means were compared with a *t*-test in trial 1 and with Tukey-Kramer test in trial 2. Significance level was set at 0.05. The results of both long-term studies are presented in Table 3. Overall mortality/culling was low and not affected by treatments. In both trials, the final body weight and the daily body weight gain were higher and the feed to gain ratio lower in the birds receiving the additive at the minimum recommended level compared to the control.

**Table 2:** Design of the studies performed with chickens for fattening

| Trial | Total no birds (birds/replicate) replicates/treatment | Breed Sex | Diet composition (form) | Enzyme activity (GALU/AXC per kg feed) | |
|---|---|---|---|---|---|
| | | | | Intended | Analysed |
| 1[9] | 870<br>(15)<br>29 | Ross 308<br>Male | Wheat, rye and soybean meal<br>(mash) | 0<br>14/18 | 0<br>16/20 – 13/18 |
| 2[10] | 1,520<br>(20)<br>38 | Ross 308<br>Male | Wheat, barley, rye and soybean meal<br>(pellets) | 0<br>14/18 | 0<br>13/19 - 17/20 - 15/21 |
| 3[11] | 96<br>(8)<br>6 | Ross 308<br>Male | Maize and soybean meal<br>(pellets) | 0<br>14/18 | 0<br>13/21 |

**Table 3:** Effects of Capsozyme SB Plus on the performance of chickens for fattening in the long-term trials

| Trial | Enzyme activity (GALU/AXC per kg feed) | Daily feed intake (g) | Final body weight (g) | Daily body weight gain (g) | Feed to gain ratio | Mortality and culling(1) (%) |
|---|---|---|---|---|---|---|
| 1 | 0<br>14/18 | 97.8<br>97.7 | 2,268$^{b}$<br>2,411$^{a}$ | 63.6$^{b}$<br>67.7$^{a}$ | 1.54$^{a}$<br>1.45$^{b}$ | 2.1/3.2<br>2.1/0.9 |
| 2 | 0<br>14/18 | 112.5<br>112.2 | 2,665$^{b}$<br>2,711$^{a}$ | 72.7$^{b}$<br>74.0$^{a}$ | 1.55$^{a}$<br>1.52$^{b}$ | 1.7<br>3.2 |

a,b: Values within one column and for the same study with different superscripts are different ($p < 0.05$).
(1): In trial one values are for mortality/culling and for trial two values report the total losses.

In the short-term study (balance trial; trial 3), diets were offered to 21-day-old chickens for fattening on *ad libitum* basis in pelleted form for 7 days containing an external marker (3 g chromic oxide/kg feed). Mortality and health status were checked every day and dead/culled animals were necropsied. Animals' body weight and feed intake were recorded at the beginning and end of the collection period on a cage basis, and feed to gain ratio was calculated. The balance was done with a 3-day adaptation period to the diets and a 4-day collection period. The excreta samples were collected by the total collection method (from each cage by means of a tray). The excreta samples were analysed for dry matter and gross energy content, and the utilisation of the energy of the diets (apparent metabolisable energy – AME; and apparent metabolisable energy corrected for nitrogen, AMEn) was calculated. At the end of the collection period (days 28–29 of age), all birds were killed,

[9] Technical dossier/Annex 10.
[10] Technical dossier/Supplementary information (June 2021)/Annex 2.
[11] Technical dossier/Annex 11.

and the ileal contents from all birds in each cage were collected, pooled and freeze-dried, and finally analysed for dry matter, crude protein, individual amino acids and chromic oxide concentration, in order to calculate apparent ileal digestibility of crude protein ($AID_{CP}$) and individual amino acids ($AID_{AA}$). For the statistical analysis, the cage was used as the experimental unit. An analysis of variance (ANOVA) was done considering the treatment as the fixed effect. Group means were compared with the Duncan's test. Significance level was set at 0.05. No chickens died during the experiment. No significant treatment-related effects on the zootechnical parameters were observed. The birds that received Capsozyme SB Plus showed higher AME (13.08 vs. 12.96 MJ/kg) and AMEn (12.31 vs. 12.21 MJ/kg) content when compared to the control.

In conclusion, the chickens for fattening that received Capsozyme SB Plus at 14 GALU/18 AXC per kg complete feed showed better zootechnical performance in two long-term trials and an improvement on the energy utilisation of the diets in a balance trial. Therefore, the additive has the potential to be efficacious in chickens for fattening at the level of 14 GALU/18 AXC/kg complete feed.

### 3.4.2. Efficacy for other poultry species/categories

The conclusions reached in chickens for fattening can be extended to chickens reared for laying. Considering that the mode of action is well known, the same conclusions can be extrapolated to minor poultry species for fattening/reared for laying.

### 3.4.3. Conclusions on the efficacy

The additive has the potential to be efficacious for chickens for fattening/reared for laying and minor poultry species for fattening/reared for laying when added to feed at 14 GALU/18 AXC per kg complete feed.

## 4. Conclusions

The use of Capsozyme SB Plus in animal nutrition under the conditions of use proposed is safe for the target species, the consumer and the environment.

The Panel cannot conclude on the skin or eye irritation potential of the additive nor on its skin sensitisation potential; however, the additive should be regarded as a respiratory sensitiser.

The additive has the potential to be efficacious for chickens for fattening/reared for laying and minor poultry species for fattening/reared for laying when added to feed at 14 GALU/18 AXC per kg complete feed.

## 5. Documentation provided to EFSA/Chronology

| Date | Event |
|---|---|
| **04/12/2020** | Dossier received by EFSA. FAD-2020-0105. Submitted by Industrial Técnica Pecuaria S.A. |
| **18/03/2021** | Reception mandate from the European Commission |
| **12/04/2021** | Acceptance mandate from the European Commission by EFSA |
| **07/06/2021** | Request of supplementary information to the applicant in line with Article 7(3) of Commission Regulation (EC) No 1304/2003 – Scientific assessment suspended. Issues: safety for the consumer/efficacy |
| **17/06/2021** | Reception of supplementary information from the applicant - Scientific assessment re-started |
| **10/11/2021** | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment |

## References

Bailey SA, Zidell RH and Perry RW, 2004. Relationships between organ weight and body/brain weight in the rat: what is the best analytical endpoint? Toxicologic Pathology, 32, 448–466. https://doi.org/10.1080/01926230490465874

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Dujardin B, Galobart J and Innocenti ML, 2017. Guidance on the assessment of the safety of feed additives for the consumer. EFSA Journal 2017;15(10):5022, https://doi.org/10.2903/j.efsa.2017.5022

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2018. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 16 pp. https://doi.org/10.2903/j.efsa.2018.5274

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Kos Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Cocconcelli PS, Glandorf B, Herman L, Prieto Maradona M, Saarela M and Anguita M, 2020. Scientific Opinion on the safety and efficacy of Capsozyme SB Plus (α-galactosidase and endo-1,4-β-xylanase) as a feed additive for poultry species for fattening or reared for laying and ornamental birds. EFSA Journal 2020;18(4):6086, 13 pp. https://doi.org/10.2903/j.efsa.2020.6086

EFSA Scientific Committee, 2012. Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579, 32 pp. https://doi.org/10.2903/j.efsa.2012.2579

Sellers RS, Morton D, Michael B, Roome N, Johnson JK, Yano BL, Perry R and Schafer K, 2007. Society of toxicologic pathology position paper: organ weight recommendations for toxicology studies. Toxicologic Pathology, 35, 751–755. https://doi.org/10.1080/01926230701595300

## Abbreviations

| | |
|---|---|
| BW | body weight |
| DM | dry matter |
| EURL | European Union Reference Laboratory |
| FEEDAP | EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed |
| NOAEL | no observed adverse effect level |