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Assessment of the application for renewal of authorisation of 6-phytase produced by *Trichoderma reesei* CBS 122001 as a feed additive for pigs and poultry, from Roal Oy

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, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Pier Sandro Cocconcelli, Boet Glandorf, Lieve Herman, Miguel Maradona Prieto, Maria Saarela, Rosella Brozzi, Jaume Galobart, Matteo Innocenti, Gloria López-Gálvez, Elisa Pettenati, Joana Revez, Konstantinos Sofianidis, Maria Vittoria Vettori, Lucilla Gregoretto and Baltasar Mayo

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 assessment of the application for renewal of authorisation of 6-phytase produced by *Trichoderma reesei* CBS 122001 (brand name: Finase[®]EC). The applicant has provided evidence that the additive currently in the market complies with the existing conditions of authorisation. The Panel concludes that the additive remains safe for poultry for fattening, breeding and laying, and all pigs, the consumer and the environment under the authorised conditions of use. Regarding user safety, the Panel reiterates that the additive is not a skin or eye irritant or sensitiser but should be considered a potential respiratory sensitiser. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. These conclusions also apply to the new proposed liquid formulation Finase[®]EC 5 L.

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Requestor: European Commission

Question number: EFSA-Q-2019-00333

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 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Roal Oy² for renewal of the authorisation of 6-phytase produced by *Trichoderma reesei* CBS 122001, when used as a feed additive for pigs other than sows, sows, poultry for fattening and breeding other than turkeys for fattening, poultry for laying and turkeys (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 14(1) (renewal of the authorisation). The particulars and documents in support of the application were considered valid by EFSA as of 2 August 2019.

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 6-phytase produced by *Trichoderma reesei* CBS 122001, when used under the proposed conditions of use, (see Section 3.1.4).

1.2. Additional information

The additive is a preparation of 6-phytase produced by a genetically modified strain of *Trichoderma reesei* CBS 122001; its brand name is Finase[®]EC.

The EFSA Panel on Additives and Products or Substances used in Animal feed (FEEDAP) issued one opinion on the safety and efficacy of 6-phytase produced by *T. reesei* CBS 122001 when used in chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for laying, ducks and other minor poultry species, piglets (weaned), pigs for fattening and sows, which included the safety aspects of the genetic modification (EFSA FEEDAP Panel and EFSA GMO Panel, 2009; EFSA FEEDAP Panel, 2010). Other two opinions were adopted on the use of the additive in turkeys (EFSA FEEDAP Panel 2010) and sows (EFSA FEEDAP Panel, 2011).

The additive 6-phytase (4a12)³ is currently authorised as a feed additive for poultry species for fattening and breeding (other than turkeys for fattening), for poultry for laying and for pigs (other than sows),⁴ for turkeys⁵ and for sows.⁶ The applicant is now seeking the renewal of those authorisations.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁷ in support of the authorisation request for the use of 6-phytase produced by a genetically modified strain of *T. reesei* CBS 122001 as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA, to deliver the present output.

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 Roal Oy, Tykkimäentie 15b, 05200, Rajamäki, Finland.

³ Identification number of the additive.

⁴ Commission Regulation (EU) No 277/2010 of 31 March 2010 concerning the authorisation of 6-phytase as a feed additive for poultry for fattening and breeding other than turkeys for fattening, for poultry for laying and for pigs other than sows (holder of authorisation Roal Oy) (Text with EEA relevance). OJ L 86, 1.4.2010, p. 13–14.

⁵ Commission Regulation (EU) No 891/2010 of 8 October 2010 concerning the authorisation of a new use of 6-phytase as a feed additive for turkeys (holder of authorisation Roal Oy) Text with EEA relevance. OJ L 266, 9.10.2010, p. 4–5.

⁶ Commission Implementing Regulation (EU) No 886/2011 of 5 September 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for sows (holder of authorisation Roal Oy) Text with EEA relevance. OJ L 229, 6.9.2011, p. 5–6.

⁷ FEED dossier reference: FAD-2019-0027.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.⁸

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of 6-phytase produced by a genetically modified strain of *T. reesei* CBS 122001 is in line with the principles laid down in Regulation (EC) No 429/2008⁹ and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013) and the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive is a preparation of 6-phytase produced by a genetically modified strain of *Trichoderma reesei* CBS 122001. It will be hereafter referred as Finase[®]EC.

Finase[®]EC is currently authorised as a feed additive for all poultry for fattening, breeding and laying, and for all pigs. This assessment regards the renewal of the authorisation of Finase[®]EC for the above-mentioned species.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is currently authorised and marketed as:

- a solid form (Finase[®]EC 40 P) with a minimum activity of 40,000 PPU¹⁰/g, that contains the enzyme preparation (16–24%), water as moisture (5%) and wheat flour (up to 100%).
- a liquid form (Finase[®]EC 10 L) with a minimum activity of 10,000 PPU/g, that contains the enzyme preparation (4–6%), sorbitol (20%), sodium benzoate (0.35%) and water (up to 100%).

The applicant is also requesting the authorisation of a new liquid form (Finase[®]EC 5 L) with a minimum activity of 5,000 PPU/g that contains the enzyme preparation (2–3%), sorbitol (20%), sodium chloride (4%), sodium benzoate (0.35%), and water (up to 100%).

The applicant stated that minor changes have been applied to the manufacturing [REDACTED] during the last years to improve the fermentation process.¹¹ The Panel considers that these modifications do not have an impact on the final product and the data provided support this conclusion.

Compliance with specifications was confirmed by analysis of three batches of Finase[®]EC 10 L¹² and five batches for Finase[®]EC 40 P¹³ and Finase[®]EC 5 L¹⁴ (all recent batches). The mean enzyme activity in Finase[®]EC 40 P was 46,580 PPU/g (range 44,400–49,000), in Finase[®]EC 10 L was 12,700 PPU/g (range 12,000–14,000) and in the Finase[®]EC 5 L was 6,016 PPU/g (range 5,620–6,280).

The same batches were tested for microbiological contamination: *Escherichia coli* and *Salmonella* spp. (absence in 25 g), coliforms at 37°C (< 1 colony forming unit (CFU)/g in the Finase[®]EC 10 L and 5L formulations, but < 10 CFU/g in the Finase[®]EC 40 P), yeasts and filamentous fungi (< 1,000 CFU/g) and total viable cells (< 1,000 CFU/g) in four batches, but 1,500 CFU/g in one batch of the Finase[®]EC 40 P formulation).

⁸ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2008-0040.pdf>

⁹ 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.

¹⁰ 1 PPU is the amount of enzyme which liberates 1 µmol of inorganic phosphate from sodium phytate per minute at pH 5.0 and 37°C.

¹¹ Technical dossier/Section II and Supplementary Information May 2020 answer.

¹² Technical dossier/Section II/Supplementary Information June 2020/Annex 6 (10L).

¹³ Technical dossier/Section II/Annex II-006_Composition & purity_FEC 40 P.pdf

¹⁴ Technical dossier/Section II/Supplementary Information June 2020/Annex 5 (5L).

Chemical contamination was measured in the same batches. Data were provided for heavy metals (cadmium, < 0.05 mg/kg; mercury, < 0.05 mg/kg; lead, < 0.05 mg/kg), and arsenic (< 0.50 mg/kg).¹⁵ Mycotoxins were also analysed in the same batches (aflatoxin (B1, B2 and G1, G2) < 0.1 µg/kg in Finase[®] EC 10 L and 5 L formulations and from < 0.1 to < 0.01 µg/kg in the Finase[®] EC 40 P formulation; fumonisins (B1, B2 and B3) < 20 µg/kg; ochratoxin A < 2 µg/kg; deoxynivalenol < 20 µg/kg in Finase[®] EC 10 L and 5L formulations, but from < 20 µg/kg to 180 µg/kg in the Finase[®] EC 40 P formulation; T2 toxin, HT-2 toxin, zearalenone and sterigmatocystin were all < 10 µg/kg. Based on these results, no concerns were identified.

No antimicrobial activity was detected in five batches of the liquid diluted (Finase[®] EC 5 L)¹⁶ and three batches of the liquid concentrated (Finase[®] EC 10 L)¹⁷ forms of the additive, following the provisions of the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018). The strains tested were *Staphylococcus aureus* ATCC 6538, *Streptococcus pyogenes* ATCC 12344, *E. coli* ATCC 11229, *Serratia marcescens* ATCC 14041, *Bacillus cereus* ATCC 2 and *Bacillus circulans* ATCC 4516. The only known secondary metabolites naturally produced by *T. reesei* are peptaibols, e.g. paracelsin A, C, and D (Frisvad et al., 2018),¹⁸ which are peptides that show antimicrobial activity. The genome of *T. reesei* contains genes for two peptaibol synthases (Kubicek et al., 2011).¹⁹ The peptides are produced under stress conditions only, not under conventional fermentation conditions (Frisvad et al., 2018). *T. reesei* seems to be unable to produce mycotoxins (EFSA, 2007; Frisvad et al., 2018; EFSA BIOHAZ Panel, 2020). Analysis of three recent batches of the common dry concentrate show that the trichothecene trichodermin is not detected in the product.²⁰

3.1.2. Characterisation of the production organism

The 6-phytase present in the additive is obtained by fermentation with a genetically modified strain of *T. reesei* which is deposited at the Central Bureau of Fungal Cultures (Centraal Bureau voor Schimmelcultures, CBS), with the deposition number CBS 122001.²²

The identification of the strain and its taxonomic identification were confirmed.

The assessment of the genetic modification was performed in a previous opinion (EFSA FEEDAP Panel and EFSA GMO Panel, 2009) and the Panel concluded that the genetic modification did not raise any safety concern. The production strain has not been subject to any further genetic modification. Nevertheless, in the current application the applicant provided further data on the genetic modification. In particular, these data concern

These data confirmed the previous conclusion of the Panel on the safety of the genetic modification of the production strain in accordance with the

¹⁵ No indication of the Limit of detection or Limit of quantification of the method.

¹⁶ Technical dossier/Section II/Supplementary Information June 2020/Annex 05_Composition & purity_FEC 5 L.pdf

¹⁷ Technical dossier/Section II/Supplementary Information June 2020/Annex 06_Composition & purity_Finase EC 10 L.pdf

¹⁸ Technical dossier/Section II/Annexes/References/Frisvad, Møller et al. 2018 - Safety of the fungal workhorses.pdf

¹⁹ Technical dossier/Section II/Annexes/References/Kubicek_et_al_2011_Genome_Biology_12_R40.pdf

²⁰ Technical dossier/Section II/Supplementary Information October 2020/Annex 5a and 5b; the limit of detection (LOD) of the method is 1.2 µg/kg.

guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

The presence of viable cells of the production strain was investigated in the formulations of Finase[®] EC 5L (four batches),²⁷ Finase[®] EC 40P (five batches),¹³ Finase[®] EC 10L (two batches)²⁸ and the liquid intermediate concentrate (three batches).²⁹ However, the analyses of two of the batches of the Finase[®] EC 5L³⁰ and of both batches of the Finase[®] EC 10L formulation were not further considered in the assessment since they were dated 2009 and 2008, respectively.

No cells were detected in any of the batches tested.³²

3.1.3. Stability and homogeneity

The stability of the additive was already assessed in the previous opinion (EFSA FEEDAP Panel and EFSA GMO Panel, 2009). The changes in the manufacturing do not imply changes in the physical chemical properties that would modify the stability. The applicant provided new stability studies for Finase[®] EC 40 P and on the stability to pelleting of Finase[®] EC 5 L, which are described below.

A study on Finase[®] EC 40 P was performed in three batches when stored at 6°C in closed transparent PET bottles; or at 20–23°C, at 25°C/60% relative humidity (RH) or at 30°C/65% RH in sealed mini bags for up to 24 months. After 24 months, the recovery of the samples stored at 6°C averaged 91% and at 20–23°C averaged 87%. After 12 months, the recovery of the samples kept at 25°C/60% RH averaged 75% and at 30°C/65% RH averaged 51%.³⁶

The stability to pelleting Finase[®] EC 40 P was re-measured in three batches at temperatures starting from 70 up to 95°C.³⁷ The recovery declined at the increase of the temperature (the recovery after pelleting at 70°C averaged 79% (range 72–85%) and at 95°C averaged 0.5% (range 0.4–0.7%).

The stability of Finase[®] EC 5 L in three batches was studied when stored in polyethylene terephthalate (PET) transparent bottles at 20–23°C or in polypropylene transparent test tubes at 6 or 37°C. After 24 months, the recovery ranged from 89% to 90% when kept at 6°C, and 68% to 69% at 20–23°C. Recovery ranged from 18% to 20% at 37°C after 12 months depending on the batch considered.³⁸

3.1.4. Conditions of use

The additive is currently authorised for use in all pigs and poultry for fattening and breeding at a minimum recommended dose of 250 PPU³⁹ /kg complete feed and for use in poultry for laying at a minimum recommended dose of 125 PPU/kg of complete feed. The maximum recommended level in all species/categories is 1,000 PPU/kg complete feed.

²⁷ Technical dossier/Section II/Annex II-004b_Composition & purity of FEC 5 L.pdf and Annex II-004a_Composition & purity of FEC 5 L.pdf

²⁸ Technical dossier/Section II/Annex II-005_Composition & purity_FEC 10L.pdf

²⁹ Technical dossier/Section II/Annex II-021.

³⁰ Technical dossier/Section II/Annex II-004a_Composition & purity of FEC 5 L.pdf.

³¹ Technical dossier/Section II/Annex II.26.

³² Technical dossier/Section II/Annex II.20.

³⁶ Technical dossier/Section II/Annex II-029_Storage stability of Finase EC 40 P.pdf

³⁷ Technical dossier/Section II/Annexes II-030 a, b, c.

³⁸ Technical dossier/Section II/Annex II-27a.

³⁹ 1 PPU is the amount of enzyme which liberates 1 µmol of inorganic phosphate from sodium phytate per minute at pH = 5.0 and 37°C.

Under the other provisions of the authorisations, it is specified that:

- i) in the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.
- ii) maximum recommended dose per kilogram of complete feed for all authorised species: 1,000 PPU.
- iii) for use in feed containing more than 0.23% phytin-bound phosphorus.
- iv) for safety: breathing protection, glasses and gloves shall be used during handling.

The applicant has not requested to modify these conditions of use.

3.2. Safety

In its previous opinions (EFSA FEEDAP Panel and EFSA GMO Panel, 2009; EFSA FEEDAP Panel, 2010, 2011), the FEEDAP Panel concluded that the additive is safe for poultry for fattening and breeding, including turkeys, for poultry for laying and for pigs, including sows at the maximum recommended level of 1,000 PPU/kg as well as for the consumers and the environment. Concerning user safety, the Panel concluded that the additive was not a skin or eye irritant or sensitiser but should be considered a potential respiratory sensitiser.

The applicant stated that no adverse effects on target animals, consumer, user or the environment have been reported as part of its quality control system.⁴⁰

Two literature searches were conducted in PubMed and Web of Science and included the search terms 'Finase[®]EC', 'safety', 'toxicity' in the first and 'Finase[®]EC', 'safety', 'toxicity' and 'phytase' in the second; A third search in PubMed, AGRIS and Scifinder, contained the search terms 'phytase', 'safe', 'toxic', 'adverse' and 'incompatibilities'. The searches covered the period 2010–2020. The number of hits identified after duplicates removal was 402. Titles and abstracts were further screened against the inclusion criteria *information concerning potentially harmful effects of phytases on humans or production animals*, resulting in 32 hits, from which 19 were EFSA scientific opinions of phytase additives. The 13 remaining publications were full-text screened and 11 were considered for this assessment. Only one publication referred to sensitising effects of several enzymes (including phytases) on manufacturer workers, while the remaining publications did not mention safety concerns.⁴¹

None of the scientific publications finally considered reported safety concerns with the additive under assessment.

The new formulation does not introduce any hazards for the target animals, consumers, users and environment not already considered in the previous assessments.

3.2.1. Conclusions on the safety

Considering the previous conclusions on the safety, the information provided and the fact that the changes in the manufacturing and the new liquid form did not introduce any causes of concern, the FEEDAP Panel considers that there is no evidence to reconsider the conclusions reached in the previous opinions (EFSA FEEDAP Panel and EFSA GMO Panel, 2009; EFSA FEEDAP Panel, 2010, 2011). Therefore, the Panel concludes that the additive remains safe for poultry for fattening, breeding and laying, and all pigs, the consumer and the environment under the authorised conditions of use. Regarding user safety, the Panel reiterates that the additive is not a skin or eye irritant or sensitiser, but should be considered a potential respiratory sensitiser.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation, including the introduction of the new additive formulation.

⁴⁰ Technical dossier/Section II/Supplementary Information June 2020/FEC_renewal_Supplementary information.pdf.

⁴¹ Technical dossier/Section III/Supplementary Information June 2020/FEC_renewal_Supplementary information.pdf and Annex 13_Budnik_et_al_2017_Occup_Environ_Med_74_39-45.pdf.

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 Regulation⁴² and Good Manufacturing Practice.

4. Conclusions

The applicant has provided evidence that the additive currently in the market complies with the existing conditions of authorisation.

The Panel concludes that the additive remains safe for poultry for fattening, breeding and laying, and all pigs, the consumer and the environment under the authorised conditions of use. Regarding user safety, the Panel reiterates that the additive is not a skin or eye irritant or sensitiser but should be considered a potential respiratory sensitiser.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

These conclusions also apply to the new proposed liquid formulation Finase[®] EC 5 L.

5. Documentation as provided to EFSA/Chronology

Date	Event
15/04/2019	Dossier received by EFSA. 6-phytase. Submitted by Roal Oy
20/05/2019	Reception mandate from the European Commission
02/08/2019	Application validated by EFSA – Start of the scientific assessment
18/09/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: 1. Characterisation of the additive: a) Characterisation of the production strain, b) Genetic modifications of the production strain, c) Purity, d) Manufacturing. 2) Safety</i>
16/06/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
02/09/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: 1. Characterisation of the additive: a) Characterisation of the production strain, b) Genetic modifications of the production strain, c) Purity, d) Manufacturing. 2) Safety</i>
14/10/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
18/11/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

- EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. EFSA Journal 2007;5(12):587, 16 pp. <https://doi.org/10.2903/j.efsa.2007.587>
- EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis K, Allende A, Alvarez-Ordóñez A, Bolton D, Bover-Cid S, Chemaly M, Davies R, De Cesare A, Hilbert F, Lindqvist R, Nauta M, Peixe L, Ru G, Simmons M, Skandamis P, Suffredini E, Coconcelli PS, Fernández Escámez PS, Maradona MP, Querol A, Suarez JE, Sundh I, Vlaskovic J, Barizzzone F, Correia S and Herman L, 2020. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA (2017–2019). EFSA Journal 2020;18(2):5966, 56 pp. <https://doi.org/10.2903/j.efsa.2020.5966>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2010. Scientific Opinion on the safety of Finase[®] EC (6-phytase) as a feed additive for turkeys for fattening. EFSA Journal 2010;8(3):1553, 4 pp. <https://doi.org/10.2903/j.efsa.2010.1553>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Scientific Opinion on the safety of Finase[®] EC (6-phytase) as feed additive for sows. EFSA Journal 2011;9(3):2111, 5 pp. <https://doi.org/10.2903/j.efsa.2011.2111>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013. Guidance on the renewal of the authorisation of feed additives. EFSA Journal 2013;11(10):3431, 8 pp. <https://doi.org/10.2903/j.efsa.2013.3431>

⁴² Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 268, 8.2.2005, p. 1.

- EFSA FEEDAP Panel and EFSA GMO Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed and Panel on Genetically Modified Organisms), 2009. Scientific Opinion on the safety and efficacy of Finase® EC (6-phytase) as a feed additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, ducks and other minor poultry species, piglets (weaned), pigs for fattening and sows. EFSA Journal 2009;7(11):1380, 27 pp. <https://doi.org/10.2903/j.efsa.2009.1380>
- 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, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Kärenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. <https://doi.org/10.2903/j.efsa.2018.5206>
- Frisvad JC, Møller LLH, Larsen TO, Kumar R and Arnau J, 2018. Safety of the fungal workhorses of industrial biotechnology: update on the mycotoxin and secondary metabolite potential of *Aspergillus niger*, *Aspergillus oryzae*, and *Trichoderma reesei*. Applied Microbiology and Biotechnology, 2018, 9481–9515. <https://doi.org/10.1007/s00253-018-9354-1>
- Kubicek CP, Herrera-Estrella A, Seidl-Seiboth V, Martinez DA, Druzhinina IS, Thon M, Zeilinger S, Casas-Flores S, Horwitz BA, Mukherjee PK, Mukherjee M, Kredics L, Alcaraz L, Aerts A, Antal Z, Atanasova L, Cervantes-Badillo MG, Challacombe J, Chertkov O, McCluskey K, Coulpier F, Deshpande N, von Döhren H, Ebbole DJ, Esquivel-Naranjo EU, Fekete E, Flippi M and Glaser F, Gómez-Rodríguez EY, 2011. Comparative genome sequence analysis underscores mycoparasitism as the ancestral life style of *Trichoderma*. Genome Biology, 12, R40. <https://doi.org/10.1186/gb-2011-12-4-r40>

Abbreviations

CBS	Centraal Bureau voor Schimmelcultures
CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
PET	polyethylene terephthalate