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Safety and efficacy of Panavital feed (D-glyceric acid) for chickens for fattening

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Abstract

Panavital feed is a preparation of D-glyceric acid intended to be used as a zootechnical additive in chickens for fattening. The active substance (D-glyceric acid) of the additive [REDACTED] by fermentation with *Gluconobacter frateurii*. The additive is intended to be used in chickens for fattening at a concentration from [REDACTED]. The FEEDAP Panel notes that the data provided for the characterisation of the active substance are incomplete and that data on the characterisation of the formulated additive are not provided. Based on the information available, the FEEDAP Panel cannot assess the qualitative and quantitative composition of Panavital feed. Due to lack of data, the safety of the production strain claimed to be used to produce the active substance cannot be evaluated. Based on the data provided by the applicant, the FEEDAP Panel cannot conclude on the safety of Panavital feed for the target species, the consumer, the user and the environment and on the efficacy of Panavital feed when used as feed additive.

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Table of contents

| | |
|---|----|
| Abstract..... | 1 |
| 1. Introduction..... | 4 |
| 1.1. Background and Terms of Reference as provided by the requestor..... | 4 |
| 1.2. Additional information..... | 4 |
| 2. Data and methodologies..... | 4 |
| 2.1. Data..... | 4 |
| 2.2. Methodologies..... | 4 |
| 3. Assessment..... | 4 |
| 3.1. Characterisation..... | 5 |
| 3.1.1. Manufacturing process..... | 5 |
| 3.1.2. Characterisation of the active substance..... | 5 |
| 3.1.3. Characterisation of the additive..... | 6 |
| 3.1.4. Characterisation of the production organism..... | 6 |
| 3.1.5. Stability and homogeneity..... | 6 |
| 3.1.6. Conclusions on the characterisation..... | 6 |
| 3.1.7. Conditions of use..... | 6 |
| 3.2. Safety..... | 6 |
| 3.2.1. Safety of the production strain..... | 6 |
| 3.2.2. Safety for the target species..... | 7 |
| 3.2.3. Safety for the consumer..... | 7 |
| 3.2.3.1. Residue studies..... | 7 |
| 3.2.3.2. Toxicological studies..... | 7 |
| 3.2.4. Safety for the user and environment..... | 7 |
| 3.3. Efficacy for chickens for fattening..... | 8 |
| 3.3.1. Conclusions on efficacy..... | 8 |
| 3.4. Post-market monitoring..... | 8 |
| 4. Conclusions..... | 8 |
| Documentation as provided to EFSA/Chronology..... | 8 |
| References..... | 9 |
| Abbreviations..... | 9 |
| Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Panavital feed (D-glyceric acid)..... | 11 |

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 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 received a request from Replicon Health Oy² for authorisation of the product Panavital feed (D-glyceric acid), when used as a feed additive for chickens for fattening (category: zootechnical additive; functional group: other zootechnical additives).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 15 March 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 the product Panavital feed (D-glyceric acid), when used under the proposed conditions of use (see Section 3.1.7).

1.2. Additional information

The product Panavital feed (D-glyceric acid) is not authorised as a feed additive in the European Union.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier³ in support of the authorisation request for the use of Panavital feed (D-glyceric acid) as a feed additive.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the D-glyceric acid in animal feed. The Executive Summary of the EURL report can be found in Annex A.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Panavital feed (D-glyceric acid) is in line with the principles laid down in Regulation (EC) No 429/2008⁴ and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018a), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017b) and Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c).

3. Assessment

Panavital feed is a preparation of D-glyceric acid intended to be used as a zootechnical additive in chickens for fattening (functional group: other zootechnical additives). [REDACTED]

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 Replicon Health Oy, Tekniikantie 2, 02150 Espoo (Finland).

³ FEED Dossier reference: FAD-2018-0073.

⁴ 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.

3.1. Characterisation

3.1.1. Manufacturing process

3.1.2. Characterisation of the active substance

Figure 1: Chemical structure of D-glyceric acid calcium salt dihydrate

The purity of five independent production batches of the active substance was assayed by

However, from the data provided, it is not clear if these concentrations were quantified using a reference standard.

⁵ Technical dossier/Section II/Annex 8a and Annex_II_8b.

[REDACTED]
[REDACTED] The FEEDAP Panel notes that this method is not sensitive enough to detect the presence of heavy metals and arsenic at the concentration of few mg/kg additive.
[REDACTED]

3.1.3. Characterisation of the additive

The commercial preparation of the additive Panavital feed [REDACTED]

The applicant did not provide any data on batch-to-batch variation analysis of the active substance and did not propose specifications for the additive under assessment.

No information on the possible presence of chemical impurities or microbial contamination in the final product was provided. The possible presence of viable cells from the production strain in the final products was not studied.

[REDACTED] No data on dusting potential of the additive were provided, but the applicant assumes it to that of wheat flour.

3.1.4. Characterisation of the production organism

[REDACTED]
[REDACTED] The active substance glyceric acid under assessment is produced by a non-genetically modified strain of *G. frateurii*. [REDACTED]

[REDACTED] No certificate of deposition was provided.
[REDACTED]

[REDACTED] However, the taxonomical identification has not been confirmed by the applicant. No information was provided on the antimicrobial susceptibility (by phenotype or genotype), antimicrobial activity, and the toxigenic potential of the production strain.

3.1.5. Stability and homogeneity

The applicant did not provide stability studies in which the content of the active substance was analysed. Instead, [REDACTED]

[REDACTED] However, the Panel considered that this information does not provide evidence on the shelf-life of the additive.

No data were provided on the stability of the additive in premixtures/feed and in water for drinking and on the capacity to homogeneously distribute in these matrices.

3.1.6. Conclusions on the characterisation

The FEEDAP Panel notes that the data provided for the characterisation of the active substance are incomplete as quantitative analysis of D-glyceric acid, calcium and water were provided only for one batch. Similarly, insufficient data were provided to characterise the production strain. Data on the characterisation of the formulated additive (including batch to batch variation, purity and physico-chemical properties) were not provided. Based on the data available, the FEEDAP Panel cannot assess the qualitative and quantitative composition and therefore cannot conclude on the characterisation of the additive under assessment.

3.1.7. Conditions of use

Panavital feed is intended to be used as a feed additive in feed for chickens for fattening at a concentration from [REDACTED]

3.2. Safety

3.2.1. Safety of the production strain

The identity of the production strain as *G. frateurii* was not confirmed by the applicant. No information was provided on the antimicrobial susceptibility, antimicrobial activity, and toxigenic

potential of the production strain. The possible presence of viable cells of the production strain and/or its DNA in the final product was not investigated. Therefore, the FEEDAP Panel cannot conclude on the safety of the active substance D-glyceric acid of Panavital feed, produced by fermentation with *G. frateurii* [REDACTED], regarding the production strain.

Furthermore, the FEEDAP Panel noted that, according to the applicant, other strains may be used to produce the active substance. However, no information was provided on any other production strains.

3.2.2. Safety for the target species

The applicant provided a trial in chickens for fattening [REDACTED] which could not be considered further in the assessment due to the following limitations: [REDACTED]

[REDACTED]; the applicant [REDACTED] but these were not described, only partial results in graphs are given, raw data, statistical analysis and report describing the study were not provided.

In the absence of adequate data, the FEEDAP Panel cannot conclude on the safety of the additive Panavital feed for chickens for fattening.

3.2.3. Safety for the consumer

3.2.3.1. Residue studies

The applicant provided a report [REDACTED] One study was conducted [REDACTED] the other one was performed [REDACTED]

[REDACTED] These studies were not further considered since in the first study only muscle samples obtained from a limited number of animals were reported, and in the second study no control was included. Moreover, the reporting of the studies is not sufficient.

3.2.3.2. Toxicological studies

The applicant submitted a limited set of toxicological studies performed using D-glyceric acid, consisting of an *in vitro* study (cultured neuro cells) [REDACTED] and two *in vivo* toxicity studies. The first *in vivo* study is a 3-week rat study,¹⁴ the second one is aimed at investigating the effects of D-glyceric acid on cellular respiration in the worm *Caenorhabditis elegans*. [REDACTED]

These studies were not further considered in the assessment. The *in vitro* study was conducted on rat cortical neurons. This investigation does not allow the identification of possible adverse effects on organs and tissues other than those at level of nervous system and so it cannot be used for the assessment. Moreover, the reporting of the study is limited. The *in vivo* study in rats was poorly reported (e.g. raw data, statistical outputs not provided), only considered effects on body weight and feed consumption and no evaluation on other toxicological parameters was conducted (e.g. histopathology not evaluated). The study in *C. elegans* was not considered relevant for the toxicological evaluation of the substance under assessment. Furthermore, in the absence of a proper characterisation of the additive, the correlation between the test item used in the toxicological studies and the additive under assessment remains unclear.

No other toxicological studies, as required in the relevant guidance document (EFSA FEEDAP Panel, 2017a,b,c) were submitted.

Therefore, in the absence of adequate data, the FEEDAP Panel cannot conclude on the safety of Panavital feed for the consumers.

3.2.4. Safety for the user and environment

The applicant did not provide any data to support the safety of the additive for the users or the environment. Therefore, the Panel cannot conclude on the safety of the additive for the users and the environment.

¹⁴ [REDACTED] Technical dossier/Section III/Annex_III_5. [REDACTED]

3.3. Efficacy for chickens for fattening

Panavital feed is intended to be used as zootechnical additive in chickens for fattening under the functional group 'other zootechnical' – [REDACTED]

In support of the efficacy of the product the applicant submitted only summary data on five efficacy trials performed in chickens for fattening. [REDACTED]

However, the details on the methodologies followed in all these studies were not provided, analytical confirmation of the levels of the additive in the diets was not given and the results were only briefly described.

The applicant also submitted data on three field trials. The FEEDAP Panel notes the limited acceptability of these data due to the lack of a proper control and the inadequacy of the reporting.

Consequently, the FEEDAP Panel is not in the position to perform a proper assessment of the studies provided by the applicant to support the efficacy of the additive.

3.3.1. Conclusions on efficacy

Based on the information provided, the FEEDAP Panel cannot conclude on the efficacy of Panavital feed when used as a feed additive in chickens for fattening at a concentration ranging from 10 to 150 mg/kg of feed and at a concentration ranging from 6.5 to 130 mg/L in water for drinking.

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 Regulation¹⁷ and Good Manufacturing Practice.

4. Conclusions

The FEEDAP Panel concludes that the active substance (D-glyceric acid) and the additive are not properly characterised.

Owing to the lack of data, the FEEDAP Panel cannot conclude on the safety of the production strain.

Based on the data provided by the applicant, the FEEDAP Panel cannot conclude on the safety of Panavital feed for the target species, for the consumer, for the user and for the environment.

Based on the data provided, the FEEDAP Panel cannot conclude on the efficacy of Panavital feed when used as a feed additive in chicken for fattening.

Documentation as provided to EFSA/Chronology

| Date | Event |
|------------|--|
| 19/10/2018 | Dossier received by EFSA. Panavital feed (D-glyceric acid) for broiler chickens. Submitted by Replicon Health Oy |
| 07/12/2018 | Reception mandate from the European Commission |
| 15/03/2019 | Application validated by EFSA – Start of the scientific assessment |
| 14/06/2019 | Comments received from Member States |

¹⁷ 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 35, 8.2.2005, p. 1.

| Date | Event |
|------------|--|
| 25/04/2019 | 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: Methods of analysis</i> |
| 14/11/2019 | No supplementary information received from the applicant - Scientific assessment re-started |
| 19/11/2019 | Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives |
| 17/03/2020 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment |

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Abbreviations

| | |
|---------|--|
| DTA | differential thermogravimetric analysis |
| EURL | European Union Reference Laboratory |
| FEEDAP | EFSA Panel on Additives and Products or Substances used in Animal Feed |
| GC–MS | gas chromatography–mass spectrometry |
| HPLC | high-performance liquid chromatography |
| ICP–OES | inductively coupled plasma–optical emission spectroscopy |
| IUPAC | International Union of Pure and Applied Chemistry |
| MRL | maximum residue limit |
| RI | refractive index |

UV ultraviolet
XRD X-ray diffraction
XRF X-ray fluorescence

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Panavital feed (D-glyceric acid)

In the current application authorisation is sought under Article 4(1) for D-glyceric acid under the category/functional group (4d) “zootechnical additives”/“other zootechnical additives”, according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, authorisation is sought for the use of the feed additive for broiler chickens.

The feed additive is to be marketed as D-glyceric acid calcium salt dihydrate corresponding to approximately of 74% (w/w) of D-glyceric acid as an active substance.

The feed additive is intended to be incorporated into premixtures, feedingstuffs and water for drinking. The Applicant proposed the levels of D-glyceric acid ranging from 10 to 200 mg/kg feedingstuffs and 6.5 to 130 mg/L water. Furthermore, the Applicant proposed the Maximum Residue Limits (MRLs) for D-glyceric acid ranging from 500 to 1000 mg/kg tissues.

For the quantification of the D-glyceric acid content in the feed additive the Applicant proposed an in-house method based on high performance liquid chromatography (HPLC) coupled to an ultraviolet (UV) and a refractive index (RI) detection. The method was further verified by using another in-house method based on gas chromatography-mass spectrometry (GC-MS).

Based on the available information, the EURL recommends the HPLC-UV/RI method submitted by the Applicant for official control to quantify the D-glyceric acid content in the feed additive.

For the quantification of the D-glyceric acid content in feedingstuffs the Applicant submitted an in-house method based on isotope dilution gas chromatography coupled to mass spectrometry (GC-MS) after the derivatisation. Based on unacceptable performance characteristics demonstrated of the validation and verification studies, the EURL cannot evaluate nor recommend any method for official control to quantify the D-glyceric acid content in the feedingstuffs.

For the quantification of the D-glyceric acid content in premixtures the Applicant proposed no analytical method and no validation, neither verification data were submitted. Based on the available information, the EURL cannot evaluate nor recommend any method for official control to quantify the D-glyceric acid content in premixtures.

For the quantification of the D-glyceric acid content in water for drinking the Applicant suggested using the above-mentioned methods based on HPLC and GC-MS. However, no proves of the applicability of the methods to quantify the D-glyceric acid at the proposed levels in water (6.5 to 130 mg/L) were submitted by the Applicant. Based on the available information, the EURL cannot evaluate nor recommend any method for official control to quantify the D-glyceric acid content in water for drinking.

For the quantification of the D-glyceric acid content in tissues the Applicant submitted the above-mentioned GC-MS method. Acceptable performance characteristics were reported in the frame of the validation study for the quantification of the D-glyceric acid content in two spiked muscle samples and real samples of tissues and plasma. However, the Applicant did not provide the verification data from the second independent laboratory which would demonstrate the transferability of the proposed GC-MS method to another laboratory. Based on the available information, the EURL cannot evaluate nor recommend any method for official control to quantify the D-glyceric acid content in the tissues (or plasma).

For the identification/characterisation of the feed additive the Applicant submitted several methods based on i) X-ray diffraction (XRD) for the determination of crystallinity of the feed additive; ii) X-ray fluorescence (XRF) and inductively coupled plasma-atomic emission spectrometry (ICP-AES) for the determination of calcium content in the feed additive; high performance liquid chromatography (HPLC) for the identification of glyceric acid in the feed additive; and differential thermo gravimetric analysis (DTA) for the determination of crystalline water content in the feed additive. In addition, the EURL considers an infrared spectrometry (IR) together with the above-mentioned methods fit-for-purpose.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.