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Safety and efficacy of a feed additive consisting of manganese chelate of amino acids hydrate for all animal species (Zinpro Animal Nutrition (Europe) Inc.)

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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 safety and efficacy of manganese chelate of amino acids hydrate, brand name Availa[®]Mn, for all animal species, based on a dossier submitted for the modification of the terms of the authorisation of the additive. The additive is currently authorised using amino acids derived from soya protein and with a minimum content of 8% manganese. The applicant proposed (i) to include amino acids from other sources such as hydrolysed corn gluten, hydrolysed potato protein and hydrolysed poultry feather meal; (ii) to introduce a minimum specification for free amino acids of 17%; and (iii) to introduce a tighter specification on the mineral content (manganese), with an inclusion level of 8–9%. The additive, produced using different proposed sources of hydrolysed proteins, complies with the specifications set by Commission Regulation (EU) 2017/1490. The FEEDAP Panel considers that the use of the different proposed sources of hydrolysed proteins (i.e. soy, feather meal, potato and corn gluten) do not modify the conclusions reached in the previous assessments on the safety for the target species, consumers, environment and efficacy of the additive above. Concerning the safety for the users, the additive should be considered as a skin and eye irritant and a skin sensitiser. The additive has a high dusting potential; however, in the absence of data on the concentration of zinc in the dust it is not possible to make the assessment of the exposure by inhalation.

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Keywords: nutritional additive, compounds of trace elements, manganese chelate, Availa[®] Mn, safety, efficacy

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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 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a request from Zinpro Animal Nutrition (Europe) Inc.² for modification of the terms authorisation of the product manganese chelate of amino acids hydrate, when used as a feed additive for all animal species (category: nutritional additive; functional group: compound of trace elements).

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 13(3) (modification of the authorisation 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 19 January 2021.³

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 manganese chelate of amino acids hydrate, when used under the proposed conditions of use (see Section 3.1.4).

1.2. Additional information

The additive 'manganese chelate of amino acids hydrate' is used as a nutritional additive to meet the manganese requirement of all animal species. The safety and efficacy of the additive was the subject of an EFSA opinion delivered in 2013 (EFSA FEEDAP Panel, 2013).

The additive is currently authorised in the European Union (EU) for all animal species, under the category of nutritional feed additive and functional group of compounds of trace elements (registration number 3b504).⁴

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the use of manganese chelate of amino acids hydrate as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies.

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.⁶

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 Zinpro Animal Nutrition (Europe), Inc. Akkerdistel 2E. 5831 PJ. Boxmeer. The Netherlands.

³ A new mandate was received in EFSA on 29/1/2020.

⁴ Commission Implementing Regulation (EU) 2017/1490 of 21 August 2017 concerning the authorisation of manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide as feed additives for all animal species. OJ L 216, 22.8.2017, p. 1.

⁵ FEED dossier reference: FAD-2019-0082.

⁶ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/default/files/amendment-finrep-manganese.pdf>

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of manganese chelate of amino acids hydrate is in line with the principles laid down in Regulation (EC) No 429/2008⁷ and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on studies concerning the safety of use of the additive for the environment (EFSA FEEDAP Panel, 2019) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive, manganese chelate of amino acids as a nutritional feed additive (functional group: compounds of trace elements) is a source of manganese for all animal species in feed up to the maximum authorised manganese levels in the EU. The additive will be referred in this scientific opinion as Availa®Mn (trade name of the additive).

The authorisation outlines the additive composition as 'manganese amino acid complex where the manganese and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 8% manganese'.

With this application the applicant is requesting a modification of the current authorisation as follows: (i) to include other sources of amino acids such as hydrolysed corn gluten, hydrolysed potato protein and hydrolysed poultry feather meal; (ii) to introduce a minimum specification for free amino acids of 17%; and (iii) to introduce a tighter specification on the mineral content (manganese), with an inclusion level of 8–9%.

3.1. Characterisation

3.1.1. Manufacturing process

[REDACTED]

3.1.2. Characterisation of the additive

The additive contains manganese chelate of amino acids hydrate (32–33%), calcium carbonate (20–21%) and cellulose (46–47%).

The current authorisation specifies a manganese content $\geq 8\%$. The applicant is proposing to introduce the following specifications: $\geq 17\%$ free amino acids and to limit the manganese content to a level of 8–9%.

The applicant provided analytical data on five batches of the additive with amino acids derived from each of the proposed sources of hydrolysed proteins (i.e. soy, feather meal, potato and corn gluten; five batches each). Additional five batches derived from a (unspecified) mixture of the new sources of

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 Technical dossier/Section II/Annexes/Annex_ II-36.

⁹ Technical dossier/Section II/Annexes/Annex_ II-37.

¹⁰ Technical dossier/Section II/Annexes/Annex_ II-38.

protein were provided. The batches were analysed for manganese, free amino acids and total amino acids. The results (in range) are reported in Table 1.

Table 1: Batch-to-batch variation for Availa®Mn when the amino acids have been sourced from soy, feather meal, potato and corn.

Protein source	Manganese % ^(a)	Free amino acids % ^(b)	Total amino acids % ^(b)
Soy ^(c)	8.2–8.8	17.1–20	23.3–23.8
Feather meal ^(d)	8.2–8.8	17.3–20.5	23.2–24
Potato ^(e)	8.2–8.8	17.6–21.1	23.1–24.1
Corn gluten ^(f)	8.4–8.9	18.5–19.6	23.1–24.1
Mix ^(g)	8.3–8.6	20.1–20.6	21.1–21.6

(a): Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) – EN 15510.

(b): ISO 13903:2005 Animal feeding stuffs – Determination of amino acids.

(c): Technical dossier/Section II/Annexes/Annex_II-10, II-11, II-12, II-13, II-14.

(d): Technical dossier/Section II/Annexes/Annex_II-15, II-16, II-17, II-18, II-19.

(e): Technical dossier/Section II/Annexes/Annex_II-20, II-21, II-22, II-23, II-24.

(f): Technical dossier/Section II/Annexes/Annex_II-25, II-26, II-27, II-28, II-29.

(g): Technical dossier/Section II/Annexes/Annex_II-5, II-6, II-7, II-8 and II-9.

All the batches analysed comply with the current authorisation and with the newly proposed specifications.

Three batches of the additive with amino acids derived from each source of hydrolysed proteins (i.e., soy, feather meal, potato and corn gluten) were analysed for impurities. The results (in range) are reported in Table 2.

Table 2: Results of the analysis for impurities (in range) for the different proposed sources of hydrolysed proteins.

Protein source	Arsenic (mg/kg)	Cadmium (mg/kg) ^(a)	Lead (mg/kg)	Mercury (mg/kg) ^(a)	Nickel (mg/kg)	Aflatoxin B1 (µg/kg)	Ochratoxin A (µg/kg) ^(a)
Soy ^(b)	0.95–2.13	0.11–0.20	7.23–8.25	< 0.08	1.19–1.31	1	< 0.1
Feather meal ^(c)	0.95–2.13	< 0.1	7.17–8.36	< 0.08	0.77–0.91	3–4	< 0.1
Potato ^(d)	0.95–2.13	0.12–0.18	9.04–9.37	< 0.08	1.01–1.54	5–6	< 0.1
Corn gluten ^(e)	0.46–0.71	< 0.1	4.23–5.48	< 0.08	1.51–1.86	4–6	< 0.1

(a): '<' refers to the limit of detection (LOD).

(b): Technical dossier/Section II/SIn_310521/Annexes/Annex_1, 2, 3.

(c): Technical dossier/Section II/SIn_310521/Annexes/Annex_4, 5, 6.

(d): Technical dossier/Section II/SIn_310521/Annexes/Annex_7, 8, 9.

(e): Technical dossier/Section II/SIn_310521/Annexes/Annex_10, 11, 12.

Based on the results, no concern arises on possible presence of impurities in the final product.

No information on the dioxins content was provided in the current submission although the applicant states that dioxins are routinely analysed as part of the quality control system.¹¹

The dusting potential of three batches of the additive with amino acids derived from each source of hydrolysed proteins was determined using the Stauber–Heubach method.¹² Results showed values on average of 2,425 mg/m³ (range 2,360–2,546 mg/m³) for soy, 1,633 mg/m³ (range 1,602–1,682 mg/m³) for feather meal, 1,244 mg/m³ (range 1,175–1,331 mg/m³) for potato and 1,582 mg/m³ (range 1,544–1,656 mg/m³) for corn gluten.

3.1.3. Characterisation of the compound

The applicant stated that the proposed modifications in the manufacturing process do not result in a different product to the one currently authorised.

¹¹ Technical dossier/Section II/SIn_310521.

¹² Technical dossier/FAD-2019-0082_SIn_050821/FAD-2019-0082_EFSA Availa Mn Supplementary Information Request_20210705.

The compound of trace element is manganese chelate of amino acids hydrate, registration number 3b504, molecular formula $[R-NH_2-CH-COO]_{(1-3)}Mn - X$, chemical formula $Mn-(X)_{1-3},n \cdot H_2O$ where X is equal to any amino acid coming from hydrolysed protein sources. No IUPAC and CAS number were made available.

The complex is a 1:1 metal to amino acid, there is a counter ion (bisulfate) associated with the manganese that completes the complex. Therefore, the molecular weights of the complex vary depending on which free amino acid and counter ions are present in the complex. The molecular weight range will be between 227 and 326 Da.¹³

The applicant provided the analysis of the molecular weight distribution in one batch of the additive, analysed with a size exclusion chromatography with UV detection at 220 nm,¹⁴ resulting in 96% < 500 Da % area and 4% > 500% Da area. These results show compliance with the specification of the current authorisation on maximum 10% of molecules exceeding 1,500 Da.

No new data have been provided regarding the physical properties or stability of the additive other than on dusting potential. Since the changes introduced in the manufacturing process are not expected to have a significant effect on these characteristics, the data described in the previous opinion still apply (EFSA FEEDAP Panel, 2013).

3.1.4. Conditions of use

Availa®Mn is intended to be used in all animal species or categories as a source of manganese. The additive is intended to be used in all types of feed, either in mashed or pelleted form. No minimum inclusion level is recommended.

The following maximum levels of manganese in complete feed with a moisture content of 12% are currently authorised in the EU¹⁵:

- Fish: 100 mg manganese/kg complete feed
- Other species and categories: 150 mg manganese/kg complete feed.

The applicant did not request any modification on the conditions of use as authorised.

3.2. Safety and efficacy

The safety of manganese chelate of amino acids hydrate was already assessed by the FEEDAP Panel in its previous opinion (EFSA FEEDAP Panel, 2013). In this opinion the Panel concluded that 'Manganese chelate of amino acids hydrate is considered a safe source of manganese for all animal species/categories, provided that the current maximum total contents of manganese authorised in feed are respected. [...] The use of the additive in animal nutrition is of no concern for the safety of consumers, provided that the current maximum total contents of manganese authorised in feed are respected'.

The additive should be considered as a skin and eye irritant and as a skin sensitiser. The additive has a high dusting potential; however, in the absence of data on the concentration of manganese in the dust, it is not possible to make the assessment of the exposure by inhalation.

In the previous opinion, the Panel concluded that 'the use of manganese chelate of amino acids, hydrate, in animal nutrition for all animal species is not of concern for the environment, provided that the current maximum total contents of manganese authorised in feed are respected'.

With regard to efficacy, the Panel concluded that 'Manganese chelate of amino acids, hydrate, is an effective source of manganese for all animal species and categories'.

Taking into account the proposed modifications in the manufacturing process and that the characterisation and the conditions of use of the additive are the same as the ones already assessed and authorised, the Panel considers that the use of the different proposed sources of hydrolysed proteins (i.e. soy, feather meal, potato and corn gluten) do not modify the conclusions on the safety and efficacy of the additive above.

¹³ The lowest MW would be with 1 manganese molecule plus 1 glycine (the lowest MW amino acid) and 1 bisulfate anion. This would be about 227 Da (75.06 for glycine, 97.07 for bisulfate and 55 for manganese). The highest MW would be with 1 manganese molecule plus 1 arginine (Tryptophan is destroyed under our hydrolysis conditions) and 1 bisulfate anion. This would be about 326 Da (174 for arginine, 97.07 for bisulfate and 55 for manganese).

¹⁴ Technical dossier/Section II/SIn_310521/Annexes/Annex_13, The calculation of molecular weight distribution was based on a calibration line consisting of glutamic acid and lysine.

¹⁵ Commission Implementing Regulation (EU) 2017/1490 of 21 August 2017 concerning the authorisation of manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide as feed additives for all animal species. OJ L 216, 22.8.2017, p. 1.

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 Regulation¹⁶ and Good Manufacturing Practice.

3.4. Conclusions

Manganese chelate of amino acids hydrate produced using various new proposed sources of hydrolysed proteins (i.e. soy, feather meal, potato and corn gluten) complies with the specifications set by Commission Regulation (EU) 2017/1490. The FEEDAP Panel considers that the conclusions on safety and efficacy reached in the previous assessment apply to the manganese chelate of amino acids hydrate produced using the different proposed sources of hydrolysed proteins.

The FEEDAP Panel concludes that manganese chelate of amino acids hydrate is a safe source of manganese for all animal species, considering the maximum contents for total manganese in feedingstuffs set in the EU.

Manganese chelate of amino acids hydrate used in animal nutrition is not expected to pose a risk for the consumer safety up to the maximum authorised levels of total manganese in feedingstuffs.

The additive should be considered as a skin and eye irritant and a skin sensitiser. The additive has a high dusting potential; however, in the absence of data on the concentration of manganese in the dust, it is not possible to make the assessment of the exposure by inhalation.

The FEEDAP Panel concludes that the use of manganese-containing feed additives in animal production would not pose a risk for the environment, provided that the current maximum total contents of manganese authorised in feed are respected.

Manganese chelate of amino acids hydrate has the potential to act as an efficacious source of manganese in meeting animal requirements.

4. Documentation as provided to EFSA/Chronology

Date	Event
09/12/2019	Dossier received by EFSA. Manganese chelate of amino acids hydrate (Availa® Mn) for all animal species. Submitted by Zinpro Animal Nutrition (Europe), Inc.
29/01/2020	Reception mandate from the European Commission
19/01/2021	Application validated by EFSA – Start of the scientific assessment
16/03/2021	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: characterisation</i>
20/04/2021	Comments received from Member States
31/05/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
05/07/2021	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: characterisation</i>
19/08/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
29/09/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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¹⁶ 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.

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Abbreviations

CAS	Chemical Abstracts Service
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
MW	molecular weight