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Safety and efficacy of a feed additive consisting of iron (II) chelate of amino acids hydrate for all animal species

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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 iron (II) chelate of amino acids hydrate for all animal species, brand name Availa[®] Fe, 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 9% iron. 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 include a minimum specification for free amino acids of 18%; (iii) to introduce a tighter specification on the mineral content (iron), with an inclusion level of 9–10%. The additive, produced using different proposed sources of hydrolysed proteins, complies with the specifications set by Commission Regulation (EU) 2017/2330. 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, iron (II) chelate, Availa[®] Fe, 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 Availa® Fe (iron (II) 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 Availa®Fe (active compound: iron (II) chelate of amino acids hydrate), when used under the proposed conditions of use (see Section 3.1.4).

1.2. Additional information

The additive iron (II) chelate of amino acids hydrate is used as a nutritional additive to meet the iron 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 3b106).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 iron (II) chelate of amino acids hydrate as a feed additive. The technical dossier was prepared following the provisions of Article 13 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 6/5/2019.

⁴ Commission Implementing Regulation (EC) No 2017/2330 of the European Commission of 14 December 2017 concerning the authorisation of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran as feed additive for piglets and amending Regulations (EC) No 1334/2003 and (EC) No 479/2006 OJ L 333, 15.12.2017, p. 41.

⁵ FEED dossier reference: FAD-2019-0083.

⁶ The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/amended_finrep_iron_group_fad-2010-0095.pdf

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Availa® Fe (iron (II) 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, iron (II) chelate of amino acids hydrate is authorised as a nutritional feed additive (functional group: compounds of trace elements) is a source of iron for all animal species in feed up to the maximum authorised iron levels in the EU. The additive will be referred in this scientific opinion as Availa®Fe (trade name of the additive).

The authorisation outlines the additive composition as 'iron (II) amino acid complex where the iron and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 9% iron'.

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 include a minimum specification for free amino acids of 18%; (iii) to introduce a tighter specification on the mineral content (iron), with an inclusion level of 9–10%.

3.1. Characterisation

3.1.1. Manufacturing process

[REDACTED]

3.1.2. Characterisation of the additive

The additive contains iron (II) chelate of amino acids hydrate reported as iron (9%), calcium carbonate (10–20%) and cellulose (40–50%).

The current authorisation specifies an iron content $\geq 9\%$. The applicant is proposing to introduce the following specifications: $\geq 18\%$ free amino acids and to limit the iron content to a level of 9–10%.

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

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.

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

Protein source	Iron % ^(a)	Free amino acids % ^(b)	Total amino acids % ^(b)
Soy ^(c)	9.1–9.7	19.3–21.8	24.7–25.6
Feather meal ^(d)	9.2–9.8	19.9–21.2	24.8–25.6
Potato ^(e)	9.3–9.7	18.9–22.2	24.7–25.4
Corn gluten ^(f)	9.1–9.6	18.6–22.1	24.7–25.4
Mix ^(g)	9.2–9.6	22.1–22.6	23.4–23.8

(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 the 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)	2.10–2.49	0.65–0.83	2.42–2.65	< 0.08	0.76–0.92	1–2	< 0.1
Feather meal ^(c)	< 0.19	< 0.1	0.74–0.85	< 0.08	0.48–0.66	2–3	< 0.1
Potato ^(d)	1.38–1.56	1.29–1.57	1.08–1.16	< 0.08	1.19–1.31	3–5	< 0.1
Corn gluten ^(e)	1.33–1.41	1.12–1.36	1.44–1.62	< 0.08	1.29–1.36	2–4	< 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 3,092 mg/m³ (range 3,080–3,112 mg/m³) for soy, 2,677 mg/m³ (range 2,517–2,800 mg/m³) for feather meal, 2,163 mg/m³ (range 2,097– 2,221 mg/m³) for potato and 2,217 mg/m³ (range 2,174– 2,296 mg/m³) for corn gluten (mg airborne dust per m³ of air).

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-2019-0081_SIn_050821/FAD-2019-0081_EFSA Availa Cu Supplementary Information Request_20210705.

The compound of trace element is iron (II) chelate of amino acids hydrate, molecular formula $[R-NH_2-CH-COO]_{(1-3)}Fe - X$, chemical formula $Fe-(X)_{1-3},n \cdot H_2O$, 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 iron 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 228 Da to 327 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 95% <500 Da % area and 5% >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®Fe is authorised for use as a source of iron for all animal species and categories. No minimum inclusion level is recommended.

The following maximum levels of iron in complete feed with a moisture content of 12% are currently authorised in the EU⁴:

- Ovine: 500 mg iron/kg complete feed
- Bovines: 450 mg iron/kg complete feed
- Poultry: 450 mg iron/kg complete feed
- Piglets up to 1 week before weaning: 250 iron/kg complete feed
- Pet animals: 600 mg iron/kg complete feed
- Other species: 750 mg iron/kg complete feed.

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

3.2. Safety and Efficacy

The safety of iron (II) 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 the additive 'is considered safe for all animal species/categories when used up to the currently authorised maximum content of total iron in complete feed. The FEEDAP Panel is not in the position to derive a maximum safe iron concentration in feed for horses or fish. Since iron chelate of amino acids, hydrate, will be used as a substitute for other iron compounds, its use in animal nutrition would not modify consumer exposure to iron'.

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 iron in the dust it is not possible to make the assessment of the exposure by inhalation.

In the previous opinion, the Panel concluded that 'considering the high background concentration of iron in soil and water, the supplementation of feed with iron chelate of amino acids, hydrate, is not expected to pose an environmental risk'.

With regard to efficacy, the Panel concluded that the additive 'is an effective source of iron 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 iron molecule plus 1 glycine (the lowest MW amino acid) and 1 bisulfate anion. This would be about 228 Da (75 for glycine, 97 for bisulfate and 56 for iron). The highest MW would be with 1 iron molecule plus 1 arginine (Tryptophan is destroyed under our hydrolysis conditions) and 1 bisulfate anion. This would be about 327 Da (174 for arginine, 97 for bisulfate and 56 for iron).

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.

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 Regulation¹⁵ and Good Manufacturing Practice.

4. Conclusions

Iron (II) 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) 2017/2330. The FEEDAP Panel considers that the conclusions on safety and efficacy reached in the previous assessment apply to the iron chelate of amino acids hydrate produced using the different proposed sources of hydrolysed proteins.

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

Iron (II) 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 iron in feedingstuffs.

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 iron in the dust it is not possible to make the assessment of the exposure by inhalation.

The FEEDAP Panel concludes that the use of iron-containing feed additives in animal production is not expected to pose a risk for the environment.

Iron (II) chelate of amino acids hydrate has the potential to act as an efficacious source of iron in meeting animal requirements.

5. Documentation as provided to EFSA/Chronology

Date	Event
09/12/2019	Dossier received by EFSA. Iron chelate of amino acids hydrate (Availa® Fe) 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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¹⁵ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 October 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
ICP-AES	inductively coupled plasma optical (atomic) emission spectrometry
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
MW	molecular weight