Adopted: 14 March 2024

DOI: 10.2903/j.efsa.2024.8734

efsa JOURNAL

SCIENTIFIC OPINION

Safety for the user of the feed additive consisting of ferric tyrosine chelate (TYFER™) for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding (Akeso Biomedical, Inc)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | Vasileios Bampidis | Giovanna Azimonti | Maria de Lourdes Bastos | Henrik Christensen | Mojca Durjava | Birgit Dusemund | Maryline Kouba | Marta López-Alonso | Secundino López Puente | Francesca Marcon | Baltasar Mayo | Alena Pechová | Mariana Petkova | Fernando Ramos | Roberto Edoardo Villa | Ruud Woutersen | Jaume Galobart | Fabiola Pizzo | Maria Vittoria Vettori | Paola Manini

Correspondence: feedap@efsa.europa.eu

Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) was asked to deliver a scientific opinion on the safety for the users of the feed additive consisting of ferric tyrosine chelate (TYFER™) when used as a zootechnical additive for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding. The European Commission request follows a previous opinion of the FEEDAP Panel. In that opinion, the Panel identified several risks for the users of the additive; it was listed that it posed a risk to users by inhalation, should be considered as an irritant to skin, eyes and mucous membranes, and also that, due to its nickel content, should be considered as a dermal and respiratory sensitiser. In the current application, the applicant proposed a maximum content of nickel (50 mg/kg). No changes in the manufacturing process have been reported by the applicant. In the absence of new data, the FEEDAP Panel reiterates its previous conclusion that the additive should be as an irritant to skin, eyes and mucous membranes and as a dermal and respiratory sensitiser.

KEYWORDS

ferric tyrosine chelate, gut flora stabiliser, safety, TYFER™, users, zootechnical additives

CONTENTS

1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the European Commission

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

The applicant, Akeso Biomedical Inc. USA, represented in EU by Pen & Tec Consulting SLU, is seeking a Community authorisation of Ferric Tyrosine Chelate as a feed additive to be used as gut flora stabiliser and other zootechnical additive for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding (Table1).

TABLE 1 Description of the substances.

Category of additive	Zootechnical additives
Functional group of additive	Gut and flora stabilisers and other zootechnical additives
Description	Ferric Tyrosine Chelate
Target animal category	Chickens, turkeys and minor poultry species for fattening or reared for laying/breeding
Applicant	Akeso Biomedical, Inc. USA, represented in the EU by Pen & Tec Consulting SLU
Type of request	New opinion

On 23 January 2019, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety and efficacy of the product, identified several risks for the users of the additive.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment and to allow a revision of Authority's opinion. The new data have been received on 2 August 2019.

In view of the above, the Commission asks the Authority to deliver a new opinion on ferric tyrosine chelate as a feed additive for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding based on the additional data submitted by the applicant.

1.2 | Additional information

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted in 2019 an opinion on the safety and efficacy of the preparation of ferric tyrosine chelate (TYFER™) as a feed additive for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding (EFSA FEEDAP Panel, 2019).

The product has not been authorised in the European Union (EU) as a feed additive.

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of additional information[1] to a previous application of the same product.[2] The dossier was received on 2 May 2023 and the general information and supporting documentation are available on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00352.

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of ferric tyrosine chelate (TYFER™) is in line with the principles laid down in Regulation (EC) No 429/2008[3] and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023).

[1]FEED dossier reference:.

[2]FEED dossier reference: FAD-2017-00275.

[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.

3 | ASSESSMENT

The additive ferric tyrosine chelate (TYFER™) consists of ferric tyrosine chelate. It is proposed to be used as a zootechnical additive (functional groups: gut flora stabiliser, other zootechnical additives) for chickens, turkeys and minor poultry species for fattening or reared for laying at a minimum level of 20 mg/kg complete feed. For the purpose of this scientific opinion, the additive will be referred to as TYFER™.

In a previous opinion of the FEEDAP Panel on the same additive (EFSA FEEDAP Panel, 2019), the FEEDAP Panel concluded that TYFER™ posed a risk to users by inhalation and should be considered irritant to skin, eyes and mucous membranes, and also that, due to its nickel content, should be considered a dermal and respiratory sensitiser.

The applicant has submitted additional information related to the characterisation of the additive, and this new information is the subject of this opinion.

3.1 | Characterisation of the additive and manufacturing process

The additive was characterised in the previous opinion of the FEEDAP Panel in 2019 as follows: It contains by specification a minimum of 82% total tyrosine, 8.0% iron and 6% total nitrogen, and a maximum of 3.5% of water. The product under assessment has a significant proportion (88%) of particles of respirable size (< 10 μm). The dusting potential measured in three batches of the additive was in the range between 0.085 and 2.33 g/m^3 (EFSA FEEDAP Panel, 2019).

No changes in the manufacturing process have been reported by the applicant since the last opinion. In the current assessment, the applicant has reported that a maximum nickel content has been set at 50 mg nickel/kg TYFER™.[4]

The applicant provided analytical data which showed compliance with the proposed maximum content of nickel in four batches of the additive (7–15 mg nickel/kg TYFER).[5]

No new data on the physico-chemical properties of the additive have been submitted.

3.2 | Safety for the users

In the previous opinion, the FEEDAP Panel concluded that 'users may be exposed to iron and nickel from the additive by inhalation at levels exceeding the threshold limit values TLV/OEL[6] by at least two and one orders of magnitude, respectively. The FEEDAP Panel considers that the compound under assessment poses a risk to users by inhalation. The product should also be considered as an irritant to skin, eyes and mucous membranes. Due to the presence of nickel, TYFER™ should also be considered as a dermal and respiratory sensitiser' (EFSA FEEDAP Panel, 2019).

No new data have been submitted to support the safety for the user. The only aspect that has been modified is the maximum limit set for nickel.

In the current assessment, the nickel content in the additive is specified to a maximum of 50 mg/kg. Considering the dusting potential of 2330 mg/m^3 and assuming a similar proportion of nickel in the dust as in the additive, the nickel content in the dust would be up to 0.12 mg Ni/m^3. This value would exceed the transitional limit value of 0.1 mg Ni/m^3 for the inhalable fraction and 8 h time-weighted average (8 h TWA) exposure established in Directive (EU) 2022/431.[7]

Due to the presence of nickel in the additive, it should be considered a respiratory and dermal sensitiser.

4 | CONCLUSIONS

The additive should be considered as an irritant to skin, eyes and mucous membranes and as a skin and respiratory sensitiser.

ABBREVIATIONS

FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
HACCP	hazard analysis and critical control points
OEL	occupational exposure level
TLV-TWA	threshold limit value for an 8-h time-weighted average
TYFER™	ferric tyrosine chelate

[4]Technical Dossier/Supplementary Information/Annex_II_3_2_2_Conf.

[5]Technical dossier/Supplementary Information February 2024/Appendix_1.

[6]TLV: Threshould limit value. OEL: Occupational exposure limit.

[7]Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. 16.3.2022, OJ 88/1. According to Directive (EU) 2022/431,the limit value for the inhalable fraction of nickel until 18 January 2025 is 0.1 mg/m^3 (measured as nickel). After this date limit values of 0.05 and 0.01 mg/m^3 (measured as nickel) shall apply for the respirable and the inhalable fractions, respectively.

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2023-00352

COPYRIGHT FOR NON-EFSA CONTENT

EFSA may include images or other content for which it does not hold copyright. In such cases, EFSA indicates the copyright holder and users should seek permission to reproduce the content from the original source.

PANEL MEMBERS

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

REFERENCES

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., … Innocenti, M. L. (2017). Guidance on the identity, characterisation and conditions of use of feed additives. *EFSA Journal*, *15*(10), 5023. https://doi.org/10.2903/j.efsa.2017.5023

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Villa, R. E., Woutersen, R., Brantom, P., Chesson, A., … Galobart, J. (2023). Guidance on the assessment of the safety of feed additives for the users. *EFSA Journal*, *21*(12), e8469.

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Dusemund, B., Kos Durjava, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., Mantovani, A., Chesson, A., … Kouba, M. (2019). Scientific opinion on the safety and efficacy of TYFERTM (ferric tyrosine chelate) as a zootechnical feed additive for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding. *EFSA Journal*, *17*(2), 5608. https://doi.org/10.2903/j.efsa.2019.5608

How to cite this article: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., Puente, S. L., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Villa, R. E., Woutersen, R., Galobart, J., Pizzo, F., … Manini, P. (2024). Safety for the user of the feed additive consisting of ferric tyrosine chelate (TYFER™) for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding (Akeso Biomedical, Inc). *EFSA Journal*, *22*(4), e8734. https://doi.org/10.2903/j.efsa.2024.8734