

Modification of the terms of authorisation regarding the additive consisting of liquid L-lysine base produced with *Corynebacterium glutamicum* NRRL B-67439 and NRRL B-67535 for all animal species (ADM specialty ingredients (Europe) B.V.)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | Roberto Edoardo Villa | Giovanna Azimonti | Eleftherios Bonos | Henrik Christensen | Mojca Durjava | Birgit Dusemund | Ronette Gehring | Boet Glandorf | Maryline Kouba | Marta López-Alonso | Francesca Marcon | Carlo Nebbia | Alena Pechová | Miguel Prieto-Maradona | Ilen Röhe | Katerina Theodoridou | Lieve Herman | Montserrat Anguita | Matteo L. Innocenti | Elisa Pettenati | Jordi Tarrés-Call | Fabiola Pizzo | Rosella Brozzi

Correspondence: feedap@efsa.europa.eu

Abstract

Following a request from the European Commission, the EFSA 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 liquid L-lysine base produced with a genetically modified strain of *Corynebacterium glutamicum* as a nutritional feed additive for all animal species. The L-lysine base liquid produced with *C. glutamicum* NRRL B-67535 and NRRL B-67439 is currently authorised as a nutritional additive for all animal species. The present application is aimed at modifying the current authorisation to include *C. glutamicum* NRRL B-68248 as a production strain. The new production strain qualifies for the qualified presumption of safety approach when used for production purposes. It was unambiguously identified as *C. glutamicum* and was shown not to harbour acquired antimicrobial resistance determinants for antibiotics of human and veterinary importance. All the introduced sequences or mutations were considered to be safe, and no viable cells or DNA of the NRRL B-68248 strain was detected in the final product. Therefore, the final product does not pose any safety concern associated with the production strain. L-lysine base produced using *C. glutamicum* NRRL B-68248 does not represent a risk for the target species, the consumer or the environment. The additive was considered to be neither irritant to skin or the eyes, nor a dermal sensitiser. L-lysine base produced with *C. glutamicum* NRRL B-68248 is considered to be an efficacious source of the essential amino acid L-lysine for non-ruminant animal species. For the supplemental L-lysine to be as efficacious in ruminants as in non-ruminant species, it would require protection against degradation in the rumen.

KEY WORDS

amino acid, *Corynebacterium glutamicum*, efficacy, liquid lysine base, NRRL B-68248, nutritional additive, safety

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

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 ADM Specialty Ingredients (Europe) B.V.² for the modification of the terms of the authorisation of the additive consisting of liquid L-lysine base produced with *Corynebacterium glutamicum* NRRL B-68248, when used as a feed additive for all animal species (category: nutritional additives; functional group: amino acids, their salts and analogues).

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). The dossier was received on 11 July 2023 and the general information and supporting documentation are available at <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00482>. The particulars and documents in support of the application were considered valid by EFSA as of 01 December 2023.

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 feed additive consisting of liquid L-lysine base produced with *Corynebacterium glutamicum* NRRL B-68248, when used under the proposed conditions of use (see **Section 3.1.4**).

1.2 | Additional information

The EFSA Panel on Additives and Products or Substances used in Animal feed (FEEDAP) issued two opinions on the safety and efficacy of liquid L-lysine base produced with the *C. glutamicum* strains NRRL B-67439 NRRL B-67535 and NRRL B-50775 when used as a nutritional feed additive for all animal species (EFSA FEEDAP Panel, 2019a, 2019b).

This liquid L-lysine base is currently authorised for use as a nutritional additive in complete feed and water for drinking for all animal species (3c320).³

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁴ in support of the authorisation request for the use of liquid L-lysine base produced with *C. glutamicum* NRRL B-68248 as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002⁵ and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,⁶ a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 22 May to 14 June 2024 for which no comments were received.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 01 December 2023 to 01 March 2024; the comments received were considered for the assessment.

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

¹Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

²ADM Specialty Ingredients (Europe) B.V., Kingsfordweg 43 GP Amsterdam The Netherlands – Netherlands.

³Commission Implementing Regulation (EU) 2020/997 of 9 July 2020 concerning the authorisation of L-lysine base, liquid, L-lysine sulfate and L-lysine monohydrochloride, technically pure, as feed additives for all animal species. OJ L 221, 10.07.2020, p. 90.

⁴Dossier reference: FEED-2023-14757.

⁵Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

⁶Decision <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the liquid L-lysine base produced with *C. glutamicum* strain NRRL B-67535 in animal feed are valid and applicable for the current application.⁷

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of liquid L-lysine base produced with *C. glutamicum* strain NRRL B-68248 is in line with the principles laid down in Regulation (EC) No 429/2008⁸ and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019c), EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2021) and Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023).

3 | ASSESSMENT

The L-lysine base liquid produced with *Corynebacterium glutamicum* NRRL B-67535 is currently authorised as a nutritional additive (functional group: amino acids, their salts and analogues) for all animal species. The present application is aimed at modifying the current terms of the authorisation to include *C. glutamicum* NRRL B-68248 as a production strain.

3.1 | Characterisation

3.1.1 | Characterisation of the production organism

The L-lysine base present in the additive is obtained by fermentation with a genetically modified strain of *C. glutamicum* which is deposited in the US Agricultural Research Culture Collection under the accession number NRRL B-68248.⁹ This production strain shares the parental strain (*C. glutamicum* ██████████) with the one previously evaluated and currently authorised (*C. glutamicum* NRRL B-67535, EFSA FEEDAP Panel, 2019a).

The production strain was identified as *C. glutamicum* by whole genome sequence (WGS) analysis with an average nucleotide identity value of 98.3% with the type strain *C. glutamicum* ATCC 13032^T.¹⁰ In a phylogenetic analysis conducted based on the alignment of 146 genes between the production strain and other strains from the same genus, strain NRRL B-68248 clustered with the *C. glutamicum* strains ATCC 13869 and BF100, confirming that the production strain (NRRL B-68248) belongs to the *C. glutamicum* species.

The susceptibility of the production strain to the battery of antibiotics recommended by the FEEDAP Panel (EFSA FEEDAP Panel, 2018b) was tested and all the minimum inhibitory concentration values fell below the cut-off values for Gram positives.¹¹ Therefore, the strain is susceptible to all the tested antibiotics.

The WGS data of the production strain were analysed for the presence of antimicrobial resistance genes using the ResFinder and the NCBI Bacterial Antimicrobial Resistance Reference Gene databases. No hits were identified above the thresholds established by EFSA (EFSA, 2021).¹²

Information related to the genetically modified microorganism

Characterisation of the recipient or parental microorganism

The recipient strain is *C. glutamicum* ██████████ which was obtained by classical mutagenesis.¹³

⁷Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

⁸Commission 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.

⁹Annex 10.

¹⁰Annex 13 and Annex 14.

¹¹Annex 15.

¹²Annex 13 and Annex 14.

¹³Annex 11.

Description of the genetic modification

The production strain *C. glutamicum* NRRL B-68248 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] The absence of the antimicrobial resistance genes transiently introduced during the genetic modification process was confirmed by the WGS interrogation described above.

[REDACTED]:

- [REDACTED]
[REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
[REDACTED]
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- [REDACTED]
[REDACTED].

[REDACTED]:

- [REDACTED]
- [REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
- [REDACTED]
[REDACTED]

[REDACTED].

3.1.2 | Manufacturing process

According to the applicant, the manufacturing process has not been modified as compared to the one previously assessed for the additive, except for the change of the production strain.

L-Lysine is produced [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] The applicant states that no antimicrobials, including antibiotics, are employed in the manufacturing processes.

3.1.3 | Characterisation of the active substance/additive

L-Lysine (IUPAC name (2S)-2,6 diaminohexanoic acid; synonym α,ϵ diaminocaproic acid) is identified with the CAS No 56-87-1 and the EINECS No 200-294-2, has a molecular weight of 146.2 g/mol. The molecular formula is $\text{NH}_2-(\text{CH}_2)_4-\text{CH}(\text{NH}_2)-\text{COOH}$. The molecular structure is given in [Figure 1](#).

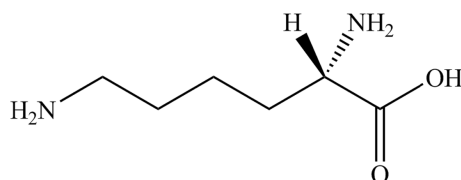


FIGURE 1 Molecular structure of L-lysine.

L-Lysine base, liquid, is currently authorised as an aqueous solution of L-lysine with a minimum of 50% L-lysine.

Analytical data of eight batches showed an average content of L-lysine 'as is' of [REDACTED] (range [REDACTED]) and water of [REDACTED] (range [REDACTED]).¹⁴ Other analysed constituents (average values) were [REDACTED]

[REDACTED]¹⁵

On a 'as is' basis, the sum of the quantified components was on average 98.5% (range 98.2%–99.4%).

The same eight batches of the additive were analysed for cadmium, lead, mercury and arsenic levels and all batches showed concentrations below the limit of quantification of the method (LOQ) applied for all analytes.¹⁶

Three out of the eight batches were further analysed for dioxins and dioxin-like PCBs, mycotoxins and microbiological contamination.¹⁷ Dioxins and the sum of dioxins plus dioxin like PCBs concentrations ranged 0.05–0.10 ng WHO-PCDD/F-TEQ/kg and 0.05–0.10 ng WHO-PCDD/F-PCB-TEQ/kg, respectively. The analysis of mycotoxins included aflatoxins (B1, G1, B2, G2), fumonisins (B1, B2, B3), 3-acetyl-deoxynivalenol, deoxynivalenol, HT-2 toxin, T2-toxin, zearalenone and ochratoxin A. In all cases, the analysed concentration was below the LOQ of the analytical method, except for fumonisin B1, which ranged from 37 to 60 µg/kg.¹⁸

Microbiological contamination was tested by determining levels of *Pseudomonas* spp., total coliforms, *Escherichia coli*, *Salmonella* spp., aerobic plate count, Enterobacteriaceae, yeasts and filamentous fungi. No *Salmonella* was detected in 25 g samples. The other microbial contaminants were < 10 CFU/g.

The FEEDAP Panel considers that the results of the microbiological analyses and the amounts of the detected impurities do not raise safety concerns.

The presence of viable cells of the production strain was analysed in three production batches of the additive, [REDACTED]

[REDACTED]¹⁹

[REDACTED]. No colonies were detected.

The presence of DNA of the production strain was analysed in three production batches of the additive, [REDACTED]

[REDACTED]²⁰

[REDACTED] The limit of detection of 1 ng/mL was determined. No DNA was detected in any of the samples.

The additive appears as a fluid liquid, soluble in water, and it has a pH (analysed in three batches) of 10.1.²¹ The viscosity and density were measured in three batches of the additive. The viscosity (at 25°C) ranged from 56.0 to 57.9 cP,²² and the density (at 20°C) was 1150 kg/m³ in all three batches.²³

The particle size of the additive was investigated in three batches using scanning electron microscopy. No small particles including nanoparticles (< 500 nm) were detected.²⁴

As the manufacturing process and the composition of the additive have not been modified, the outcome of the studies related to shelf-life, stability and homogeneous distribution in feed of the previous assessment (EFSA FEEDAP Panel, 2019a) is considered valid.

¹⁴Annex 1 COAs lysine ADM. Lysine analysed by AOAC Official method 999.13.

¹⁵Annex 1 COAs lysine ADM. [REDACTED]

¹⁶Annex 3 Heavy metals lysine ADM. LOQ in µg/kg was 4 for cadmium, lead, mercury and arsenic.

¹⁷Annex 2 Dioxins + Microbio + Mycotoxins combined Lysine ADM.

¹⁸LOQ in µg/kg was 1 for T2-toxin. It was 5 for zearalenone and ochratoxin A. It was 10 for Fumonisin B2 and B3, Aflatoxin B1, B2, G1 and G2, deoxynivalenol and HT-2 toxin. It was 20 for 15-acetyl-deoxynivalenol.

¹⁹Annex 4 and Answers from the applicant – characterisation.

²⁰Annex 5 and Answers from the applicant – characterisation.

²¹Annex 12 pH lysine ADM.

²²Annex 6 Viscosity lysine ADM.

²³Annex 7 Density lysine ADM.

²⁴Annex 9 nano particles lysine ADM.

3.1.4 | Conditions of use

The additive is currently authorised for use in feed for all animal species, without a minimum or maximum content.²⁵

Under other provisions:

- The lysine content shall be indicated on the labelling of the additive.
- L-lysine base, liquid, may be placed on the market and used as an additive consisting of a preparation.
- For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation and for the skin and eyes. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing, skin and eye protection.
- The additive may be also used via water for drinking.
- Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'

The applicant is seeking the modification of the terms of the authorisation to allow the inclusion of *C. glutamicum* NRRL B-68248 as production strain and the use of lysine base liquid produced with this strain in feed for all animal species, without a minimum or maximum content.

3.2 | Safety

The safety of L-lysine base produced with *C. glutamicum* NRRLB-67535 was assessed by the FEEDAP Panel (EFSA FEEDAP Panel, 2019a). Considering that the manufacturing process and the composition of the additive have not been modified, except for the production strain, the Panel considers that the only safety aspect that needs to be considered is the change of the strain.

3.2.1 | Safety for the target species, consumers, and environment

The production strain belongs to a species, *C. glutamicum*, that qualifies for the qualified presumption of safety (QPS) approach for safety assessment when used for production purposes (EFSA BIOHAZ Panel, 2023). The strain was unambiguously identified as *C. glutamicum* and was shown not to harbour acquired antimicrobial resistance determinants for antibiotics of human and veterinary importance. All the introduced sequences or mutations are considered to be safe. No viable cells or DNA of the production strain were detected in three batches of the additive. Consequently, no safety concerns for the target animals, consumers and the environment are expected from the additive concerning the production strain and the fermentation residues that may be present in the final additive.

Therefore, the FEEDAP Panel reiterates its previous conclusions that the additive is safe for the target species, consumer and the environment.

3.2.2 | Safety for the user

No specific studies were submitted to support the safety for the user of the product under assessment.

The applicant submitted an acute dermal irritation study,²⁶ an acute eye irritation study²⁷ and a skin sensitisation study²⁸ conducted with a L-lysine liquid 50% produced with a different production strain (*C. glutamicum* KCTC 12307BP) and having a pH of 9.96. These studies have already been evaluated in the context of a previous opinion (EFSA FEEDAP Panel, 2019d) and the FEEDAP Panel concluded that the test item was neither irritant to skin or eyes nor a dermal sensitiser.

The FEEDAP Panel considered the following: (i) the physico-chemical characteristics of both lysine products ($\geq 50\%$ lysine, $\leq 48\%$ water, density 1.12–1.17 g/mL) are the same; (ii) the manufacturing process of both lysine products is similar; and (iii) historical data on pH measurements of several batches of the lysine under assessment show values not exceeding 10.4 and similar to the pH of the test item used in the user safety studies, and concluded that the outcome of the studies mentioned above are applicable to the product under assessment.

Therefore, the additive under assessment is not considered to be irritant to skin or eyes, nor a dermal sensitiser.

²⁵Commission implementing regulation (EU) 2020/997 of July 2020 concerning the authorisation of L-lysine base, liquid, L-lysine sulfate and L-lysine monohydrochloride, technically pure, as feed additives for all animal species. OJ L 221, 10.7.2020, p. 90–94.

²⁶Annex 28 Safety acute dermal OECD 404 lysine ADM.

²⁷Annex 29 Safety acute eye OECD 405 lysine ADM.

²⁸Annex 30 Safety skin OECD 406 lysine ADM.

3.3 | Efficacy

The Panel considers that the proposed change in the production strain will not have an impact on the efficacy of the additive. Therefore, L-Lysine base produced using *C. glutamicum* strain NRRL B-68248 is considered to be an efficacious source of the essential amino acid L-lysine for non-ruminant animal species. For the supplemental L-lysine to be as efficacious in ruminants as in non-ruminant species, it would require protection against degradation in the rumen.

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 Regulation²⁹ and good manufacturing practice.

4 | CONCLUSIONS

The production strain *C. glutamicum* NRRL B-68248 is genetically modified and the FEEDAP Panel concludes that the genetic modification raises no safety concerns. No viable cells or DNA of the production strain were detected in the final product. Therefore, the final product does not pose any safety concern in regard to the production strain.

L-Lysine base produced with *C. glutamicum* NRRL B-68248 does not represent a risk for the target species, consumers or the environment.

On the basis of the information submitted, the additive was considered to be neither irritant to skin or the eyes, nor a dermal sensitiser.

L-Lysine base produced with *C. glutamicum* NRRL B-68248 is considered to be an efficacious source of the essential amino acid L-lysine for non-ruminant animal species. For the supplemental L-lysine to be as efficacious in ruminants as in non-ruminant species, it would require protection against degradation in the rumen.

ABBREVIATIONS

CAS	Chemical Abstracts Service
CFU	colony forming unit
DM	dry matter
EINECS	European Inventory of Existing Chemical Substances
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
GC-MS	gas chromatography–mass spectrometry
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
LOQ	limit of quantification
MIC	minimum inhibitory concentration
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development

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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-2023-00482

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²⁹Regulation (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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REFERENCES

- EFSA (European Food Safety Authority). (2021). EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain. *EFSA Journal*, 19(7), 6506. <https://doi.org/10.2903/j.efsa.2021.6506>
- EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Álvarez-Ordóñez, A., Bolton, D., Bover-Cid, S., Chemaly, M., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., Prieto Maradona, M., ... Herman, L. (2023). Scientific Opinion on the update of the list of qualified presumption of safety (QPS) recommended microorganisms intentionally added to food or feed as notified to EFSA. *EFSA Journal*, 21(1), 7747. <https://doi.org/10.2903/j.efsa.2023.7747>
- 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. (2017a). Guidance on the assessment of the safety of feed additives for the consumer. *EFSA Journal*, 15(10), 5022. <https://doi.org/10.2903/j.efsa.2017.5022>
- 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. (2017b). 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), 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., ... Martino, L. (2017c). Guidance on the assessment of the safety of feed additives for the target species. *EFSA Journal*, 15(10), 5021. <https://doi.org/10.2903/j.efsa.2017.5021>
- 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., ... Martino, L. (2018a). Guidance on the assessment of the efficacy of feed additives. *EFSA Journal*, 16(5), 5274. <https://doi.org/10.2903/j.efsa.2018.5274>
- 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., ... Galobart, J. (2018b). Guidance on the characterisation of microorganisms used as feed additives or as production organisms. *EFSA Journal*, 16(3), 5206. <https://doi.org/10.2903/j.efsa.2018.5206>
- 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., Kouba, M., 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., Costa, L., ... Ramos, F. (2019a). Scientific Opinion on the safety and efficacy of L-lysine monohydrochloride and concentrated liquid L-lysine (base) produced by fermentation using *Corynebacterium glutamicum* strains NRRL-B-67439 or NRRL B-67535 for all animal species. *EFSA Journal*, 17(11), 5886. <https://doi.org/10.2903/j.efsa.2019.5886>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bampidis, V., Bastos, M. L., Christensen, H., Dusemund, B., Kouba, M., 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., ... Wallace, R. J. (2019b). Scientific opinion on the safety and efficacy of L-lysine monohydrochloride and concentrated liquid L-lysine (base) produced by fermentation using *Corynebacterium glutamicum* strain NRRL B-50775 for all animal species based on a dossier submitted by ADM. *EFSA Journal*, 17(1), 5537. <https://doi.org/10.2903/j.efsa.2019.5537>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Bastos, M., Christensen, H., Dusemund, B., Kouba, M., 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., Brock, T., de Knecht, J., ... Azimonti, G. (2019c). Guidance on the assessment of the safety of feed additives for the environment. *EFSA Journal*, 17(4), 5648. <https://doi.org/10.2903/j.efsa.2019.5648>
- 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., Kouba, M., Kos Durjava, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Sanz, Y., Villa, R. E., Woutersen, R., Costa, L., Dierick, N., ... Ramos, F. (2019d). Scientific Opinion on the safety of concentrated L-lysine (base), L-lysine monohydrochloride and L-lysine sulfate produced using different strains of *Corynebacterium glutamicum* for all animal species based on a dossier submitted by FEFANA asbl. *EFSA Journal*, 17(1), 5532. <https://doi.org/10.2903/j.efsa.2019.5532>
- 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(11), e8469. <https://doi.org/10.2903/j.efsa.2023.8469>

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