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SCIENTIFIC OPINION

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Safety and efficacy of a feed additive consisting of L-arginine produced with *Corynebacterium glutamicum* KCCM 80393 for all animal species (Daesang Europe BV)

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of L-arginine produced with a genetically modified strain of *Corynebacterium glutamicum* (KCCM 80393) when used as a nutritional additive in feed and water for drinking for all animal species and categories. The Panel concluded that the product under assessment does not give rise to any safety concern with regard to the genetic modification of the production strain. No DNA of the production strain was detected in the final product. L-Arginine produced by fermentation with *C. glutamicum* KCCM 80393 is safe for the target species when supplemented in appropriate amounts to the diet according to the nutritional needs of the target species. The FEEDAP Panel has concerns on the use of L-arginine in water for drinking. The use of L-arginine produced by fermentation with *C. glutamicum* KCCM 80393 in animal nutrition is considered safe for the consumers and for the environment. Regarding the user safety, in the absence of data, the FEEDAP Panel cannot conclude on the potential of the additive to be irritant to skin and/or eyes, or to be a dermal or respiratory sensitiser. The additive L-arginine produced by fermentation with *C. glutamicum* KCCM 80393 is regarded as an efficacious source of the essential amino acid L-arginine for non-ruminant nutrition. For the supplemental L-arginine to be as efficacious in ruminants as in non-ruminant species, it requires protection against degradation in the rumen.

KEYWORDS

amino acid, *Corynebacterium glutamicum* KCCM 80393, efficacy, L-arginine, nutritional additive, safety

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003[1] 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 Daesang Europe B.V.[2] for the authorisation of the additive consisting of L-arginine produced by fermentation with *Corynebacterium glutamicum* KCCM 80393, 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 4(1) (authorisation of a feed additive or new use of a feed additive). The dossier was received on 27 June 2024 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2024-00423. The particulars and documents in support of the application were considered valid by EFSA as of 25 September 2024.

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 L-arginine produced by fermentation with *C. glutamicum* KCCM 80393, when used under the proposed conditions of use (see Section 3.1.4).

1.2 | Additional information

The L-arginine produced with *C. glutamicum* KCCM 80393 has not been previously authorised as a feed additive in the European Union. L-Arginine produced by fermentation with different microbial strains is currently authorised for its use in all animal species as a nutritional additive and as a sensory additive.[3]

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has published several opinions on the safety and efficacy of L-arginine produced by fermentation with different strains of *C. glutamicum* or *Escherichia coli* when used as an amino acid in feed.[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 dossier[5] in support of the authorisation request for the use of L-arginine as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 30 September 2024 to 20 December 2024; the comments received were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[6] 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,[7] 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 31 January to 21 February 2025 for which no comments were received.

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

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the L-arginine produced with *C. glutamicum* KCCM 80393 in animal feed.[8]

[1]Regulation (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.

[2]Daesang Europe B.V., Van Heuven Goedhartlaan 937, 1181 LD Amstelveen, The Netherlands.

[3]See the European Union register of feed additives. Available online: https://ec.europa.eu/food/food-feed-portal/screen/feed-additives/search.

[4]Scientific opinions available online: https://efsa.onlinelibrary.wiley.com/journal/18314732.

[5]Dossier reference: FEED-2024-27091.

[6]Regulation (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.

[7]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[8]Evaluation report received on 9/04/2025 and 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.

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and efficacy of L-arginine produced with *C. glutamicum* KCCM 80393 is in line with the principles laid down in Regulation (EC) No 429/2008[9] 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 FEEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023), EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2024) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024).

3 | ASSESSMENT

The additive L-arginine (≥ 98.5% on dry matter basis) produced with *C. glutamicum* KCCM 80393 is intended to be used as a nutritional additive (functional group: amino acids, their salts and analogues) in feed and water for drinking for all animal species.

L-Arginine is considered as a non-essential amino acid for most adult mammalian species including humans, but it is classified as essential for birds, fish, possibly reptiles and also for strict carnivores. For mammalian neonates, it is considered to be essential.

3.1 | Characterisation

3.1.1 | Characterisation of the production organism

L-Arginine is produced with a genetically modified strain of *C. glutamicum*, which is deposited in the Korean Culture Centre of Microorganisms with accession number KCCM 80393.[10]

The taxonomic identification of the production strain, KCCM 80393, [redacted].[11] [redacted] belongs to the *C. glutamicum* species.

The susceptibility of the production strain to antimicrobials was tested using a broth microdilution method and including the data set of antimicrobials recommended by EFSA for *Corynebacterium* and other Gram positives (EFSA FEEDAP Panel, 2018).[12] All minimum inhibitory concentration values were below the cut-off values, and therefore, the strain is considered susceptible to all relevant antibiotics.

The WGS data were interrogated for the presence of antimicrobial resistance (AMR) genes [redacted].[13] [redacted] therefore, it can be concluded that no acquired AMR genes were identified.

Information related to the genetically modified microorganism

Description of the genetic modification

[redacted] The genetic modification was targeted to increase the production of L-arginine.

The genetic modifications listed below were introduced to obtain the production strain *C. glutamicum* KCCM 80393.[14] [redacted].

[redacted]

[9]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.

[10]2.2.1.2.a certificate of Deposition KCCM 80393.

[11]2.2.1.2.c1 Bioinformatics T1701R1939.

[12]2.2.2.2 MIC T1701R1919.

[13]2.2.1.2.c1 Bioinformatics T1701R1939.

[14]2.2.1.2.b Characteristics and strain development KCCM80393 Arg.

[redacted]

[15]

[redacted]

3.1.2 | Manufacturing process

L-Arginine is produced by fermentation with *C. glutamicum* KCCM 80393. [redacted]

[16]

The applicant stated that no antimicrobials are used in the production process.

3.1.3 | Characterisation of the active substance/additive

L-Arginine (International Union of Pure and Applied Chemistry (IUPAC) name: (S)-2-amino-5-guanidinopentanoic acid; synonym 2-amino-5-guanidinovaleric acid, is identified with the Chemical Abstracts Service (CAS) No 74-79-3 and the European Inventory of Existing Commercial chemical Substances (EINECS) No 200-811-1. It has a molecular mass of 174.2 Da. The molecular formula of L-arginine is $C_6H_{14}N_4O_2$. The structural formula is given in Figure 1.

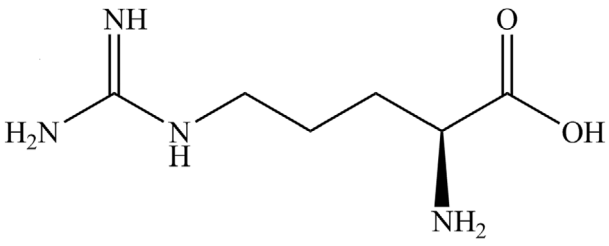

FIGURE 1 Structural formula of L-arginine.

The specifications of the feed additive are minimum 98.5% L-arginine on a dry matter (DM) basis and maximum 0.5% moisture.

[15] 2.2.1.2.c1 Bioinformatics T1701R1939.
[16] 2.3.1.a Manufacturing description ARG.

Compliance with the specifications was shown in five batches in which L-arginine was on average 99.5% on a DM basis (98.9%–100.1%).[17] Water content was on average 0.3% (0.0%–0.5%).

The same batches were analysed by another method and showed an average value of 98.9% arginine (range: 98.8%–99.1%).[18] Loss on drying was on average 0.4% (0.34%–0.45%) and residue on ignition was on average 0.04% (0.03%–0.05%).

The specific optical rotation measured in eight batches of the additive ranged from +27.12 to +27.72° which falls within the reference range (+25.5 to +28.5°) set in the European Pharmacopoeia (2025) and confirms the L-enantiomer of arginine as the additive.[19]

3.1.3.1 | *Impurities*

Three batches of the additive were analysed for impurities. Cadmium, lead, mercury and arsenic concentrations were below the limit of quantification (LOQ) of the analytical methods.[20] Levels of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (DL-PCBs) were below the corresponding LOQ. The calculated upper bound (UB) concentration was 0.14 ng WHO-TEQ/kg for the sum of PCDD/Fs, and 0.27 ng WHO-TEQ/kg for the sum of PCDD/Fs and DL-PCBs. The UB for the sum of non-DL-PCBs was 3 µg/kg.[21] Regarding the mycotoxin content, the analysis of the same batches showed that the levels of zearalenone, aflatoxins (unspecified) and fumonisin were below the limit of detection (LOD) of the analytical methods. Ochratoxin A concentrations were below the LOQ of the analytical method and ranged from 4.0 to 5.2 µg/kg. Concentrations of citrinin were below or equal to the LOD, and concentrations of deoxynivalenol ranged from 157 to 330 µg/kg.[22]

The same three batches of the product were analysed for microbiological contamination: *Salmonella* spp., yeasts and moulds, and *Escherichia coli* were not detected in 25 g samples.[23,24] *Enterobacteriaceae* were not detected in 10 g samples.[25]

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

The presence of viable cells of the production strain was investigated in three batches of the additive, each tested in triplicate.[26] [redacted]

The presence of DNA from the production strain was tested in three batches of the additive in triplicate.[27] [redacted]. No DNA of the production strain was detected.

3.1.3.2 | *Physical properties of the additive*

L-Arginine is a solid brown-white crystalline powder. The reported solubility in water is 182 g/L at 25°C,[28] and the reported bulk density is 1460 kg/m^3.[29]

No information on dusting potential was made available on the additive under assessment. The applicant referred to data on dusting potential of a similar L-arginine produced by a different strain of *C. glutamicum*.[30] The Panel considers these data not relevant for the current assessment.

3.1.3.3 | *Stability and homogeneity*

The applicant provided data on the shelf-life, stability in premixtures, stability in compound feed and on the capacity of the additive to distribute homogeneously that was obtained with an L-arginine produced by a different strain of *C. glutamicum* (KCTC 10423BP). As the composition of the additive, its physical characteristics and the manufacturing process are very

[17]Annex 2.1.3 BtB impurities 142240 and Other supporting document – 2.1.3.a Method 1522009. Analytical method was stated to be in accordance with Regulation (EU) No 152/2009, Appendix III, G and F method.

[18]Annex 2.1.5.b Optical rotation CoA. Analytical method for arginine was Food Chemicals Code (FCC)/USP.

[19]Annex 2.1.5.b Optical rotation CoA and Annex 2.1.5.a Dusting potential L-arginine.

[20]Annex 2.1.3 BtB impurities 142240. LOQ in mg/kg was 0.002 for cadmium and mercury, and 0.01 for arsenic and lead.

[21]Annex 2.1.3 BtB impurities 142240. Upper bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification. TEQ = toxic equivalency factors for PCDD/Fs and DL-PCBs established by WHO in 2005 (van den Berg et al., 2006).

[22]Annex 2.1.3 BtB impurities 142240. LOD in µg/kg was 0.05 for aflatoxins, 2.8 for ochratoxin A, 15 for citrinin, 17 for zearalenone and 25 for fumonisin. LOQ in in µg/kg was 5.8 for ochratoxin A.

[23]Annex 2.1.3 BtB impurities 142240. LOD were a single colony forming unit (CFU)/25 g samples.

[24]Sect_2.6 Consolidated 250107.

[25]Sect_2.6 Consolidated 250204.

[26]2.1.4.b Absence viable cells T1701R1907.

[27]2.1.4.c Absence DNA T1701R1937.

[28]Technical dossier text-Sect_2.1-2.2 Consolidated 240904.

[29]2.5.2.c MSDS L-arginine.

[30]Annex 2.1.5.a Dusting potential L-Arginine.

similar, the FEEDAP Panel considers that the outcome of the shelf-life, stability in compound feed and premixtures and the capacity to distribute homogeneously in feed of the L-arginine evaluated in the previous scientific opinion (EFSA FEEDAP Panel, 2016) can be applied to the L-arginine under assessment.

New data on the stability of three batches of the additive in water for drinking was provided.[31] L-Arginine was added at 2% in water for drinking and kept at 20 C for 48 h (packaging not described). No loss of L-arginine was detected at the end of the storage period.

3.1.4 | Conditions of use

L-Arginine is intended to be used in feed and water to achieve an adequate amino acid profile and to meet the L-arginine requirements for all animal species and categories. It can be added directly to complete feed, through complementary feed, premixtures and water for drinking. No inclusion levels have been proposed by the applicant, as the requirements, in quantitative terms, depend on the nutrient composition, in particular the amino acid composition of the unsupplemented diet, the species, the animal's age, the physiological state of the animal, the performance level of the animal and the environmental conditions.

3.2 | Safety

3.2.1 | Safety of the production organism

The production organism *C. glutamicum* KCCM 80393 is a genetically modified strain which was developed to increase the production of L-arginine. The production strain belongs to a species, *C. glutamicum*, that qualifies for the qualified presumption of safety (QPS) approach to safety assessment when used for production purposes (EFSA BIOHAZ Panel, 2023a). The taxonomic identification of the production strain was unequivocally established, KCCM 80393 does not carry acquired AMR genes and the genetic modification does not raise safety concerns. No viable cells nor DNA of the production strain were detected in the final product. Therefore, the FEEDAP Panel concludes that the additive does not pose any safety concerns regarding the genetically modified production strain.

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

The L-arginine requirements of the target animal species and the safety of this amino acid in non-ruminant and ruminant nutrition are well known by feed formulators and available in general publications on animal nutrition.

The additive is highly purified (contains > 98.5% L-arginine and < 1% unidentified material on DM basis) and is produced by fermentation using a strain that is considered safe. Concerns on the use of the additive would not derive from the L-arginine, which is considered safe, but may arise from residues of the fermentation process/production strain remaining in the final product.

The production strain qualifies for the QPS safety assessment approach; the genetic modifications performed are considered safe, and no viable cells and DNA of the production strain were found in the final product. L-Arginine produced with *C. glutamicum* KCCM 80393 is safe for the target species when used to supplement the diet in appropriate amounts to satisfy the animal requirements. However, due to the risk of nutritional imbalances and hygienic reasons associated with the use of amino acids via water for drinking (EFSA FEEDAP Panel, 2010), the FEEDAP Panel has concerns on the safety of the simultaneous oral administration of amino acid-containing additives via feed and water for drinking.

The absorption and metabolic fate of L-arginine in the animals is well known. The amino acid L-arginine, supplemented to feed, will be incorporated into proteins of tissues and/or products of animal origin and any of its potential excess will be metabolised and excreted. Therefore, the protein composition of tissues and products of animal origin will not be affected by using L-arginine in animal nutrition. Therefore, the Panel considers that the use of the additive in animal nutrition is safe for the consumer.

The amino acid L-arginine is a physiological and natural component of animals and plants. It is not excreted as such, but as urea/uric acid and carbon dioxide. The use of the product L-arginine in animal nutrition would not lead to any localised increase in the concentration in the environment. The use of the additive in water for drinking, when given in addition to complete diets with a well-balanced amino acid profile, would disturb the nitrogen balance and increase nitrogen excretion via urine. It is concluded that the use of the product L-arginine produced by fermentation with *C. glutamicum* KCCM 80393 as a feed additive does not represent a risk to the environment.

[31] Annex 2.1.3 Btb impurities 142240.

3.2.3 | Safety for the user

No studies were submitted to support the safety of the additive for the user.

In the absence of data, the FEEDAP Panel cannot conclude on the potential of the additive to be irritant to skin or eyes, or on its potential to be a dermal sensitiser.

3.3 | Efficacy

Efficacy studies are not required for amino acids that occur naturally in plant and animal proteins. The nutritional role of the amino acid L-arginine is well established in the scientific literature.

For the supplemental L-arginine to be as efficacious in ruminants as in non-ruminant species, it requires 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 Regulation[32] and good manufacturing practice.

4 | CONCLUSIONS

The production strain *C. glutamicum* KCCM 80393 is genetically modified but raises no safety concerns. No viable cells nor DNA of the production strain were detected in the final product. The FEEDAP Panel concludes that the additive does not pose any safety concern with regard to the production strain.

L-Arginine produced by fermentation with *C. glutamicum* KCCM 80393 is safe for the target species when supplemented in appropriate amounts to the diet according to the nutritional needs of the target species. The FEEDAP Panel has concerns on the use of L-arginine in water for drinking.

The use of L-arginine produced by fermentation with *C. glutamicum* KCCM 80393 in animal nutrition is considered safe for the consumers and for the environment.

Regarding the user safety, in the absence of data, the FEEDAP Panel cannot conclude on the potential of the additive to be an irritant to skin and/or eyes, or to be a dermal or respiratory sensitiser.

The additive L-arginine produced by fermentation with *C. glutamicum* KCCM 80393 is regarded as an efficacious source of the amino acid L-arginine for non-ruminant nutrition. For the supplemental L-arginine to be as efficacious in ruminants as in non-ruminant species, it requires protection against degradation in the rumen.

ABBERVIATIONS

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
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
LOQ	limit of quantification
MIC	minimum inhibitory concentration
OECD	Organisation for Economic Co-operation and Development

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REQUESTOR

European Commission

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[32]Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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