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SCIENTIFIC OPINION

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Safety and efficacy of a feed additive consisting of L-tryptophan produced with *Corynebacterium glutamicum* KCCM 80346 for all animal species (CJ Europe GmbH)

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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 the feed additive consisting of L-tryptophan produced by fermentation with a genetically modified strain of *Corynebacterium glutamicum* (KCCM 80346) when used as a nutritional additive in feed and water for drinking for all animal species and categories. Viable cells of the production strain and its DNA were not detected in the additive. L-Tryptophan manufactured by fermentation using *C. glutamicum* KCCM 80346 does not give rise to any safety concern with regard to the genetic modification of the production strain. The use of L-tryptophan (≥ 98%) produced with *C. glutamicum* KCCM 80346 to supplement feed is safe for non-ruminant species. There may be a risk for an increased production of toxic metabolites when unprotected tryptophan is used in ruminants. The FEEDAP Panel has concerns on the use of L-tryptophan in water for drinking. The use of L-tryptophan produced with *C. glutamicum* KCCM 80346 in animal nutrition raises no safety concerns to consumers of products from animals receiving the additive and to the environment. L-tryptophan produced with *C. glutamicum* KCCM 80346 is not irritant to the eyes and skin, and it is not a skin sensitiser. The additive L-tryptophan is regarded as an effective source of the amino acid L-tryptophan for all non-ruminant species. To be as efficacious in ruminants as in non-ruminants, it should be protected from ruminal degradation.

KEYWORDS

amino acids, *Corynebacterium glutamicum* KCCM 80346, L-tryptophan, nutritional additives, safety, their salts and analogues

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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 CJ Europe GmbH[2] for the authorisation of the additive consisting of L-tryptophan produced with *Corynebacterium glutamicum* KCCM 80346 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 6 December 2023, and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00866. The particulars and documents in support of the application were considered valid by EFSA as of 27 February 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-tryptophan produced with *C. glutamicum* KCCM 80346, when used under the proposed conditions of use (see **Section 3.1.6**).

1.2 | Additional information

The additive contains L-tryptophan produced with *C. glutamicum* KCCM 80346, and it has not been previously authorised as a feed additive in the European Union.

L-Tryptophan produced by fermentation with different production strains is currently authorised for use in feed for all animal species in the European Union.[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 dossier[4] in support of the authorisation request for the use of L-tryptophan produced with *C. glutamicum* KCCM 80346 as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] 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 the pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 4 June to 25 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 1 March to 1 June 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 or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' knowledge, 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 L-tryptophan in animal feed.[7]

[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]CJ Europe GmbH. Unterschweinstiege 2–14, 60,549 Frankfurt am Main (Germany).
[3]European Register of Feed additives, available online: https://ec.europa.eu/food/food-feed-portal/screen/feed-additives/search.
[4]Dossier reference: FEED-2023-20130.
[5]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.
[6]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.
[7]Evaluation report received on 27/02/2025 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-tryptophan produced with *C. glutamicum* KCCM 80346 is in line with the principles laid down in Regulation (EC) No 429/2008[8] 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, 2019); 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-tryptophan under assessment is produced by fermentation with a genetically modified strain of *C. glutamicum* (KCCM 80346) and it 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.

3.1 | Characterisation

3.1.1 | Characterisation of the production organism

L-Tryptophan is produced with a genetically modified strain of *C. glutamicum*, which is deposited at the Korean Culture Collection of Microorganisms (KCCM) with the accession number KCCM 80346.[9]

The taxonomic identification of the production strain, KCCM 80346, was confirmed [redacted].[10] [redacted].

The antimicrobial susceptibility of the production strain was tested against the battery of antibiotics described for '*Corynebacterium* and other Gram-positive' in the Guidance on characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b).[11] [redacted] and therefore, the strain is considered susceptible to the relevant antibiotics.

[redacted].[12]

The WGS data of the production strain were searched for the presence of antimicrobial resistance (AMR) genes [redacted].[13] [redacted] the EFSA thresholds (EFSA, 2021), [redacted].[14] [redacted] (EFSA BIOHAZ Panel, 2023a), and therefore, it can be concluded that no acquired AMR genes were identified and the strain raises no concerns.

3.1.1.1 | *Information related to the genetically modified microorganism*

Characterisation of the parental microorganism

The parental strain is the [redacted] strain *C. glutamicum* [redacted].[15]

[8]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.
[9]Annex 2.2.2. Certificate of strain deposition.
[10]Annex 2.2.3. WGS data.
[11]Annex 2.2.4. Antimicrobial susceptibility.
[12]Annex 2.2.3. WGS data.
[13]Annex 2.2.3. WGS data.
[14]Annex Q1_Intrinsic AMR 80346.
[15]Annex 2.2.1. Strain information.

Description of the genetic modification

[redacted][16]

[16]Annex 2.2.3. WGS data, Annex 2.2.5. Sequencing analysis, Annex 2.2.1. Strain information and Annex_Q2. Genetic modification of the production strain.

[redacted][17] [redacted][18] Any genetic modification, including intended and unintended modifications, was reported, no concerns were identified.

[redacted] (see Section 3.1.1).[19]

3.1.2 | Manufacturing process

L-tryptophan is produced by fermentation with *C. glutamicum* KCCM 80346.[20] [redacted][21]

The applicant declared that no antimicrobials are used in the manufacturing process.[22]

3.1.3 | Characterisation of the additive

L-Tryptophan (International Union of Pure and Applied Chemistry (IUPAC) name: (2S)-2-amino-3-(1H-indol-3-yl) propanoic acid; synonyms: (S)-α-amino-1-H-indole-3-propanoic acid, L-α-aminoindole-3-propionic acid, l-α-amino-3-indolepropionic acid, 2-amino-3-indolylpropanoic acid, L-β-3-indolylalanine) has the Chemical Abstracts Service (CAS) No 73-22-3 and European Inventory of Existing Commercial Chemical Substances (EINECS) No 200-795-6. The chemical formula is $C_{11}H_{12}N_2O_2$, the molecular weight is 204.23 g/mol. The structural formula is given in Figure 1.

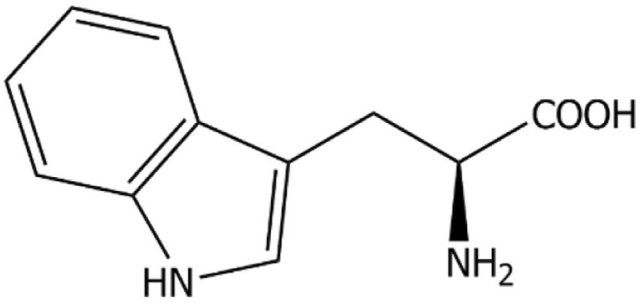

FIGURE 1 Structural formula of L-tryptophan.

According to the specification, the product contains ≥ 98% L-tryptophan on a dry matter (DM) basis and ≤ 1% moisture.[23]

The analysis of five batches of the additive showed an average content of L-tryptophan of 98.9% on a DM basis (98.1%–100.7%).[24] Moisture and crude ash were < 0.2% and < 0.4%, respectively. The amount of unidentified material in DM basis was < 1%.

The specific optical rotation was measured in three batches of the additive and ranged from −30.65 to −30.95°.[25] This range is within the reference values established for L-tryptophan in the European Pharmacopoeia (−30.0 to −33.0°) and confirms the L-enantiomer of tryptophan.[26]

[17] Annex 2.2.1. Strain information.
[18] Annex 2.2.3. WGS data and Annex_Q2. Genetic modification of the production strain.
[19] Annex 2.2.3. WGS data.
[20] Annex 2.3.1. Manufacturing Process.
[21] Annex Q1 Manufacturing Process.
[22] 2.3. Manufacturing Process.
[23] Annex 2.1.1. Technical Data Sheet.
[24] Annex 2.1.3. Batch to batch variation. Method of analysis in accordance with Commission Regulation 152/2009 Appendix III, method G.
[25] Annex 2.1.2. Optical rotation.
[26] European Pharmacopoeia monograph 1/2017:1272.

Three batches of the additive were analysed for cadmium, lead, mercury and arsenic, showing values below the limit of quantification (LOQ) of the corresponding methods.[27] Microbiological contamination was analysed in the same three batches and included yeasts (< 100 colony forming units (CFU)/g), filamentous fungi (< 100 CFU/g), *Enterobacteriaceae* (< 10 CFU/g) and *Salmonella* spp., which was not detected in 25 g samples. *E. coli* was not detected in the batches analysed.[28]

Polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and coplanar dioxin-like polychlorinated biphenyls (PCBs) were analysed in three batches and found to be below the corresponding LOQ.[29] The calculated upper bound concentrations were 0.057 ng WHO-PCDD/F-TEQ/kg for the sum of dioxins and 0.116 ng WHO-PCDD/F-PCB-TEQ/kg for the sum of dioxins and dioxin-like PCBs (all expressed in 88% dry matter).

The same three batches were analysed for mycotoxins.[30] Aflatoxins (B1, B2, G1, G2), ochratoxin A, zearalenone, deoxynivalenol, fumonisins (B1, B2, B3) T-2 toxin and HT-2 toxin were below the LOQ of the corresponding methods.

1,1′-Ethylidene-bis-l-tryptophan (EBT) was not detected in the three batches analysed, while 1-methyl-1,2,3,4-tetrahydro-beta-carboline-3-carboxylic acid (MTCA) levels ranged from 0.27 to 0.35 mg/kg.[31] Both compounds, formed during the biotechnological manufacturing process, do not represent a safety concern according to the European Pharmacopoeia (2023) that established a maximum permitted content of EBT (impurity A) and the sum of all other impurities (B-L, including MTCA) in L-tryptophan (99%–100%) as 10 and 390 mg/kg, respectively.

The FEEDAP Panel considers that the microbial contamination and the amounts of the above-detected impurities do not raise safety concerns.

The presence of viable cells of the production strain was investigated [redacted].[32] [redacted]

The presence of DNA of the production strain in the final product was analysed [redacted].[33] [redacted].

3.1.4 | Physical properties of the additive

The additive appears as a white to slightly yellowish white crystals or a crystalline powder. The bulk density measured in three batches ranged from 356 to 389 kg/m^3.[34] The reported solubility in water was 10.6 g/L (at 25°C).[35]

The dusting potential of three batches of the additive was determined using the Stauber-Heubach method and showed values ranging from 1045 to 1490 mg/m^3.[36] The particle size distribution of the product was analysed in the same three batches by laser diffraction, and the results showed that the fraction of particles having a diameter < 100 μm was 90%–93%, < 50 μm was 77.4%–81.5%, < 10 μm was 18.2%–19.7% and < 1 μm was 1.1%–1.2%.

3.1.5 | Stability and homogeneity

The shelf-life of the additive (three batches) was studied when stored at 25°C and 40°C in kraft paper bags and polyethylene liners for 6 months.[37] No losses were observed at the end of the storage period.

The stability of the additive (three batches) in a vitamin–mineral premixture for chickens for fattening was studied when supplemented at 100,000 mg/kg and stored at 25°C in aluminium bags for 6 months.[38] No losses were observed at the end of the storage period.

[27] Annex 2.1.4b. Purity (contaminants). LOQ in mg/kg were 0.04 for arsenic; 0.015 for lead; 0.010 for cadmium and mercury.

[28] Annex_Q3. Annex 2.1.4a. Purity microbiology.

[29] Annex 2.1.4b. Purity (contaminants). 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 dioxins, furans and dioxin-like PCBs established by the WHO in 2005 (van den Berg et al., 2006).

[30] Annex 2.1.4b. Purity (contaminants). LOQ in μg/kg were 0.2 for aflatoxins B1, B2, G1, G2; 0.5 for ochratoxin A; 5 for zearalenone; 10 for deoxynivalenol; 50 for fumonisins B1, B2, B3; 2 for T-2 toxin and HT-2 toxin.

[31] Annex Q4 EBT MCA Analysis result.

[32] Annex 2.2.6. Absence viable cells.

[33] Annex 2.2.7. DNA absence.

[34] Annex 2.1.5. Physical state.

[35] Annex 2.1.1. Technical Data Sheet.

[36] Annex 2.1.5. Physical state.

[37] Annex 2.4.1. Storage stability.

[38] Annex 2.4.2. Stability and homogeneity in feeds.

The stability of the additive (three batches) in mash and pelleted compound feed for chickens (based on wheat, maize and soybean meal) was studied when supplemented at 3000 mg/kg.[39] Pelleting temperature was 70–75°C, and no losses were observed due to the pelleting process. After pelleting, samples were stored at 25°C in aluminium bags for 3 months. No losses were observed for both mash and pelleted feeds.

The stability of the additive (three batches) in water for drinking was studied when supplemented at 5 mg/mL. The samples were stored at room temperature for 48 h.[40] Losses observed ranged from 0.2% to 3.6%.

The capacity for homogeneous distribution of the additive (one batch) in premixtures and complete feed (mash and pelleted forms) for chickens for fattening described above was studied in 10 subsamples.[41] The coefficient of variation (CV) of the premixture was 2.5%. As regards the complete feed, total tryptophan was analysed, and the background content of tryptophan in feed (protein-bound tryptophan) was subtracted from the total amount. CVs were 3.9% and 3.1% for the mash feed and pelleted feed, respectively.

3.1.6 | Conditions of use

L-Tryptophan is intended to be used in complete feed for all animal species, directly or through complementary feed, premixtures or water. No inclusion levels have been proposed as the requirements, in quantitative terms, depend on the species, the age of the animal, the physiological state of the animal, the performance level, the environmental conditions and the amino acid composition of the un-supplemented diet.

3.2 | Safety

3.2.1 | Safety of the production microorganism

The production organism *C. glutamicum* KCCM 80346 is a genetically modified strain developed to increase the production of L-tryptophan. 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, 2023b). The taxonomic identification of the production strain was unequivocally established, it does not carry acquired antimicrobial resistance 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 concern regarding the genetically modified *C. glutamicum* KCCM 80346 strain.

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

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

Safety concerns on the use of the additive may derive from the amino acid itself, L-tryptophan and/or on the residues/metabolites derived from the fermentation process.

The additive is produced by fermentation with a genetically modified *C. glutamicum* strain (KCCM 80346), and no safety concerns were identified for the production strain (See Section 3.2.1), the fermentation process and its residues/metabolites. Moreover, the resulting product is highly purified (≥ 98% tryptophan and < 1% unidentified material on a DM basis).

For non-ruminant species, the FEEDAP Panel considers that the use of the additive is safe when added to supplement the diets with appropriate amounts to satisfy animal requirements. The FEEDAP Panel reiterates that ruminal metabolism of unprotected L-tryptophan may result in the production of toxic quantities of 3-methylindole (skatole), which causes pulmonary disease (fog fever; emphysema) in cattle and goats (Hammond et al., 1979). Consequently, only a protected form of L-tryptophan should be used in ruminants. Finally, the FEEDAP Panel reiterates its previous statement that amino acids, their salts and analogues should generally not be used in water for drinking because of the risk of imbalances and for hygiene reasons (EFSA FEEDAP Panel, 2010). Moreover, it may result in an increased nitrogen excretion via urine. Therefore, the FEEDAP Panel has concerns on the safety of the simultaneous oral administration of tryptophan-containing additives via feed and water for drinking.

The absorption and metabolic fate of L-tryptophan in the organism is well known. The amino acid L-tryptophan, 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 the use of L-tryptophan in animal nutrition. EBT and MTCA present in a specific brand of L-tryptophan produced by fermentation were implicated in the eosinophilia–myalgia syndrome outbreak that occurred in humans in New Mexico in 1989 (Hertzman et al., 1990). The analysed concentrations of EBT in L-tryptophan produced with *C. glutamicum*

[39]Annex 2.4.2. Stability and homogeneity in feeds.

[40]Annex_Q6. Annex 2.4.3. Stability in water.

[41]Annex 2.4.2. Stability and homogeneity in feeds.

KCCM 80346 were not detected in the additive, and those of MTCA were 0.27–0.35 mg/kg (see Section 3.1.3). Therefore, the Panel considers the use of the additive in animal species as safe for the consumer.

The amino acid L-tryptophan is a physiological and natural component of animals and plants. When consumed, it will be absorbed, and the non-absorbed fraction will be incorporated into the intestinal microbial mass and excreted as such. The use of amino acids 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. The use of the product L-tryptophan in animal nutrition would not lead to any localised increase in the concentration in the environment. The use of L-tryptophan produced with *C. glutamicum* KCCM 80346 as a feed additive does not represent a risk to the environment.

3.2.2.1 | *Conclusions on the safety for the target species, consumers and the environment*

The use of L-tryptophan produced with *C. glutamicum* KCCM 80346 to supplement feed is safe for non-ruminant species. There may be a risk for an increased production of the toxic metabolite skatole when unprotected tryptophan is used in ruminants. The FEEDAP Panel has concerns on the use of L-tryptophan in water for drinking.

The use of L-tryptophan produced by fermentation with *C. glutamicum* KCCM 80346 in animal nutrition is considered safe for the consumers and for the environment.

3.2.3 | Safety for the user

3.2.3.1 | *Effect on respiratory system*

Based on the highest dusting potential measured value (1490 mg/m^3), the FEEDAP Panel considers that the exposure of users through inhalation is likely.

An acute inhalation study was performed following the OECD Guideline (TG) 403.[42] The mass median aerodynamic diameter (MMAD) of the dust ranged from 3.9 to 4.0 µm (gsd 1.8–2.0). The lethal concentration 50 (LC_{50}) of L-tryptophan was more than 5.2 mg/L. The additive is not toxic by inhalation.

3.2.3.2 | *Effect on eyes and skin*

The skin irritation potential of the additive was investigated in an in vitro human reconstructed epidermis assay (EpiSkin) performed according to OECD TG 439.[43] Based on the results of the study, the additive is classified as non-irritant to the skin (UN GHS 'No Category').

The eye irritation potential of the additive was investigated in an in vitro bovine corneal opacity and permeability assay (BCOP) performed according to OECD TG 437.[44] Based on the results of the study, the additive is classified as non-irritant to the eyes (UN GHS 'No Category').

The skin sensitisation potential of the additive was evaluated with a local lymph node assay following the OECD TG 429.[45] Based on the results of the study, the additive is classified as a non-skin sensitiser (UN GHS 'No Category').

3.2.3.3 | *Conclusions on safety for the user*

On the basis of the studies submitted, the additive was shown to be not irritating to the eyes and skin or a skin sensitiser. Considering the dusting potential of the additive, inhalation exposure is likely.

3.3 | Efficacy

Efficacy studies are not required for amino acids naturally occurring in the proteins of plants and animals. The nutritional role of the amino acid L-tryptophan is well established in the scientific literature. The additive feed grade L-tryptophan is regarded as an effective source of the amino acid L-tryptophan.

This amino acid is essential in non-ruminant and ruminant animals. The Panel notes that, for the supplemental L-tryptophan to be as efficacious in ruminants as in non-ruminant species, it requires protection against degradation in the rumen; otherwise, it will be used by the ruminal microbiota.

[42] Annex 3.3.1. Acute inhalation.
[43] Annex 3.3.2. Skin irritation.
[44] Annex 3.3.3. Eye irritation.
[45] Annex 3.3.4. Skin sensitization.

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[46] and good manufacturing practice.

4 | CONCLUSIONS

The production strain *C. glutamicum* KCCM 80346 does not raise safety concerns regarding the genetic modifications. No viable cells or 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 production strain.

The use of L-tryptophan produced with *C. glutamicum* KCCM 80346 in feed is safe for non-ruminant target species. The use of rumen-protected L-tryptophan in ruminants is considered safe, while there may be a risk for an increased production of the toxic metabolite skatole when unprotected tryptophan is used.

The FEEDAP Panel has concerns on the safety for the target species resulting from the simultaneous oral administration of L-tryptophan via water for drinking and feed due to possible amino acid imbalances and for hygienic reasons in case of use in water.

The use of L-tryptophan produced by fermentation with *C. glutamicum* KCCM 80346 in animal nutrition is considered safe for the consumers and for the environment.

Regarding user safety, L-tryptophan produced with *C. glutamicum* KCCM 80346 is not irritating to the eyes and skin, and it is not a skin sensitiser.

The feed additive consisting of L-tryptophan produced by fermentation with *C. glutamicum* KCCM 80346 is regarded as an effective source of the amino acid L-tryptophan for all non-ruminant species. In order to be as efficacious in ruminants as in non-ruminants, it should be protected from ruminal degradation.

ABBREVIATIONS

CFU	colony forming unit
CV	coefficient of variation
DM	dry matter
EBT	1,1′-ethylidene-bis-L-tryptophan
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
LOQ	limit of quantification
MIC	minimum inhibitory concentration
MTCA	1-methyl-1,2,3,4-tetrahydro-beta-carboline-3-carboxylic acid
OECD	Organisation for Economic Co-operation and Development
PCBs	polychlorinated biphenyls
PCDDs	Polychlorinated dibenzo-p-dioxins
PCDFs	polychlorinated dibenzofurans
WGS	Whole-genome sequencing

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[46]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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