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Assessment of the feed additive consisting of *Enterococcus faecium* DSM 21913, *Bifidobacterium animalis* DSM 16284 and *Ligilactobacillus salivarius* DSM 16351 (Biomin® C3) for chickens for fattening, chickens reared for laying and minor poultry species other than laying for the renewal of its authorisation and extension of use in all poultry species for fattening and reared for laying/breeding (Biomin GmbH)

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of the feed additive containing *Enterococcus faecium* DSM 21913, *Bifidobacterium animalis* ssp. *animalis* DSM 16284 and *Ligilactobacillus salivarius* (formerly *Lactobacillus salivarius*) DSM 16351 (Biomin® C3) as a zootechnical feed additive (functional group: gut flora stabiliser) in the context of the renewal of the authorisation for chickens for fattening, chickens reared for laying and minor poultry species other than laying. In addition, the applicant requested the extension of use in all poultry species for fattening and reared for laying/breeding. The applicant provided evidence that the additive currently in the market complies with the conditions of the authorisation. There is no new evidence that would lead the Panel to reconsider previous conclusions that the additive is safe for the target species, consumers and the environment under the authorised conditions of use. This conclusion also applies to the target species for which a request for an extension of use is made. The Panel concluded that Biomin® C3 is not irritant to skin or eyes but should be considered as a respiratory sensitiser due to its proteinaceous nature. No conclusions could be drawn on the skin sensitisation potential of the additive. The evaluation of the efficacy is not needed in those species for which an authorisation exists. The Panel considered that the additive is efficacious in all growing poultry species at the same inclusion level of 1×10^8 CFU/kg feed and the equivalent level in water of 5×10^7 CFU/L.

Keywords: zootechnical additives, gut flora stabiliser, *Enterococcus faecium* DSM 21913, *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351, safety, renewal

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1. Introduction

1.1. Background and terms of reference

Regulation (EC) No 1831/2003 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. In addition, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Biomin GmbH for the modification of the current authorisation and the renewal of the authorisation of the additive consisting of *Enterococcus faecium* DSM 21913, *Bifidobacterium animalis* subsp. *animalis* DSM 16284 and *Ligilactobacillus salivarius* DSM 16351 (Biomin® C3), when used as a feed additive for growing poultry (category: zootechnical additive; functional group: gut flora stabiliser).

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) and under Article 14(1) (renewal of the authorisation). The dossier was received on 17/06/2022 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00374. The particulars and documents in support of the application were considered valid by EFSA as of 22 December 2022.

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 *E. faecium* DSM 21913, *B. animalis* DSM 16284 and *L. salivarius* DSM 16351 (Biomin® C3), when used under the proposed conditions of use (see **Section 3.1.3**).

1.2. Additional information

The product under assessment is based on viable cells of *Enterococcus faecium* DSM 21913, *Bifidobacterium animalis* DSM 16284 and *Ligilactobacillus salivarius* (formerly *Lactobacillus salivarius*) DSM 16351 under the trade name Biomin® C3.

In 2012, the FEEDAP Panel issued an opinion on the safety and efficacy of the additive for chickens for fattening (EFSA FEEDAP Panel, 2012). In 2015, the Panel adopted another opinion on the use of the additive in chickens reared for laying and minor avian species other than laying species (EFSA FEEDAP Panel, 2015). In addition, the applicant was seeking authorisation for use in water for drinking for chickens for fattening and the additional species and the removal of the maximum dose from the present authorisation.

The additive is currently authorised for its use in feed and water for drinking of chickens for fattening, chickens reared for laying and minor poultry species other than laying[1,2] (4b1890).

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[3] in support of the authorisation request for the use of a preparation consisting of *Enterococcus*

[1] Commission Implementing Regulation (EU) 2015/1105 of 8 July 2015 concerning the authorisation of a preparation of Bifidobacterium animalis ssp. animalis DSM 16284, Lactobacillus salivarius ssp. salivarius DSM 16351 and Enterococcus faecium DSM 21913 as a feed additive for chickens reared for laying and minor poultry species other than laying, the authorisation of that feed additive for use in water for drinking for chickens for fattening and amending Regulation (EU) No 544/2013 as regards the maximum content of that feed additive in complete feedingstuff and its compatibility with coccidiostats (holder of the authorisation Biomin GmbH).

[2] Commission Implementing Regulation (EU) No 544/2013 of 14 June 2013 concerning the authorisation of a preparation of Bifidobacterium animalis ssp. animalis DSM 16284, Lactobacillus salivarius ssp. salivarius DSM 16351 and Enterococcus faecium DSM 21913 as a feed additive for chickens for fattening (holder of authorisation Biomin GmbH).

[3] Dossier reference: FEED-2022-6591.

faecium DSM 21913, *Bifidobacterium animalis* DSM 16284 and *Ligilactobacillus salivarius* DSM 16351 (Biomin® C3) as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 5 January to 5 April 2023 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[4] 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,[5] 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,[5] EFSA carried out a public consultation on the non-confidential version of the technical dossier from 20 July 2023 to 10 August 2023 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 or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' (elicitation) knowledge, to deliver the present output.

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 active agent in animal feed are valid and applicable for the current application.[6]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Biomin® C3 is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the 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 renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3. Assessment

The additive under assessment (herein and after referred to as Biomin® C3) contains viable cells of *Enterococcus faecium* DSM 21913, *Bifidobacterium animalis* subsp. *animalis* DSM 16284 and *Ligilactobacillus salivarius* DSM 16351. It is currently authorised as a zootechnical additive (functional group: gut flora stabilisers) in feed and water for drinking for chickens for fattening, chickens reared for laying and minor poultry species other than laying.

This assessment regards the renewal of the authorisation of Biomin® C3 for the above-mentioned species and its extension of use to all poultry species for fattening and reared for laying/breeding.

3.1. Characterisation

3.1.1. Characterisation of the active agents

3.1.1.1. *Enterococcus faecium* DSM 21913

The *E. faecium* strain was originally isolated from the digestive tract of a healthy farm animal and is deposited in the DSMZ with the accession number DSM 21913.[8] It has not been genetically modified.[9]

[4] 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.
[5] Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements
[6] The full report is available on the EU Science Hub: https://joint-research-centre.ec.europa.eu/publications/fad-2009-0034_en
[7] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.
[8] 2_1 and 2_2 Sect_II Identity_Characterisation_C3 and Annex II_04.
[9] Annex II_21.

The taxonomic identification of the active agent as *E. faecium* was confirmed by analysis of its whole genome sequence (WGS) data. This was based on an ANI analysis which showed an OrthoANI value of 99% compared to the type strain *E. faecium* DSM 20477^T, as well as by alignment-free genome distance estimation and phylogenetic analysis using 35 core genes which showed that *E. faecium* strains were the closest genomes.

The WGS data were screened for the presence of plasmids against the [redacted] One putative plasmid sequence was identified.[10]

The susceptibility of the active agent DSM 21913 to antimicrobials was tested against the battery of antibiotics recommended by EFSA (EFSA FEEDAP Panel, 2018b) by microdilution assay.[11] All the minimum inhibitory concentration (MIC) values for the strain were equal to or fell below the corresponding cut-off values. Therefore, *E. faecium* DSM 21913 is considered to be susceptible to all relevant antibiotics.

The WGS data of the active agent DSM 21913 were interrogated for the presence of antimicrobial resistance (AMR) genes by a search against the [redacted] (thresholds: 80% identity, 70% length of the subject sequence at nucleotide and/or protein level).[12] Hits obtained were the *eat(A)* (encoding an efflux pump (ABC-type transporter) harbouring the Thr450Ile mutation, *msrC* (encoding an efflux pump transporter) and *aac(6′)* (encoding an aminoglycoside 6′-N-acetyltransferase). All these genes are considered intrinsic in *E. faecium* ([redacted]), and thus, of no concern.

According to the FEEDAP guidance (EFSA FEEDAP Panel, 2018b), the safety of *E. faecium* should be assessed by demonstrating the absence of genetic markers typical of the clinical isolates *E. faecium* clade A (IS*16*, *esp*, *hyl*Efm) and the susceptibility to ampicillin (≤ 2 mg/L). *E. faecium* DSM 21913 was susceptible to ampicillin (MIC 0.25 mg/L). The WGS data of DSM 21913 were interrogated for the presence of genes encoding for [redacted] and no hits of concern were detected. Moreover, the presence of IS*16*, *hyl*Efm and *esp* genes in the genome of DSM 21913 was excluded using [redacted].[13]

Although the species is not expected to produce antimicrobials, the presence of antimicrobial activity was tested in the culture supernatant of *E. faecium* DSM 21913.[14] This was done using a disc-diffusion agar method against the following reference strains: *Escherichia coli* ATCC 25922, *Pseudomonas aeruginosa* ATCC 27853, *Staphylococcus aureus* ATCC 25923, *Enterococcus faecalis* ATCC 29212 and *Bacillus subtilis* ATCC 6633. No antimicrobial activity was detected.

3.1.1.2. *Bifidobacterium animalis* DSM 16284

The *B. animalis* strain was originally isolated from the digestive tract of a healthy farm animal and is deposited in the DSMZ with the accession number DSM 16284.[15] It has not been genetically modified.[9]

The active agent DSM 16284 was taxonomically identified as *B. animalis* ssp. *animalis* based on an OrthoANI value of 98.7% with the type strain *B. animalis* ssp. *animalis* ATCC 25527^T (whereas similarity with *B. animalis* ssp. *lactis* strains was ≤ 95.6%).[16] This was further confirmed by alignment-free genome distance estimation and phylogenetic analysis using 117 core genes which showed that *B. animalis* ssp. *animalis* strains were the closest genomes.

The antimicrobial susceptibility of the active agent DSM 16284 was tested against the battery of antibiotics recommended by the FEEDAP Panel (EFSA FEEDAP Panel, 2018b) by microdilution assay.[17] All the MIC values for the strain were equal to or fell below the corresponding cut-off values, except for clindamycin which was higher than the cut-off value (2 vs. 1 mg/L). A MIC value of one dilution higher than the cut-off is within the normal range variation of the method. Therefore, *B. animalis* DSM 16284 is considered susceptible to all relevant antibiotics.

[10] Annex II_20 Bioinformatics_Efaecium_21913_updated.
[11] Annex II_30.
[12] Annex II_20 Bioinformatics_Efaecium_21913_updated, Annex II_20A Bioinformatics_Efaecium_21913_updated_Appendix2 and Annex II_20B Bioinformatics_Efaecium_21913_updated_Appendix3.
[13] Annex II_19.
[14] Annex II_27.
[15] 2_1 and 2_2 Sect_II Identity_Characterisation_C3 and Annex II_02.
[16] Annex II_15 and Annex II_18.
[17] Annex II_28.

The WGS data of the active agent DSM 16284 were interrogated for the presence of AMR genes as described above for *E. faecium* DSM 21913.[18] No hits of concern were identified.

3.1.1.3. *Ligilactobacillus salivarius* DSM 16351

The *L. salivarius* strain was originally isolated from the digestive tract of a healthy farm animal and it is deposited in the DSMZ with the accession number DSM 16351.[19] It has not been genetically modified.[9]

The taxonomic identification of the active agent as *L. salivarius* was confirmed by analysis of its WGS data.[20] This was based on an ANI analysis which showed an OrthoANI value of 97.2% compared to the type strain *L. salivarius* DSM 20555^T, as well as by alignment-free genome distance estimation and phylogenetic analysis using 41 core genes which showed that *L. salivarius* strains were the closest genomes.

The WGS data were screened for the presence of plasmids against the [redacted] and six contigs showing complete or partial plasmid sequences were identified.[13]

The antimicrobial susceptibility profile of the active agent was tested against the battery of antibiotics recommended by EFSA (EFSA FEEDAP Panel, 2018b) by microdilution assay.[21] All the MIC values for the strain were equal to or fell below the corresponding cut-off values. Therefore, *L. salivarius* DSM 16351 is considered to be susceptible to all relevant antibiotics.

The WGS data of the active agent DSM 16351, including plasmids, were interrogated for the presence of AMR genes as described for *E. faecium* DSM 21913.[13] No hits were identified.

3.1.2. Characterisation of the additive

Biomin® C3 is a preparation consisting of approximately 48% bacterial cells mixed in the following ratio: 40% w/w *E. faecium* DSM 21913, 5% w/w *L. salivarius* DSM 16351, 3% w/w *B. animalis* DSM 16284 and a carrier (52% w/w sugar spheres: sucrose, maize starch and water). Other excipients of the product include cryoprotectants (Inulin 1.5% w/w) and coating substances (4% w/w hydrogenated vegetable oil, 0.02% w/w hydroxypropyl methyl cellulose, 0.02% w/w methyl cellulose and 0.2% w/w xantham gum[22]).

The additive[23] is currently authorised as a solid preparation with a minimum content of the active agents in colony forming units (CFU) per gram of additive of 3×10^9 *B. animalis* DSM 16284, 1×10^9 *L. salivarius* DSM 16351 and 6×10^9 *E. faecium* DSM 21913 (ratio 3:1:6).

The applicant declared that no changes to the manufacturing process were implemented since the original authorisation was granted in 2013.[24]

Analytical data to confirm the specifications regarding the batch-to-batch variation were provided for five recent batches.[25] Average content was 9.6×10^9 CFU/g additive (range 8.7–11.5 × 1010) for *E. faecium* DSM 21913; 3.9×10^9 CFU/g additive (range 3.2–4.2 × 10^9) for *B. animalis* DSM 16284 and 1.5×10^9 (range 1.3–1.9 × 10^9) CFU/g additive for *L. salivarius* DSM 16351 which showed compliance with the specifications of the additive in the authorising regulation. The mean total bacterial cell count was 1.5×10^{10} (range 1.4–1.7 × 10^{10}) CFU/g.

Three of the above-mentioned batches of the additive were analysed for cadmium, lead, mercury and arsenic. Levels showed values below the limit of quantification (LOQ) of the analytical methods.[26]

The analysis of mycotoxins, including aflatoxins (B1, G1, B2, G2), deoxynivalenol, zearalenone, ochratoxin A, fumonisin B1 and B2, HT-2 Toxin and T-2 Toxin, showed values below the limit of detection (LOD) of the analytical methods.[27]

[18] Annex II_18.
[19] 2_1 and 2_2 Sect_II Identity_Characterisation_C3 and Annex II_03.
[20] Annex II_16 and Annex II_19.
[21] Annex II_29.
[22] The Panel notes that the additives hydroxyproyl methyl cellulose, methyl cellulose and xantham gum are currently under re-evaluation.
[23] 2_1 and 2_2 Sect_II Identity_Characterisation_C3.
[24] 2_3 Sect_II Manufacturing_C3.
[25] Annex II_05.
[26] Annex II_06 Heavy metals analysis; LOQ (mg/kg): Cadmium < 0.2; Lead < 0.5; Mercury < 0.02; Arsenic < 0.5.
[27] Annex II_07 Mycotoxin analysis; LOD (μg/kg): Deoxynivalenol 20 μg/kg, Zearalenone 5 μg/kg, Aflatoxin B1 0.5 μg/kg, Aflatoxin B2 1 μg/kg, Aflatoxin G1 1 μg/kg, Aflatoxin G2 1 μg/kg, Ochratoxin A 0.5 μg/kg, Fumonisin B1 10 μg/kg, Fumonisin B2 10 μg/kg, HT-2 Toxin 15 μg/kg and T-2 Toxin 10 μg/kg.

Microbiological contamination was analysed by the determination of yeasts and filamentous fungi (< 1000 CFU/g), coliforms (< 1000 CFU/g), Enterobacteriaceae (< 1000 CFU/g), *Escherichia coli* (< 10 CFU/g) and *Salmonella* spp. (no detection in 25 g).[28]

The dusting potential on the same three batches of the additive was determined using the Stauber-Heubach method and showed a mean value of 362 mg/m^3 (range 300–420 mg/m^3) (mg airborne dust per m^3 of air).[29]

Since the formulation and manufacturing process of the additive have not changed, the data supporting the stability and homogeneity assessed in the previous opinion are considered to be still valid for the current assessment (EFSA FEEDAP Panel, 2012).

3.1.3. Conditions of use

The additive is currently authorised at a minimum content of 1×10^8 CFU/kg complete feed or 5×10^7 CFU/L water for drinking of chickens for fattening, chickens reared for laying and minor poultry species other than laying.

Under other provisions of the authorisation, a feed additive for chickens reared for laying and minor poultry species other than laying and for the use in water for drinking for chickens for fattening, it is specified that:

1) In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
2) The use is permitted in feed containing the following coccidiostats: maduramicin ammonium, diclazuril, robenidine hydrochloride, decoquinate, narasin, nicarbazin or narasin/nicarbazin.
3) The additive may be used also via water for drinking. The water for drinking containing the additive may be used simultaneously with feed containing the mentioned permitted coccidiostats.
4) For safety: breathing protection, glasses and gloves shall be used during handling.
5) The homogeneous dispersion of the additive shall be ensured in the water for drinking.
6) Simultaneous use with antibiotics shall be avoided.

The applicant wishes to maintain the same conditions of use for those species for which it is authorised and has requested an extension of the authorisation to include all poultry for fattening or reared for laying/breeding with a minimum content of 1×10^8 CFU/kg complete feed and of 5×10^7 CFU/L water for drinking.

3.2. Safety

In the previous assessments (EFSA FEEDAP Panel, 2012, 2015), the FEEDAP Panel concluded that Biomin® C3 is safe for the target species, consumers and the environment when administered via complete feed or water for drinking without a maximum level. The additive was considered non-irritant to skin or eyes, not a skin sensitiser, but a potential respiratory sensitiser owing to its proteinaceous nature.

For the present dossier, the applicant states that no adverse events have been reported since the market authorisation of Biomin® C3.[30]

During the current assessment, the identity of the *B. animalis* and *L. salivarius* strains has been unambiguously established and the antibiotic resistance qualifications have been met. Consequently, the FEEDAP Panel considers that *B. animalis* DSM 16284 and *L. salivarius* DSM 16351 are suitable for the QPS approach to safety assessment and presumed safe for the target species, consumers and the environment (EFSA, 2007; EFSA BIOHAZ, 2023).

The *E. faecium* strain was unambiguously identified and found not to belong to the hospital-associated clade and not to express resistance to clinically relevant antibiotics. The metabolic end products of the species are those typical of lactic acid bacteria and do not raise concerns. Therefore, the use of *E. faecium* DSM 21913 in animal nutrition is not expected to raise concerns for the target species, consumers and the environment.

[28] Annex II_08.
[29] Annex_10.
[30] Annex III_02.

A literature search was performed in order to demonstrate that, in the light of the current knowledge, the additive remains safe under the approved conditions for target species, consumers, users and the environment.

A first literature search[31] was conducted using seven databases (CAB Abstracts (OVID), EBSCOhost Academic Search Premier, Medline (OVID), ProQuest, SciFinder, Scopus and Web of Science) covering the period 2015–2021. After the removal of duplicates and applying the exclusion criteria, no publications were considered relevant for the assessment. The literature presented some limitations (i.e. it did not cover the period since the original authorisation of the additive, the list of publications was not provided), therefore, a second literature search[32] was conducted using six databases (all previous databases except CAB Abstract (OVID)) covering the period since the last authorisation, from 2013 until March 2023. The keywords included relevant terms to search for the three strains separately and combined. The number of hits identified after duplicate removal was 380. Titles and abstracts were further screened against the exclusion criteria resulting in 6 hits, but none of them were considered relevant for the assessment because (i) they described beneficial effects in animals challenged with coccidia or (ii) described beneficial effects in soil after using the poultry manure.

Regarding the safety for the user, no new data have been provided to reconsider the previous conclusions. In the last assessment, the Panel concluded that the additive is not a skin sensitiser based on a Buhler test following OECD guideline 406. However, the FEEDAP Panel notes that the OECD test guidelines available at present are designed to assess the skin sensitisation potential of chemical substances only and that currently no validated assays for assessing the sensitisation potential of microorganisms are available. Therefore, Biomin® C3 can be considered non-irritant to skin or eyes but should be treated as a potential respiratory sensitiser and no conclusions can be drawn on the skin sensitisation potential of the additive.

3.2.1. Safety aspects related to the new use of the additive

The current application requests the extension of use of the additive to all poultry for fattening or reared for laying/breeding.

In the previous opinions, two tolerance studies in chickens for fattening were provided, one to support the safety of the additive when used in feed (EFSA FEEDAP Panel, 2012) and a second one to extend the authorisation in feed and water for drinking in chickens reared for laying and minor poultry species reared up to the point of lay (EFSA FEEDAP Panel, 2015). Based on the results of the tolerance studies provided, on the presumed safety of the *B. animalis* and *L. salivarius* strains and the absence of pathogenicity of *E. faecium* DSM 21913, the Panel concluded that the additive was safe for the target species at the proposed conditions of use.

The FEEDAP Panel considers that the conclusions already reached on the safety of the additive in chickens for fattening can be extended to all poultry species for fattening or reared for laying/breeding at the same conditions of use. Moreover, the Panel considers that the proposed extension of use to the new species/categories would not introduce risks for consumers, users and the environment not already evaluated in the previous opinions.

3.2.2. Conclusions on safety

Considering all the above and the fact that the manufacturing and composition of the additive have not been modified, the FEEDAP Panel concludes that there is no evidence to reconsider its previous conclusions on the safety of the product for the target species, consumers and environment under the authorised conditions of use.

The Panel concludes that the additive is safe for all poultry for fattening or reared for laying/ breeding when supplemented with the additive under the authorised conditions of use.

Since the proposed extension of use to the new species/categories would not introduce risks not already evaluated in the previous opinions, the Panel considers that the conclusions of the previous assessments regarding the safety for the consumers and environment still apply to the present assessment. Therefore, Biomin® C3 is also considered to be safe for the consumers and the environment.

The additive is not an eye/skin irritant, but it should be considered a respiratory sensitiser. No conclusion can be drawn on the dermal sensitisation potential of the additive.

[31] Annex_III_01.
[32] Annex_III_1A.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of use for those species/categories for which there is an authorisation. Therefore, there is no need to assess the efficacy of the additive in the context of the renewal of the authorisation.

The current application includes the extension of use to all poultry species for fattening or reared for laying/breeding. The Panel has concluded in a previous opinion that the additive Biomin® C3 was efficacious at the minimum concentration of 1×10^8 CFU/kg feed and at the equivalent concentration in water for drinking of 5×10^7 CFU/L in chickens for fattening, chickens reared for laying and minor poultry species reared up to the point of lay (EFSA FEEDAP Panel, 2012). The Panel in accordance to the provisions of the FEEDAP Panel Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a) considers that the conclusions already reached in chickens for fattening can be extrapolated to all poultry for fattening or reared for laying/breeding at the same inclusion levels, including the use of coccidiostats for which an authorisation exists.

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[33] and good manufacturing practice.

4. Conclusions

The applicant provided evidence that the additive currently in the market complies with the terms of the authorisation.

The FEEDAP Panel concludes that Biomin® C3 remains safe for chickens for fattening, chickens reared for laying and minor poultry species other than laying, for the consumers and the environment under the authorised conditions of use.

Biomin® C3 should be considered non-irritant to skin or eyes but should be treated as a potential respiratory sensitiser. No conclusions can be drawn on the skin sensitisation potential of the additive.

The present application for renewal of the authorisation does not include a proposal for amending the conditions of the original authorisation that would have an impact on the efficacy of the additive.

Regarding the extension of use to all poultry for fattening and reared for laying/breading, the Panel concludes that the additive is safe for the target species, consumers and the environment, and efficacious at the minimum inclusion level of 1×10^8 CFU/kg complete feed and at the equivalent level in water of 5×10^7 CFU/L.

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[redacted]

Abbreviations

AMR	Antimicrobial resistance
ATCC	American Type Culture Collection
BIOHAZ	EFSA Scientific Panel on Biological Hazards
CFU	Colony forming unit
DMSZ	Deutsche Sammlung von Mikroorganismen und Zellkulturen
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection
LOQ	limit of quantification
NCBI	National Center for Biotechnology Information
OECD	Organisation for Economic Co-operation and Development
QPS	Qualified presumption of safety
WGS	whole genome sequence