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Safety and efficacy of the feed additive consisting of *Clostridium butyricum* FERM BP-2789 (Miya-Gold[®] S) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), piglets (suckling and weaned) and minor porcine species (Miyarisan Pharmaceutical Co. Ltd.)

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Abstract

The feed additive under assessment (trade name: Miya-Gold[®] S) is based on viable spores of *Clostridium butyricum* FERM BP-2789. It is authorised for use in minor avian species (excluding laying birds), weaned piglets and minor weaned porcine species, chickens reared for laying, turkeys for fattening and turkeys reared for breeding. This opinion concerns the request for renewal of the authorisation of Miya-Gold[®] S for the species/categories for which an authorisation exists, the use in chickens for fattening, for which the previous authorisation had expired, and the extension of use to suckling piglets and suckling minor porcine species. The applicant provided evidence that the additive currently in the market complies with the conditions of authorisation. There is no new evidence that would lead the Panel to reconsider previous conclusions that Miya-Gold[®] S remains safe for the animal species/categories, the consumer and the environment under the current and previously authorised conditions of use. This conclusion applies also to the new target species for which a request of use is made. Regarding the safety for the user, the Panel concluded that the additive is not irritant to skin and eyes and that sensitisation via respiratory route cannot be excluded. There is no need for assessing the efficacy of Miya-Gold[®] S in the context of the renewal of the authorisation in chickens reared for laying, turkeys for fattening and reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species. The additive has the potential to be efficacious in chickens for fattening, suckling piglets and suckling minor porcine species at the level of 2.5×10^8 CFU/kg complete feedingstuff. Miya-Gold[®] S is compatible with decoquinat, dicalazuril, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monensin sodium, robenidine, salinomycin sodium and semduramicin.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003¹ 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. 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 Huvepharma N.V. on behalf of Miyarisan Pharmaceutical Co. Ltd.² for authorisation of the feed additive consisting of *Clostridium butyricum* FERM BP-2789 (Miya-Gold® S), when used as a feed additive for chickens for fattening, suckling piglets and suckling minor porcine species and renewal of the authorisation of the product for chickens reared for laying, turkeys for fattening, turkey reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species (category: zootechnical additives; functional group: gut flora stabilisers).

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) and under Article 14(1) (renewal of the authorisation). The particulars and documents in support of the application were considered valid by EFSA as of 4 February 2020.

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 *C. butyricum* FERM BP-2789 (Miya-Gold® S), when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The additive is based on viable spores of *C. butyricum* FERM BP-2789.

EFSA has issued four opinions on the safety and efficacy of the additive based on *C. butyricum* FERM BP-2789 for chickens for fattening (EFSA, 2009), for weaned piglets, weaned minor porcine species and minor avian species (EFSA FEEDAP Panel, 2011), for chickens for fattening, chickens reared for laying and minor avian species (EFSA FEEDAP Panel, 2013a) and for turkeys for fattening and turkeys reared for breeding (EFSA FEEDAP Panel, 2014).

The additive (4b1830) is authorised for use in feed for minor avian species (excluding laying birds), weaned piglets and minor weaned porcine species,³ chickens reared for laying,⁴ turkeys for fattening and turkeys reared for breeding.⁵

The additive was also authorised (until 19 October 2019) as a feed additive for chickens for fattening.⁶ However, as an application for renewal of the authorisation was not sent one year before

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

² Miyarisan Pharmaceutical Co. Ltd. represented in the EU by Huvepharma NV Belgium, Uitbreidingstraat 80, B-2600 Berchem, Belgium.

³ Commission Implementing Regulation (EU) No 373/2011 of 15 April 2011 concerning the authorisation of the preparation of *Clostridium butyricum* FERM-BP 2789 as a feed additive for minor avian species except laying birds, weaned piglets and minor porcine species (weaned) and amending Regulation (EC) No 903/2009 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U.) OJ L 102, 16.04.2011, p. 10, amended by Commission Implementing Regulation (EU) No 357/2013.

⁴ Commission Implementing Regulation (EU) No 374/2013 of 23 April 2013 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for chickens reared for laying (holder of authorisation Miyarisan Pharmaceutical Europe S.L.U.) OJ L 112, 24.4.2013, p. 13 and amendment.

⁵ Commission Implementing Regulation (EU) No 1108/2014 of 20 October 2014 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.) OJ L 301, 21.10.2014, p. 16 and amendment.

⁶ Commission Regulation (EC) No 903/2009 of 28 September 2009 concerning the authorisation of a preparation of *Clostridium butyricum* MIYAIRI 588 (FERM P-1467) as a feed additive for chickens for fattening (holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Mitsui & Co. Deutschland GmbH) OJ L 256, 29.9.2009, p. 111–112, amended by Commission Implementing Regulation (EU) No 357/2013.

its expiry date, the authorisation expired and the applicant submitted a new application for authorisation of the additive for this target species.

The additive is authorised as a novel food ingredient to be used in food supplements with a maximum dose of 1.35×10^8 colony forming units (CFU) per day.⁷

The applicant has requested the renewal of the authorisation for the product consisting of *C. butyricum* FERM BP-2789 (Miya-Gold® S) for the species/categories for which there is an authorisation. Moreover, the applicant has requested the authorisation for use of the additive in feed for chickens for fattening and the extension of use of the additive to suckling piglets and suckling minor porcine species.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁸ in support of the authorisation request for the use of the product consisting of *C. butyricum* FERM BP-2789 (Miya-Gold® S) as a feed additive.

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.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessments are valid and applicable for the current application.⁹

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of the product consisting of *C. butyricum* FERM BP-2789 (Miya-Gold® S) is in line with the principles laid down in Regulation (EC) No 429/2008¹⁰ and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013b), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b).

3. Assessment

This assessment regards the renewal of the authorisation of the feed additive consisting of *C. butyricum* FERM BP-2789 (Miya-Gold® S) when used as a zootechnical additive (functional group: gut flora stabilisers) for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species. It also regards the request for authorisation for use in feed for chickens for fattening, for which the previous authorisation had expired, and the request for an extension of use to suckling piglets and suckling minor porcine species. It will be hereafter referred to as Miya-Gold® S.

3.1. Characterisation

3.1.1. Characterisation of the additive

Miya-Gold® S is a greyish-white granular powder based on viable spores of *C. butyricum* FERM BP-2789. In previous applications, two formulations were described: Miya-Gold® S, guaranteeing a minimum concentration of *C. butyricum* FERM BP-2789 of 5.0×10^8 CFU/g additive, and a more concentrated formulation, Miya-Gold® EU, guaranteeing a minimum concentration of *C. butyricum*

⁷ Commission Implementing Decision of 11 December 2014 authorising the placing on the market of *Clostridium butyricum* CBM 588 as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L 359, 16.12.2014, p. 153–154.

⁸ FEED dossier reference: FAD-2019-0058.

⁹ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2008-0012.pdf> and <https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2010-0005.pdf>

¹⁰ 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.

FERM BP-2789 of 1×10^{10} CFU/g additive. The applicant states that the product is present on the market only in the form of Miya-Gold® S.

The applicant stated that no changes in the manufacturing process have been introduced since the original authorisation was granted. The spores of *C. butyricum* FERM BP-2789 are harvested by centrifugation, washed, diluted in corn starch (60%), calcium carbonate (25%) and lactose (9%), and spray-dried. The spore powder is diluted with Brewers' yeast (20%), glucose, corn starch and zeolite as anti-caking agent. The additive contains about 2% of spent growth medium.

The additive currently authorised contains viable spores of *C. butyricum* FERM BP-2789 at the minimum concentration of 5×10^8 CFU/g additive. Compliance with this specification was demonstrated in three recent batches of Miya-Gold® S (5.0×10^8 CFU/g in all three batches).¹¹

Three recent batches of Miya-Gold® S were analysed for chemical and microbiological contamination.¹² The analysis of chemical contamination included cadmium (< limit of quantification (LOQ)), lead (range 1.5–2.2 mg/kg), mercury (< LOQ), arsenic (< LOQ except for 0.5 mg/kg in one batch), aflatoxins B1, B2, G1, G2 (< LOQ), ochratoxin A (< LOQ), deoxynivalenol (< LOQ), zearalenone (< LOQ except for 15.8 µg/kg in one batch), fumonisins B1, B2 (< LOQ), T-2 toxin (< LOQ), and HT-2 toxin (< LOQ).¹³ Polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/F) and dioxin-like polychlorinated biphenyls (PCBs) were below the corresponding LOQs in three batches of the additive. The levels of dioxins and the sum of dioxins and dioxin-like-PCBs (upper bond) were calculated to be 0.16 ng WHO-PCDD/F-TEQ/kg and 0.30 ng WHO-PCDD/F-PCB-TEQ/kg, respectively.

The same three batches were analysed for microbial contamination and the analysis included *Salmonella* spp. (not detected in 25 g), Enterobacteriaceae (< 40 CFU/g), yeasts (< 40 CFU/g except for 1.5×10^2 CFU/g in one batch) and filamentous fungi (from < 40 to 91 CFU/g).¹⁴

The above-mentioned impurities/contaminants do not represent a safety concern.

3.1.2. Characterisation of the active agent

Miya-Gold® S is based on viable spores of a *C. butyricum* strain isolated from soil. The strain is deposited at the National Institute of Technology and Evaluation, International Patent Organism Depository, Japan, with the accession number FERM BP-2789.¹⁵

The taxonomic identification of the strain FERM BP-2789 as *C. butyricum* was established

[REDACTED]

The susceptibility of the strain to the antibiotics recommended by the FEEDAP Guidance (EFSA FEEDAP Panel, 2018a),

[REDACTED]

(EFSA FEEDAP Panel, 2018a).

[REDACTED]

¹⁶ The WGS of the active agent, [REDACTED], was interrogated for the presence of antimicrobial resistance (AMR) genes [REDACTED]

¹¹ Technical dossier/Section II/Annex Sect. II/Annex II_1_3_2.

¹² Technical dossier/Section II/Annex Sect. II/Annex II_1_4_2.

¹³ LOQ: 1.0 µg/kg for aflatoxin B1, B2, G1, G2; 0.5 µg/kg for ochratoxin A; 0.05 µg/kg for deoxynivalenol; 5 µg/kg for zearalenone; 20 µg/kg for fumonisin B1, B2; 10 µg/kg for T-2 toxin; 10 µg/kg for HT-2 toxin. LOQ and LOD were, respectively: 0.10 mg/kg and 20 µg/kg for cadmium; 0.30 mg/kg and 50 µg/kg for lead; 0.10 mg/kg and 20 µg/kg for mercury; 0.30 mg/kg and 50 µg/kg for arsenic.

¹⁴ Limit of detection (LOD): 10 CFU/25 g for *Salmonella* spp.; 10 CFU/g for *Enterobacteriaceae*, yeasts and filamentous fungi.

¹⁵ Technical dossier/Section II/Annex Sect. II/Annex II_2_1_2_181 and Supplementary information July 2020/annexes/Annex II.2.1.2.184.

¹⁶ Technical dossier/Supplementary information July 2020/annexes/Annex II_2_2_2_9.

The WGS of the active agent, [REDACTED], was interrogated for the presence of toxin and virulence factors genes [REDACTED]

No antimicrobial activity was detected in the supernatant of *C. butyricum* FERM BP-2789 analysed [REDACTED]

3.1.3. Conditions of use

The additive Miya-Gold® S is currently authorised for use in feed for chickens reared for laying, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species at a minimum recommended inclusion level of 2.5×10^8 CFU/kg complete feed and in turkeys for fattening and turkeys reared for breeding at a minimum recommended inclusion level of 1.25×10^8 CFU/kg complete feed. The applicant has not asked to modify these conditions of use.

The use of the additive is authorised in feed containing the authorised coccidiostats as follows:

- in chickens reared for laying: monensin sodium, diclazuril, salinomycin sodium or lasalocid sodium;
- in minor avian species (excluding laying birds): monensin sodium, diclazuril, maduramicin ammonium, robenidine, narasin, narasin/nicarbazin, semduramicin, decoquinate, salinomycin sodium or lasalocid sodium;
- in turkeys for fattening and turkeys reared for breeding: monensin sodium, robenidine, maduramicin ammonium, lasalocid sodium or diclazuril.

In the other provisions of the authorisation it is specified that: 'For safety: breathing protection and safety glasses shall be used during handling'.

In addition, the applicant proposed the use of the product at the minimum recommended inclusion level of 2.5×10^8 CFU/kg feed for chickens for fattening, as it was previously authorised, and proposed the extension of use of the additive to suckling piglets and suckling minor porcine species at a minimum recommended inclusion level of 2.5×10^8 CFU/kg complete feed.

The applicant also requested the authorisation for the simultaneous use of the additive with the coccidiostats: decoquinate, diclazuril, halofuginone, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monensin sodium, robenidine, salinomycin sodium and semduramicin.

3.2. Safety

Safety aspects regarding the use of Miya-Gold® S in feed including the safety for the target animals, consumers, users and the environment have been evaluated in previous opinions (EFSA, 2009; EFSA FEEDAP Panel, 2011, 2013a, 2014). The Panel concluded that the additive is safe for the target species evaluated and the use of the product as a feed additive would be of no concern for the consumers of products derived from animals fed with the additive, or for the environment. Regarding the safety for the user, the Panel concluded that the additive is not irritant to skin and eyes. As the particle size data indicate that a significant proportion of the product is potentially respirable, sensitisation via respiratory route cannot be excluded.

The data newly provided allow to confirm the identification of the active agent as *C. butyricum*. Based on the WGS data provided, the active agent is not expected to produce any toxic compound and does not harbour acquired AMR genes.

The FEEDAP Panel notes that the additive was previously assessed for its use in chickens for fattening (EFSA, 2009; EFSA FEEDAP Panel, 2013a) and authorised for this use for ten years. Consequently, the Panel considers that the approach used for the renewal of the authorisation can be applied also in the case of the assessment of this new use in chickens for fattening.

¹⁷ Technical dossier/Section II/Annex Sect. II/Annex II_2_1_2_14.

In line with the requirements established in the EFSA guidance on the renewal (EFSA FEEDAP Panel, 2013b), the applicant performed a literature search in order to provide evidence that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, users and the environment. The applicant searched in a total of three relevant databases (CAB Abstracts, PubMed and Veterinary Science Database).¹⁸ The search covered the period 2009–2019 and the search terms and search strategy were provided. The main search terms regarded the safety for the target animals (pigs and poultry), safety for the consumers, workers and the environment, interactions/incompatibilities and safety of the microorganism. The literature search did not identify hits other than previous EFSA opinions.

The applicant stated that no adverse events have been detected under its post-marketing monitoring plan.¹⁹

Therefore, the FEEDAP Panel concludes that there is no new evidence that would lead the Panel to reconsider its previous conclusions on the safety of the product for target species evaluated, consumers and the environment under the current and previously authorised conditions of use.

The applicant has requested for an extension of use of the additive to suckling piglets and suckling minor porcine species.

The FEEDAP Panel evaluated in the past tolerance trials which showed that the additive is safe for weaned piglets (EFSA FEEDAP Panel, 2011). Therefore, the Panel considers that the conclusions reached in weaned piglets can be extended to suckling piglets and extrapolated to suckling minor porcine species. Consequently, the additive is considered safe for suckling piglets and suckling minor porcine species at the minimum recommended inclusion level of 2.5×10^8 CFU/kg complete feed.

3.2.1. Conclusions on safety

Based on the above and the fact that the manufacturing process, the composition of the additive and the conditions of use for the species/categories for which the additive is or had been authorised have not been modified, the FEEDAP Panel considers that there is no evidence to reconsider the conclusions reached in previous assessments. The Panel concludes that the additive Miya-Gold® S remains safe for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species, the consumer and the environment under the current and previously authorised conditions of use. Regarding the safety for the user, the Panel concludes that the additive is not irritant to skin and eyes and that sensitisation via respiratory route cannot be excluded.

Miya-Gold® S is considered safe for suckling piglets and suckling minor porcine species at the minimum recommended inclusion level of 2.5×10^8 CFU/kg complete feed.

3.3. Efficacy

3.3.1. Efficacy for weaned piglets, weaned minor porcine species, chickens reared for laying, minor avian species (excluding laying birds), turkeys for fattening and turkeys reared for breeding

The efficacy of Miya-Gold® S was previously established in weaned piglets and weaned minor porcine species at a minimum recommended inclusion level of 2.5×10^8 CFU/kg complete feed (EFSA FEEDAP Panel 2011), chickens reared for laying and minor avian species (excluding laying birds) at a minimum recommended inclusion level of 2.5×10^8 CFU/kg complete feed (EFSA FEEDAP Panel, 2013a) and in turkeys for fattening and turkeys reared for breeding at a minimum recommended level of 1.25×10^8 CFU/kg complete feed (EFSA FEEDAP Panel, 2014). The conditions of use for these target species have not been modified and, therefore, no further assessment is needed for the renewal of the authorisation in these species.

3.3.2. Efficacy for suckling piglets and suckling minor porcine species

The applicant asked for the extension of use to suckling piglets and suckling minor porcine species at the level of 2.5×10^8 CFU/kg complete feed.

¹⁸ Technical dossier/Section III/Bibliography Sect. III/RCVS_2019.

¹⁹ Technical dossier/Section III/Annexes Sect. III/Annex_III_1.

Considering that efficacy has been demonstrated in weaned piglets at the level of 2.5×10^8 CFU/kg complete feed and the fact that the mode of action of the additive can be reasonably assumed to be the same, the conclusions from the efficacy studies in weaned piglets can be extended/extrapolated to suckling piglets and suckling minor porcine species for the period in which solid feed is given (EFSA FEEDAP Panel, 2018b). Therefore, the FEEDAP Panel considers that the additive has the potential to be efficacious in these species at the proposed conditions of use.

3.3.3. Efficacy for chickens for fattening

The efficacy of the additive when used in chickens for fattening at 2.5×10^8 CFU/kg complete feed was already assessed in the previous opinions of the FEEDAP Panel (EFSA 2009; EFSA FEEDAP Panel, 2013a). The Panel concluded that the additive had some potential to improve the performance of chickens for fattening at 2.5×10^8 CFU/kg complete feed (EFSA FEEDAP Panel, 2013a). Subsequently, the authorisation was modified to include this minimum recommended inclusion level.

The applicant has submitted the same studies already evaluated in the previous opinions with some new statistical analyses of the data and pooling of studies.²⁰ The Panel has assessed these data and considers that there is no new information which would lead the Panel to modify its previous conclusions. Therefore, the FEEDAP Panel concludes that the additive has the potential to be efficacious in chickens for fattening at 2.5×10^8 CFU/kg complete feed.

3.3.4. Compatibility with coccidiostats

The compatibility of Miya-Gold® S with the coccidiostats decoquinate, diclazuril, halofuginone, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monensin sodium, robenidine, salinomycin sodium and semduramicin at the maximum authorised concentrations for chickens for fattening was assessed in previous opinions (EFSA, 2009; EFSA FEEDAP Panel, 2011). The Panel concluded that compatibility was demonstrated with decoquinate, diclazuril, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monensin sodium, robenidine, salinomycin sodium and semduramicin at the maximum authorised concentrations for chickens for fattening. The Panel also concluded that halofuginone was supplied in a form not authorised in Europe and at a dose which was difficult to relate to the authorised level.

In previous opinions (EFSA FEEDAP Panel, 2011, 2014), the Panel considered that since compatibility had been demonstrated in chickens for fattening, the same conclusion would apply to its use in minor avian species and turkeys for fattening and reared for breeding.

No new data have been made available that would lead the Panel to reconsider the conclusions reached previously. Therefore, the FEEDAP Panel considers that Miya-Gold® S is compatible with decoquinate, diclazuril, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monensin sodium, robenidine, salinomycin sodium and semduramicin.

3.3.5. Conclusions on 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 for assessing the efficacy of Miya-Gold® S in the context of the renewal of the authorisation in chickens reared for laying, turkeys for fattening, turkey reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species.

The current application includes the request for an extension of use to suckling piglets and suckling minor porcine species and the request for authorisation for use in feed for chickens for fattening, for which the previous authorisation had expired. The efficacy data from weaned piglets can be extended/extrapolated to suckling piglets and suckling minor porcine species. Therefore, the Panel concludes that the additive has the potential to be efficacious in suckling piglets and suckling minor porcine species at the inclusion level of 2.5×10^8 CFU/kg complete feed. There is no new information which would lead the Panel to modify its previous conclusions that the additive has the potential to be efficacious in chickens for fattening at 2.5×10^8 CFU/kg complete feed.

Miya-Gold® S is compatible with decoquinate, diclazuril, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monensin sodium, robenidine, salinomycin sodium and semduramicin.

²⁰ Technical dossier/Supplementary information July 2020/annexes/Annex IV_3_1_1, Annex IV_3_2_1, Annex IV_3_3_1, Annex IV_3_4_1, Annex IV_3_5_1, Annex IV_3_6 and Annex IV_3_7.

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 Regulation²¹ and Good Manufacturing Practice.

4. Conclusions

The additive currently in the market complies with the conditions of authorisation.

There is no new evidence that would lead the FEEDAP Panel to reconsider its previous conclusions that Miya-Gold® S is safe for chickens for fattening, chickens reared for laying, turkeys for fattening, turkey reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species, the consumer and the environment under the current or previously authorised conditions of use. This conclusion applies also to the new target species for which a request for an extension of use is made.

Regarding the safety for the user, the Panel concludes that the additive is not irritant to skin and eyes and that sensitisation via respiratory route cannot be excluded.

There is no need for assessing the efficacy of Miya-Gold® S in the context of the renewal of the authorisation in chickens reared for laying, turkeys for fattening, turkey reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species.

The FEEDAP Panel concludes that the additive has the potential to be efficacious in chickens for fattening, suckling piglets and suckling minor porcine species at the inclusion level of 2.5×10^8 CFU/kg complete feed.

Miya-Gold® S is compatible with decoquinat, diclazuril, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazine, monensin sodium, robenidine, salinomycin sodium and semduramicin.

5. Documentation as provided to EFSA/Chronology

Date	Event
23/08/2019	Dossier received by EFSA. <i>Clostridium butyricum</i> FERM BP-2789 for Chickens for fattening, Chickens reared for laying, Turkeys for fattening, Turkeys reared for breeding, Minor poultry species (excluding laying birds), Piglets (suckling and weaned piglets), Minor porcine species. Submitted by Huvepharma N.V. on behalf of Miyarisan Pharmaceutical Co. Ltd.
12/12/2019	Reception mandate from the European Commission
04/02/2020	Application validated by EFSA – Start of the scientific assessment
03/03/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation, safety for the target species, efficacy</i>
04/05/2020	Comments received from Member States
30/07/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
27/01/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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²¹ Regulation (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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Abbreviations

AMR	antimicrobial resistance
CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection
LOQ	limit of quantification
PCB	polychlorinated biphenyl
PCDD/F	polychlorinated dibenzo- <i>p</i> -dioxin and dibenzofuran
TEQ	toxic equivalent
WGS	whole genome sequences
WHO	World Health Organization