

Safety and efficacy of a feed additive consisting of *Enterococcus lactis* NCIMB 11181 (Lactiferm®) for chickens for fattening or reared for laying, other poultry species for fattening or reared for laying, and ornamental birds (Chr. Hansen A/S)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) |
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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of a feed additive consisting of *Enterococcus lactis* NCIMB 11181 (Lactiferm®) as a zootechnical additive (gut flora stabiliser) for chickens for fattening, chickens reared for laying, other poultry species for fattening or reared for laying, and ornamental birds. The additive is available in two formulations: Lactiferm WS200 and Lactiferm Basic 50. The FEEDAP Panel concluded that the use of the additive is safe for chickens for fattening or reared for laying, other poultry species for fattening or reared for laying, and ornamental birds. The Panel also concluded that the use of the feed additive is safe for consumers, and the environment. Lactiferm WS200 is not irritant to skin or eyes. Owing to the proteinaceous nature of the active agent, both formulations of the additive are considered respiratory sensitisers. It was not possible, however, to conclude on the irritancy potential for skin and eyes of the Lactiferm Basic 50 formulation or on the potential of both formulations of the additive to cause skin sensitisation. The efficacy studies submitted did not allow to draw a conclusion on the efficacy of the additive for the target species. Lactiferm® is considered compatible with the coccidiostats monensin sodium and decoquinat.

KEYWORDS

efficacy, *Enterococcus lactis* NCIMB 11181, gut flora stabiliser, Lactiferm, safety, zootechnical additives

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Chr. Hansen A/S² for the authorisation of the additive consisting of *Enterococcus lactis* NCIMB 11181³ (Lactiferm®) when used as a feed additive in feed and water for drinking for chickens for fattening or reared for laying, other poultry species for fattening or reared for laying, and ornamental birds (category: zoo-technical 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). The dossier was received on 16 December 2022 and the general information and supporting documentation are available at <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00876>. The particulars and documents in support of the application were considered valid by EFSA as of 23 May 2023.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of *E. lactis* NCIMB 11181, when used under the proposed conditions of use (see Section 3.1.3).

1.2 | Additional information

The additive is a preparation containing *Enterococcus lactis* (formerly identified as *Enterococcus faecium*) NCIMB 11181.

EFSA issued three opinions on this product when used in feed for chickens for fattening (EFSA, 2005), calves for rearing and for fattening (up to 6 months of age) and for weaned piglets (EFSA FEEDAP Panel, 2012a) and on the renewal of the authorisation for weaned piglets and for calves for rearing and for fattening (EFSA FEEDAP Panel, 2023).

The additive is currently authorised for use in feed for calves for rearing and for fattening (up to 6 months of age) and for weaned piglets (4b1708).⁴

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the use of *Enterococcus lactis* NCIMB 11181 (Lactiferm®), as a feed additive. The dossier was received on 16/12/2022 and the general information and supporting documentation is available at <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00876>.

In accordance with Article 38 of the Regulation (EC) No 178/2002⁶ and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,⁷ a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 8 December 2023 to 3 January 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 23 May to 23 August 2023 for which the received comments were considered for the assessment.

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

²Chr. Hansen A/S, 10–12 Boege Alle, DK-2970, Hoersholm (Denemark).

³Originally identified as *Enterococcus faecium*.

⁴Commission Implementing Regulation (EU) No 797/2013 of 21 August 2013 concerning the authorisation of a preparation of *Enterococcus faecium* NCIMB 11181 as a feed additive for calves for rearing and for fattening and weaned piglets (holder of authorisation Chr. Hansen A/S) and repealing Regulation (EC) No 1333/2004. OJ L 224, 22.8.2013, p. 6.

⁵Dossier reference: FEED-2022-011010.

⁶Regulation (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.

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

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 assessment regarding the methods used for the control of *E. lactis* NCIMB 11181 in animal feed are valid and applicable for the current application.⁸

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *E. lactis* NCIMB 11181 (Lactiferm®), is in line with the principles laid down in Regulation (EC) No 429/2008⁹ and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b), 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) and EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2021).

3 | ASSESSMENT

The additive (here and below referred to with its commercial name Lactiferm®) consisting of viable cells of *Enterococcus lactis* NCIMB 11181 is currently authorised as a zootechnical additive (functional group: gut flora stabilisers) for use in complete feed for weaned piglets and calves for rearing and for fattening. The assessment regards the extension of its use in feed and water for poultry for fattening or reared for laying and to ornamental birds as a zootechnical additive (functional group: gut flora stabilisers).

3.1 | Characterisation

3.1.1 | Characterisation of the active agent and manufacturing process

The active agent *Enterococcus lactis* NCIMB 11181 has been identified and characterised in a recent opinion of the FEEDAP Panel (EFSA FEEDAP Panel, 2023). The strain was unambiguously identified as *E. lactis* and shown to be susceptible to all relevant antibiotics and not to produce antimicrobial substances of relevance for human and animal health.

The qualitative composition of the fermentation medium was listed but the quantitative composition was not provided.^{10,11} However, considering the ingredients used, the Panel concluded that none raised safety concerns.

3.1.2 | Characterisation of the additive

The additive Lactiferm® is marketed in two powder formulations:

- Lactiferm® Basic 50: containing *E. lactis* NCIMB 11181 at a minimum of 5×10^{10} colony forming units (CFU)/g additive (representing 12%–16% w/w) and maltodextrin as a carrier (representing 84%–88% w/w).
- Lactiferm® WS200: a water-soluble formulation containing *E. lactis* NCIMB 11181 at a minimum concentration of 2×10^{11} CFU/g additive of the active agent (representing 45%–50% w/w) and sorbitol as a carrier (representing 50%–55% w/w).

Analysis of seven batches of the Lactiferm® Basic 50 showed a mean value of [REDACTED]. Analytical data of 6 batches of the Lactiferm® WS200 showed an average value of [REDACTED].¹² The analysed batches complied with the minimum specifications.

Specifications are set for both formulations of the additive for coliforms (< 1000 CFU/g), *Salmonella* spp. (no detection in 25 g), *Escherichia coli* (< 10 CFU/g), yeasts and filamentous fungi (< 1000 CFU/g). Analysis of the above-mentioned seven

⁸Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

⁹Commission 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.

¹⁰Annex II 3.2b Media.

¹¹ADR export file for EFSA-Q-2022-00876 and ChrHansen_Efaecium_bulk_Spent media calc_26022010_10.2023.

¹²Annex II.1.3b CoAs Basic50 + WS200 and Section II Identity Lactiferm 1.ID+2.Charat_2022_chick_v3.

batches of the additive showed compliance with these limits.¹³ Enterobacteriaceae were measured in two batches of each formulation and in all cases the result was < 10 CFU/g.¹⁴

Similarly, specifications are set for arsenic (≤ 2 mg/kg), cadmium (≤ 0.5 mg/kg), mercury (≤ 0.1 mg/kg), lead (≤ 5 mg/kg) and aflatoxin B1 (< 0.01 mg/kg). Analysis of three batches of Lactiferm® Basic 50 indicated levels of cadmium, lead and aflatoxin B1 below the limit of quantification (LOQ),¹⁵ arsenic ranged from 0.008 to 0.019 mg/kg, mercury ranged from 0.0018 to 0.0021 mg/kg. Analytical data of three batches of Lactiferm® WS200 showed levels of lead and aflatoxin B1 below the LOQ, cadmium was up to 0.005 mg/kg, arsenic ranged from 0.005 to 0.008 mg/kg and mercury ranged from 0.0053 to 0.0062 mg/kg.¹⁶ The analytical values complied with the specifications set by the applicant.

The detected amounts of the above-described impurities and microbial contamination do not raise safety concerns.

Both formulations of the additive consist of off-white-coloured particles. The dusting potential and the particle size distribution have been characterised in a previous opinion (EFSA FEEDAP Panel, 2023).^{17,18}

The shelf-life, stability and capacity to homogeneously distribute in feed have been evaluated in previous opinions (EFSA FEEDAP Panel, 2012a, 2023) and the outcome is considered valid for the current application. However, some new data have been provided that are described below.

Samples of the WS200 formulation (3 batches) guaranteeing the minimum content of 2×10^{11} CFU/g were packed in aluminium pouches and stored at 4°C and at 25°C for 24 months. Viability losses of *E. lactis* strain at the end of the storage period were negligible (< 0.5 log) at 4°C and ranged from 0 to 1.25 log at 25°C.¹⁹

The stability of three batches of the WS200 formulation of the additive in water was tested at a concentration of 2.2 to 2.4×10^7 CFU/mL at 4°C and 25°C for 48 h.²⁰ Losses were negligible (< 0.5 log) at both temperatures.

The applicant indicated that processing of feed at high temperatures and moisture (e.g. pelleting) may adversely affect the stability of the additive.

3.1.3 | Conditions of use

The additive is intended for use in complete feed or water for drinking for chickens for fattening or reared for laying, other poultry species for fattening or reared for laying, and ornamental birds at a minimum inclusion level of 3×10^{10} CFU/kg complete feed or 1.5×10^{10} CFU/L water for drinking.²¹

It is intended to be used in feed containing the coccidiostats, monensin sodium and decoquinat.

3.2 | Safety

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

Enterococcus lactis is a species that is a natural component of gut microbiota, the strain NCIMB 11181 was shown not to contain marker genes typical of hospital associated isolates responsible for clinical infections or harbour acquired genes coding for antibiotic resistance, the end-products of the metabolism of the species do not raise concerns (EFSA FEEDAP Panel, 2023). Moreover, the fermentation ingredients used in the fermentation process do not raise safety concerns. Consequently, the FEEDAP Panel concludes that Lactiferm® is safe for chickens for fattening or reared for laying, other poultry species for fattening or reared for laying, and ornamental birds, consumers, and the environment.

However, the applicant provided a tolerance/efficacy study in chickens for fattening of 35 days duration to support the safety for the target animals, testing a solid water-soluble formulation.

A total of [REDACTED] chickens for fattening were distributed in [REDACTED] three treatment groups [REDACTED].²² Two basal diets [REDACTED] were either not supplemented (control group) or supplemented with 3.0×10^{10} CFU/kg feed (1× minimum use level), or with 3.0×10^{11} CFU/kg feed (10×). Supplemental levels were confirmed by analysis. The diets were offered ad libitum in mash form for 35 days.

¹³Annex II.1.3b CoAs Basic50 + WS200 and ADR September 2023 Annex II 1.3b CoAs Basic50 + WS200 v2.

¹⁴ADR September 2023/Annex II 1.4.1 + 1a Undes subst+Enterobacteriaceae Lactiferm Basic 50 v2 and Annex II.1.4.1 + 1a Undes subst+Enterobacteriaceae Lactiferm WS200 v2.

¹⁵Annex II.1.4.1 Undes subst Lactiferm Basic50 + WS200. The limit of quantification (in mg/kg) was 0.01 for lead and 0.005 for cadmium. The LOQ (in µg/kg) was 46 for aflatoxin B1.

¹⁶Annex II.1.4.1 Undes subst Lactiferm Basic50 + WS200.

¹⁷Annex II.1.5b Dust Pot Basic+WS.

¹⁸Annex II.1.5a Part size Basic+WS.

¹⁹Annex II.4.1a Stability Lactiferm Basic50 + WS200 2021–2022.

²⁰Annex II.4.1c Stability in water Lactiferm WS 2022.

²¹ADR September 2023/2 Annex I application-form Lactiferm chicks v3.

²²Annex IV 3.680821 Tol + eff.

On Day 35, blood was sampled from two randomly selected chickens per pen and analysed for haematology²³ and biochemistry.²⁴ On Day 35, one randomly selected bird per pen was killed, weighted, subjected to gross pathology and samples of organs were collected.²⁵

A non-inferiority test comparing the 10x with the control and 1x was performed for average daily weight gain and average daily feed intake (1–35 days). The experimental data were statistically analysed using

. When differences were encountered, group means were compared with . Statistical significance was set at ≤ 0.05 .

The animals were in good health during the study and no differences were observed in mortality (including culling) between treatments. Similarly, no effects were observed in any of the performance parameters measured (see Table 2, Trial 6). The non-inferiority of the 10x group with respect to the other groups on average daily gain and feed intake was demonstrated.

Significant differences in haematological parameters were observed in the 10x group compared to the control as an increase in white blood cells (15.3 vs. 13.4×10^3 cell/ μL , respectively) and lymphocytes (12.9 vs. 11.2×10^3 cell/ μL , respectively). These values, however, were within the reference ranges of chickens in the control groups from previous trials in the same facility and were not considered relevant for the assessment. Urea, phosphorus, AST, C-reactive protein and ovotransferrin were lower and total bilirubin was higher in the 1x group compared to the control. No dose–response effect was observed, and these differences are considered of no concern.

The relative weights of the caecum (0.37, 0.42 and 0.44% for control, 1x and 10x) and caecal tonsils (0.32, 0.39 and 0.40% for control, 1x and 10x) showed a dose-dependent increase, being the weights in the 10x group significantly higher to those of the control group. The gross pathology evaluation did not show any macroscopic lesion in the organs of the chickens of the supplemented groups. Therefore, these differences were considered of no safety concern.

The results of the study support the safety of the additive for the target species.

3.2.2 | Safety for the user

The safety of the additive for the user was already assessed in the recent opinion of the FEEDAP Panel (2023). The applicant has not provided any new data, and therefore, the Panel reiterates its previous conclusions that Lactiferm WS200 is not irritant to skin or eyes. Both formulations of the additive are considered respiratory sensitizers. It is not possible to conclude on the irritating potential for skin and eyes of the Lactiferm Basic 50 or on the potential of both forms of the additive to cause skin sensitisation.

3.3 | Efficacy

3.3.1 | Efficacy for chickens for fattening

The applicant submitted six trials with a similar design to support the efficacy of the additive: five long-term efficacy studies in chickens for fattening (Trials 1–5) and the combined tolerance/efficacy study described above (see Section 3.2; Trial 6). The details on the study design are provided in Table 1, and the main results in Table 2.

²³Haematological analyses included: total red blood cell count, packed cell volume, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, total and differential counts for leucocytes, platelet counts, prothrombin time.

²⁴Biochemical analyses included: fibrinogen, sodium, potassium, chloride, calcium, phosphate, magnesium, total protein, albumin, globulin, glucose, urea/uric acid, cholesterol, creatinine, bilirubin, acute phase proteins (ovotransferrin and C-reactive protein), amylase, alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase, gamma glutamyl transferase, alkaline phosphatase and creatine kinase.

²⁵Liver, kidneys, spleen, adrenal gland, lung, stomach, pancreas, small intestine, colon, caecum, thymus, thyroid gland, heart, intestinal lymph nodes (caecal tonsils) and testes.

TABLE 1 Trial design and use level of the additive in the efficacy trials performed in chickens for fattening.

Trial	Total no of animals (animals/replicate) replicates/treatment	Breed sex (duration)	Composition feed (form)	Groups (CFU/kg feed) ^a	
				Intended	Analysed ^b
1 ²⁶	360	██████████	████████████████████	0	██████████
	12	(42 days)	██████████	1.5 × 10 ¹⁰	██████████
2 ²⁷	1120	██████████	████████████████████	0	██████████
	40	(42 days)	██████████	3 × 10 ¹⁰	██████████
3 ²⁸	2480	██████████	████████████████████	0	██████████
	48	(42 days)	██████████	3 × 10 ¹⁰	██████████
4 ²⁹	960	██████████	████████████████████	0	██████████
	32	(42 days)	██████████	3 × 10 ¹⁰	██████████
5 ³⁰	448	██████████	████████████████████	0	██████████
	32	(42 days)	██████████	3 × 10 ¹⁰	██████████
6 ³¹	960	Ross 308	████████████████████	0	██████████
	16	Male (35 days)	██████████	3 × 10 ¹⁰ 3 × 10 ¹¹	██████████

^aOr per L of water for drinking in Trial 1.

^bWhen two values are reported, it is because there was a relevant difference between the feeding phases (Phases I and II).

In all trials, ██████████ chicks were distributed in pens and randomly allocated to two dietary groups. In Trial 1, the additive was administered through water for drinking at the minimum recommended level of 1.5 × 10¹⁰ CFU/L. In Trials 2–6, the animals received the additive in feed at the minimum recommended level; two basal diets (starter and finisher) were either not supplemented (control) or supplemented with the solid water-soluble form of the additive to provide 3 × 10¹⁰ CFU/kg feed. The supplementation of the diets was confirmed analytically (see Table 1). The experimental diets were offered ad libitum for 42 days or 35 days (Trial 6).

Mortality and health status of the animals were monitored daily, and the most likely reason for culling/death was recorded. The birds were individually weighed at the start of the trial (Day 1). Thereafter, the feed intake and body weight of each pen were recorded at every diet change and at the end of the trial. The average daily feed intake, average daily gain, and feed to gain ratio were calculated and corrected for mortality for the whole production period.

The productive performance data were analysed with a general linear model, except feed intake, feed-to-gain ratio and mortality in Trial 2 (analysed by Wilcoxon test) and mortality in Trial 3 (analysed by Kruskal–Wallis test). The experimental unit used was the pen in all cases. The significance level applied was 0.05.

²⁶Annex IV.3.1.

²⁷Annex IV.3.2.

²⁸Annex IV.3.3.

²⁹Annex IV.3.4.

³⁰Annex IV.3.5.

³¹Annex IV 3.680821 Tol + eff.

TABLE 2 Effects of Lactiferm® on the performance and mortality/culling of chickens for fattening.

Trial	Groups	Daily feed intake	Final body weight	Average daily weight gain	Feed to gain ratio	Mortality and culling
	(CFU/kg complete feed)*	(g)	(g)	(g)		(%)
1	0	110.2	3109 ^b	73 ^b	1.51 ^a	4.44
	1.5 × 10 ¹⁰	110.5	3235 ^a	76 ^a	1.45 ^b	2.78
2	0	101.3 ^a	2557	59.3	1.70	2.86 ^a
	3 × 10 ¹⁰	98.3 ^b	2505	58.5	1.68	1.07 ^b
3	0	109	2910	67.9	1.61	5.80
	3 × 10 ¹⁰	110	2912	67.9	1.62	3.55
4	0	114.8 ^a	3114	72.6	1.58 ^a	2.92
	3 × 10 ¹⁰	111.3 ^b	3089	71.9	1.55 ^b	3.75
5	0	97.23	2641	60.4	1.61 ^b	7.83
	3 × 10 ¹⁰	101.0	2665	61.3	1.65 ^a	6.25 ^{**}
6	0	94.5	2348	65.5	1.44	2.5
	3 × 10 ¹⁰	93.3	2345	65.1	1.43	2.8
	3 × 10 ¹¹	95.7	2356	66.0	1.45	1.6

^{a,b}Mean values within a trial and within a column with a different superscript are significantly different $p < 0.05$.

*CFU per L of water for drinking in Trial 1.

**Resulting mortality after excluding one pen due to *Escherichia coli* infection.

No significant positive effects were observed on the performance of chickens in Trials 3, 5 and 6 between treatments. A better feed to gain ratio was observed in birds receiving the additive at the minimum proposed use level in Trials 1 and 4, resulting from an increase in the average daily gain in Trial 1 and a reduced feed intake in Trial 4. Although a reduced feed intake was also observed in birds receiving the additive in Trial 2, this did not result in an improvement of feed to gain ratio, and is therefore, considered not supportive of the efficacy. Overall, positive effects of the supplementation with Lactiferm at the minimum use level on the performance of chickens for fattening were observed in only two studies. Therefore, the FEEDAP Panel cannot conclude on the efficacy of Lactiferm in chickens for fattening or reared for laying nor for other poultry species for fattening and reared for laying or ornamental birds.

3.3.1.1 | Compatibility with coccidiostats

To support the compatibility of *E. lactis* NCIMB 11181 with monensin sodium and decoquinatone an *in vitro* study has been submitted.³² The minimum inhibitory concentration (MIC) values for the two coccidiostats were assessed using the [REDACTED] method. The MIC values obtained, > 1000 mg/L for monensin and > 320 mg/L for decoquinatone, were more than 4 times higher the maximum authorised levels for these coccidiostats (monensin: 125 mg/kg in chickens for fattening and reared for laying, 100 mg/kg in turkeys; decoquinatone 40 mg/kg in chickens for fattening). Therefore, *E. lactis* NCIMB 11181 is compatible with monensin sodium and decoquinatone.

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 Regulation³³ and Good Manufacturing Practice.

4 | CONCLUSIONS

The Panel concludes that the use of Lactiferm® is safe for chickens for fattening or reared for laying, and other poultry species for fattening or reared for laying, and ornamental birds.

The additive is safe for consumers and the environment.

Lactiferm® WS200 is not irritant to the skin or eyes but the Panel cannot conclude on the irritation potential of Lactiferm® Basic 50. The Panel cannot conclude on the skin sensitisation potential of the additive in any of its formulations. Owing to the proteinaceous nature of the active agent, the additive in any formulation is considered to be a respiratory sensitiser.

The Panel cannot conclude on the efficacy of the additive for the target species due to the lack of data. Lactiferm is compatible with monensin sodium and decoquinatone.

³²Annex_II.4.4.

³³Regulation (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.

ABBREVIATIONS

CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOQ	limit of quantification
OECD	Organisation for Economic Co-operation and Development

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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European Commission

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