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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of *Pediococcus acidilactici* CNCM I-4622 for all insect species (Danstar Ferment AG)

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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 *Pediococcus acidilactici* CNCM I-4622 as a zootechnical additive (functional group: physiological condition stabilisers) for all insects. The active agent used in the additive is already authorised for use in all animal species as a technological additive, and as a zootechnical additive in all Suidae species for fattening and for breeding, other than sows, all avian species, all fish species and all crustaceans. The active agent has been identified as a strain of *P. acidilactici* and consequently meets the qualifications required by the qualified presumption of safety (QPS) approach. The use of the additive is considered safe for all insect species, consumers and the environment. The additive is considered non-irritant to skin and eyes but a respiratory sensitiser. No conclusions can be drawn regarding its skin sensitisation potential. In the absence of adequate data, the FEEDAP Panel is not in the position to conclude on the efficacy of the additive as a physiological condition stabiliser for honeybees nor for all insect species.

KEYWORDS

efficacy, insects, *Pediococcus acidilactici* CNCM I-4622, physiological condition stabilisers, safety, zootechnical additives

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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 feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Danstar Ferment AG, represented in the EU by Lallemand SAS,[2] for the authorisation of the additive consisting of *Pediococcus acidilactici* CNCM I-4622, when used as a feed additive for all insects (category: zootechnical additive; functional group: physiological condition 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 30 May 2022 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00340. The particulars and documents in support of the application were considered valid by EFSA as of 30 September 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 *Pediococcus acidilactici* CNCM I-4622, when used under the proposed conditions of use.

1.2 | Additional information

The subject of the assessment is a preparation consisting of viable cells of *P. acidilactici* CNCM I-4622, intended for use as a zootechnical additive (functional group: physiological condition stabilisers) for all insects.

EFSA issued several opinions on the safety and efficacy of an additive based on the same active agent (Bactocell®) as a zootechnical additive, when used in feed for salmonids (EFSA, 2009a), shrimps (EFSA, 2009b), weaned piglets (EFSA FEEDAP Panel, 2010a), laying hens (EFSA FEEDAP Panel, 2010b) and on the efficacy for all fish (EFSA FEEDAP Panel, 2012a). A further opinion on the safety and efficacy of Bactocell® when used in water for drinking for weaned piglets, pigs for fattening, laying hens and chickens for fattening was adopted in 2012 (EFSA FEEDAP Panel, 2012b). In 2016, the Panel re-evaluated the product for pigs for fattening and chickens for fattening and further assessed it for minor porcine species and minor avian species (EFSA FEEDAP Panel, 2016). In 2019, the Panel assessed the application for renewal of authorisation of Bactocell® when used in weaned piglets, pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, laying hens and minor avian species for fattening and for laying and its extension of use to all growing pigs and all avian species (EFSA FEEDAP Panel, 2019a). In the same year, the Panel also assessed the application for renewal of authorisation of Bactocell® as a feed additive for all fish and shrimps and its extension of use for all crustaceans (EFSA FEEDAP Panel, 2019b). An opinion on the safety and efficacy of the same active agent when used as a silage additive was adopted in 2012 (EFSA FEEDAP Panel, 2012c) and one on the safety and efficacy of the same active agent when used as a technological additive (functional groups: acidity regulator and hygiene condition enhancers) for all animal species (EFSA FEEDAP Panel, 2022).

The additive is currently authorised for use in the European Union as a silage additive (1k2104),[3] as a zootechnical additive (4d1712)[4] for use in feed and/or in water for drinking in several terrestrial and aquatic species and as an acidity regulator (4d1712)[5] and hygiene condition enhancer (4d1712)[6] for all animal species.

[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]Danstar Ferment AG, Poststrasse 30, 6300 Zug – Switzerland; represented in the EU by Lallemand SAS, 19 rue des Briquetiers BP59, 31,702, Blagnac Cedex, France.

[3]Regulation (EU) No 1119/2012 of 29 November 2012 concerning the authorisation of preparations of *Pediococcus acidilactici* CNCM MA 18/5M DSM 11673, *Pediococcus pentosaceus* DSM 23376, NCIMB 12455 and NCIMB 30168, *Lactobacillus plantarum* DSM 3676 and DSM 3677 and *Lactobacillus buchneri* DSM 13573 as feed additives for all animal species. OJ L 330, 30.11.2012, p. 14.

[4]Regulation (EU) 2020/151 of 4 February 2020 concerning the authorisation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive for all porcine species for fattening and for breeding other than sows, all avian species, all fish species and all crustaceans and repealing Regulations (EC) No 911/2009, (EU) No 1120/2010 and (EU) No 212/2011 and Implementing Regulations (EU) No 95/2013, (EU) No 413/2013 and (EU) 2017/2299 (holder of authorisation Danstar Ferment AG represented in the Union by Lallemand SAS). OJ L 33, 5.2.2020, p. 12.

[5]Commission Implementing Regulation (EU) 2023/53 of 4 January 2023 concerning the authorisation of a preparation of Pediococcus acidilactici CNCM I-4622 as a feed additive for all animal species. OJ L 3, 05.01.2023, p. 8.

[6]Commission Implementing Regulation (EU) 2023/53 of 4 January 2023 concerning the authorisation of a preparation of Pediococcus acidilactici CNCM I-4622 as a feed additive for all animal species. OJ L 3, 05.01.2023, p. 8.

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[7] in support of the authorisation request for the use of *P. acidilactici* CNCM I-4622 as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002[8] 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,[9] 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 15/5 to 5/6/2023 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' 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.[10]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *P. acidilactici* CNCM I-4622 is in line with the principles laid down in Regulation (EC) No 429/2008[11] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012d), 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, 2019c). Scientific Opinion on the update of the list of qualified presumption of safety (QPS) recommended microorganisms intentionally added to food or feed as notified to EFSA (EFSA BIOHAZ Panel, 2023).

3 | ASSESSMENT

The additive under assessment is a preparation of *P. acidilactici* CNCM I-4622, intended for use as a zootechnical additive (functional group: physiological condition stabilisers) for all insects.

3.1 | Characterisation

The active agent was isolated from natural pasture and is deposited in the Collection Nationale de Cultures de Microorganisms (CNCM) with the accession number CNCM I-4622. It has not been genetically modified.

The active agent *P. acidilactici* CNCM I-4622 and the additive were characterised in full in a recent FEEDAP Panel opinion (EFSA FEEDAP Panel, 2022). For the current evaluation, the same information was made available, and therefore, the previous assessment applies to the current application. Regarding the active agent *P. acidilactici* CNCM I-4622, the Panel concluded that the (i) taxonomical identification was confirmed, (ii) the strain is susceptible to all the relevant antibiotics, (iii) no acquired antibiotic resistance genes were identified in the strain.

Regarding the additive (formulated with silica[12] or sodium aluminosilicate (up to maximum 5%) and sucrose (up to maximum 97%), it is specified to contain a minimum concentration of 1.0×10^{10} colony forming units (CFU) of *P. acidilactici* CNCM I-4622 per gram of additive and does not contain impurities of concerns. No specific information on the stability and homogeneity in feed for insects was made available.

[7]FEED dossier reference: FEED-2022-005091.

[8]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.

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

[10]The full report is available on the EU Science Hub: https://joint-research-centre.ec.europa.eu/publications/fad-2013-0031_en

[11]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.

[12]Currently under re-evaluation.

The additive is intended for use in feed for all insect species and categories at a proposed minimum inclusion level of 1.5×10^5 CFU/kg feed.

3.2 | Safety

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

The species *P. acidilactici* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2023). This approach requires the identification of the strain to be conclusively established and evidence provided that the strain does not show acquired resistance to antibiotics of human and veterinary importance. In the view of the FEEDAP Panel, the identity of the strain is unambiguously established as *P. acidilactici*, and the lack of antibiotic resistance confirmed. Consequently, *P. acidilactici* CNCM I-4622 is presumed safe for the target species, consumers of products from animals fed with the additive and the environment. Since no concerns are expected from other components of the additive, the additive is also considered to be safe for the target species, consumers and the environment.

The FEEDAP Panel assessed the safety of the additive for the user in its previous opinions (EFSA FEEDAP Panel, 2019a, 2019b) concluding that: the additive is considered non-irritant to skin and eyes. The additive is considered a respiratory sensitiser. 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, no conclusions can be drawn regarding skin sensitisation potential of the additive.

3.3 | Efficacy

To support the efficacy of the additive as a physiological condition enhancer for all insects, three studies with honeybees were submitted; the studies are reported in two publications (El Khoury et al., 2018 [first study] and Peghaire et al., 2020, amended by the author in Peghaire et al., 2020 [second and third studies]). In the three studies, the additive was supplemented to honeybees feed composed of a 1:1 water/sucrose syrup. In the three studies, some of the experimental groups of honeybees subject to study were infected with *Nosema ceranae*. As described in El Khoury et al. (2018) '*Nosema ceranae* is an obligate intracellular microsporidian parasite, which is the causative agent of one of the most prevalent honeybee diseases, called nosemosis (Higes et al., 2008). Honeybee's infection occurs by proliferation of *N. ceranae* spores in the midgut after the ingestion of infected food (Ptaszynska et al., 2014) and spore accumulation is often associated with high mortality or casualties (Higes et al., 2007, 2008, 2009; Martín-Hernández et al., 2007)'. In the three studies, the infection of honeybees with *N. ceranae* significantly increased the honeybee mortality, compared to the respective non-infected control groups. The FEEDAP Panel notes that, according to Commission Regulation (EU) No 2019/962,[13] feed additives belonging to the functional group 'physiological condition stabilisers' should exert their effects when fed to animals in good health. The Panel considers that honeybees infected with *N. ceranae*, in which mortality is increased because of the infection, are not to be considered as animals in good health, and therefore the results of the experimental groups infected with *N. ceranae* are not further considered.

El Khoury et al. (2018) studied the survival of young, caged honeybees infected or not with *N. ceranae*. The study included a total of 10 experimental groups with two controls (infected or not) and the corresponding groups supplemented with either *P. acidilactici* CNCM I-4622 or one each of three other microorganisms (the latter three groups are no further considered). The bees were kept in cages in total darkness (30°C and 50% RH) for a period of 27 days; sucrose syrup was available to the bees. The survival rate in the control groups (infected or not infected) showed a very sharp decrease from day 14 (survival rate of 60% and 40% for non-infected control and infected control, respectively). The FEEDAP Panel notes that the authors of the study suggested that the drastic and significant decrease of survival rate of the control groups might be due to the complete protein deficiency of the diet fed to the bees, which could have caused microbiota dysbiosis and gut inflammation. The FEEDAP Panel considers that the honeybees used in the study are not in good health, owing the unbalanced diet, in addition to the infection with Nosema, for the relevant groups. Therefore, the study is not further considered in the assessment.

The second study, presented as the first trial in Peghaire et al. (2020) and Peghaire et al. (2020), aimed at studying the effect of different factors on the survival rate of honeybees. The study included a total of eight experimental groups with three control groups (one not infected and not exposed to the pesticide fugagillin, one infected with N. ceranae but not exposed to a fugagillin and one infected with N. ceranae and exposed to fugagillin). Other five groups were infected with *N. ceranae* and fed syrup supplemented with either *P. acidilactici* CNCM I-4622 or one each of four other microorganisms (the latter four groups are no further considered). Since the bees that received the additive were infected with *N. ceranae*, the study is not considered further in the assessment.

The third study, presented as the second trial in Peghaire et al. (2020) and Peghaire et al. (2020), aimed at studying the effect of different factors on the survival rate and feed intake of honeybees. The study included a total of nine experimental

[13]Commission Regulation (EU) 2019/962 of 12 June 2019 amending Annex I to Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of two new functional groups of feed additives.

groups with five control groups (one non infected and not exposed to a combination of two pesticides (boscalid and thiamethoxam), one infected with *N. ceranae* and not exposed to pesticides, one exposed to pesticides, one treated with *P. acidilactici* CNCM I-4622 and one group treated with a different microorganism. The experimental treatments consisted in two groups of non-infected bees, exposed to the pesticides and supplemented with *P. acidilactici* CNCM I-4622 or a different microorganism. In addition, two other groups were infected and treated with one of two different microorganisms (the latter three groups are no further considered). The groups receiving the pesticides were exposed to the insecticide thiamethoxam (currently not authorised in the EU) at 1.5 µg/L diet and the fungicide boscalid, at a concentration of 100 µg/L diet; no evidence was provided that the dose selected and the use of the combination of the two pesticides would reflect a realistic exposure of bees in the European Union. The control group exposed to the pesticides showed a survival rate of 66% which was very low compared to the control group (survival rate of 91%). The FEEDAP Panel considers that the high mortality caused by the exposure of honeybees to the mixture of pesticides should be considered as the consequence of the inappropriate selection of the mixture of pesticides and their levels. Therefore, the study is not considered further in the assessment.

3.3.1 | Conclusions on efficacy

In the absence of adequate data, the FEEDAP Panel is not in the position to conclude on the efficacy of the additive as a physiological condition stabiliser for honeybees nor, therefore, for all insect species.

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[14] and Good Manufacturing Practice.

4 | CONCLUSIONS

The use of the additive *P. acidilactici* CNCM I-4622 in feed for all insects is considered safe for the target animals, the consumers and the environment.

The additive is considered non-irritant to skin and eyes but a respiratory sensitiser. No conclusions can be drawn regarding skin sensitisation potential of the additive.

In the absence of adequate data, the FEEDAP Panel is not in the position to conclude on the efficacy of the additive as a physiological condition stabiliser for honeybees nor for all insect species.

ABBREVIATIONS

CFU	colony forming unit
CG	chemical group
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
OECD	Organisation for Economic Co-operation and Development
QPS	qualified presumption of safety

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.

REQUESTOR

European Commission

QUESTION NUMBER

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[14]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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