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Safety and efficacy of a feed additive consisting of *Saccharomyces cerevisiae* CNCM I-1079 for calves, all other ruminant species and camelids for rearing and for fattening (Danstart Ferment AG)

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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 *Saccharomyces cerevisiae* CNCM I-1079 when used as a zootechnical additive (gut flora stabilisers and physiological condition stabilisers) for calves, all other ruminant species and for camelids for rearing and for fattening. The product, manufactured in two forms, as a powder and an encapsulated form, is intended for use in complete feed at a minimum inclusion level of 1×10^9 CFU/kg complete feed. *S. cerevisiae* is considered by EFSA to be suitable for the qualified presumption of safety approach to safety assessment. Since the identity of the strain has been clearly established and the additive is composed mainly by dried cells of the active agent, the use of the additive in animal nutrition is considered safe for the target species, the consumer and the environment. The additive is not a skin or eye irritant, or a skin sensitiser, but should be considered a respiratory sensitiser. However, exposure by inhalation to the encapsulated form is unlikely. The Panel was not in the position to conclude on the efficacy of the additive for the target species.

Keywords: zootechnical additive, gut flora stabilisers, physiological condition stabilisers, *Saccharomyces cerevisiae* CNCM I-1079, safety, QPS, efficacy

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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 *Saccharomyces cerevisiae* CNCM I-1079, when used as a feed additive for calves, all other ruminant species for rearing and for fattening and camelids for rearing and for fattening (category: Zootechnical additives; functional group: gut flora stabilisers and 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). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 08 December 2021.

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 *S. cerevisiae* CNCM I-1079, when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The additive is a preparation containing *S. cerevisiae* CNCM I-1079.

EFSA issued five opinions on the safety and efficacy of this product when used in feed as a feed additive for weaned piglets and sows (EFSA FEEDAP Panel, 2016), for chickens for fattening and minor poultry species (EFSA FEEDAP Panel, 2017a), for weaned piglets (EFSA FEEDAP Panel, 2017b), for all pigs (EFSA FEEDAP Panel, 2019a) and for turkeys for fattening (EFSA FEEDAP Panel, 2019b).

The additive is currently authorised (4d1703) for use in feed for chickens for fattening and for minor poultry species for fattening,[3] for piglets and sows,[4] for all pigs other than weaned piglets and sows and all minor porcine species[5] and for turkeys for fattening.[6]

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 *S. cerevisiae* CNCM I-1079 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 or other expert bodies, to deliver the present output.

[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, represented in the EU by Lallemand SAS, 19, Rue de Briquetiers, BP59, 31,702, Blagnac Cedex, France.
[3] Commission Implementing Regulation (EU) 2017/1905 of 18 October 2017 concerning an authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for chickens for fattening and for minor poultry species for fattening (holder of authorisation Danstar Ferment AG represented by Lallemand SAS). OJ L 269, 19.10.2017, p. 30.
[4] Commission Implementing Regulation (EU) 2018/347 of 5 March 2018 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for piglets and sows and amending Regulations (EC) No 1847/2003 and (EC) No 2036/2005 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS). OJ L 67, 9.3.2018, p.21.
[5] COMMISSION IMPLEMENTING REGULATION (EU) 2019/892 of 28 May 2019 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for all pigs other than weaned piglets and sows and all minor porcine species (holder of authorisation Danstar Ferment AG represented by Lallemand SAS). OJ L 142, 29.5.2019, p. 57.
[6] Commission Implementing Regulation (EU) 2020/162 of 5 February 2020 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for turkeys for fattening (holder of authorisation Danstar Ferment AG represented by Lallemand SAS). OJ L 34, 6.2.2020, p. 31.
[7] FEED dossier reference: FAD-2021-0035.

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.[8]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *S. cerevisiae* CNCM I-1079 is in line with the principles laid down in Regulation (EC) No 429/2008[9] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017d), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017e), 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) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019c).

3. Assessment

The additive containing viable cells of *S. cerevisiae* CNCM I-1079 is intended to be used as a zootechnical additive in feed for calves, all other ruminant species (lambs, goat kids, buffalo calves, calves/kids of species in the family Cervidae and other species of ruminants) and camelids (calves of camelids) for rearing and for fattening under the functional groups 'gut flora stabilisers and physiological condition stabilisers'.

3.1. Characterisation

3.1.1. Characterisation of the active agent

The active agent is a microorganism isolated from grape must deposited in the Collection Nationale de Cultures De Microorganismes (CNCM) with the accession number CNCM I-1079.[10] It has not been genetically modified.

The taxonomical identification as *S. cerevisiae* was confirmed based on the whole genome sequence data.[11] This was done by read mapping which showed that 91.4% of the reads mapped to the genome sequence of *S. cerevisiae* strain S288C. Moreover, the internal transcribed spacer region analysis showed the closest match with *S. cerevisiae* strains NRRL Y-12632 and CBS 1171.

3.1.2. Characterisation of the additive

The additive is composed of dried cells of *S. cerevisiae* CNCM I-1079 and is marketed in two forms:

- A fine, granulated free-flowing powder, with a minimum concentration of 2×10^{10} colony forming units (CFU)/g,
- A coated or microencapsulated form, with a minimum concentration of 1×10^{10} CFU/g and vegetable oil derivatives used as coating agents (40%–50%).

The additive under assessment has the same composition and method of manufacture as that considered in previous applications (EFSA FEEDAP Panel, 2016, 2017a). Therefore, all the data pertaining to composition, purity, physicochemical properties, stability and homogeneous distribution described thereof are also considered valid for this application.

The applicant has provided some data on batch-to-batch variation, purity, dusting potential and stability in feed that are described below.

[8] The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0121_en.
[9] 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.
[10] Technical dossier/Supplementary information April 2022/Annex 1.
[11] Technical dossier/Section II/Annex_II_4c.

The analysis of eight batches of the powder form of the additive showed a mean value of 4.5×10^{10} CFU/g additive (range 3.0–4.7 $\times$ 10^{10} CFU/g additive) and of six batches of the coated form showed a mean value of 1.6×10^{10} CFU/g additive (range 1.5–1.7 $\times$ 10^{10} CFU/g additive).[12]

The same batches of the additive were tested for microbial purity and showed *Escherichia coli* < 10 CFU/g, coliforms < 1,000 CFU/g, Enterobacteriaceae < 100 CFU/g (only in four batches of the granulated form) and no *Salmonella* spp. detection in 25 g of additive.[12]

Three batches of each form of the additive were analysed for dusting potential by the Stauber–Heubach method.[13] Results for the non-encapsulated form showed an average of 0.43 g/m^3 of dust (0.3–0.6 g/m^3 of dust), while the coated product was dust free.

Stability of four batches of the coated form of the additive was tested when mixed with two mash feeds for dairy cows (three batches in a feed composed mainly of soybean and rapeseed meal and one batch with a feed composed mainly of rapeseed extraction meal and rye) at the intended inclusion level of 1×10^{10} CFU/kg feed.[14] The feeds were then pelleted at temperatures ranging 65–97°C and stored at 20–25°C for 3 months. Yeast counts were measured before and after pelleting to allow for survivability testing during processing. In all cases, the decrease of cell counts after pelleting and after storage was negligible (≤ 0.5 log values).

Stability of one batch of the uncoated form was investigated when incorporated in milk replacer at the intended inclusion level of 1.5×10^{10} CFU/kg and stored in polyethylene foil sachets at room temperature for 3 months.[14] The viability loss during this time was negligible (≤ 0.5 log values).

3.1.3. Conditions of use

The additive is intended for use in feed for calves, all other ruminant species for rearing and for fattening and camelids for rearing and for fattening at the minimum recommended inclusion level of 1×10^9 CFU/kg complete feed.

3.2. Safety

The species *S. cerevisiae* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2020). The identity of the strain was confirmed as *S. cerevisiae*. Accordingly, this strain is presumed safe for the target species, the consumer and the environment. Since the additive is composed mainly by dried cells of the active agent and coating agents (in the encapsulated form) which are not expected to introduce any risk, the additive is also considered safe for the target species, the consumer and the environment.

EFSA evaluated the safety of the non-encapsulated form of the additive for the user in a previous opinion and concluded that it is not a skin or eye irritant or a skin sensitiser (EFSA FEEDAP Panel, 2016). Considering recent data on the dusting potential of this form of the additive, inhalation by exposure cannot be excluded. Owing to the proteinaceous nature of the active agent, the additive should be considered a respiratory sensitiser. However, exposure by inhalation to encapsulated form is unlikely because it is dust-free.

3.3. Efficacy

Three long-term trials in calves were submitted to support the efficacy of the additive.[15] However, none could be considered further in the assessment due to the very high incidence of respiratory and digestive disorders observed in the studies ([redacted]), suggesting a poor health status of the animals involved in the trials.

Therefore, due to the lack of adequate data, the Panel is not in the position to conclude on the efficacy of the additive for calves, all other ruminant species (lambs, goat kids, buffalo calves, calves/kids of species in the family Cervidae and other species of ruminants) and camelids (calves of camelids) for rearing and for fattening.

[12] Technical dossier/Section II/Annex_II_2 and Supplementary information April 2022/Annex 2.
[13] Technical dossier/Section II/Annex II_3b and Supplementary information April 2022/2022-04-14_reply_sin_let.
[14] Technical dossier/Section II/Annex_II_5f.
[15] Technical dossier/Section IV/Annexes_IV_2a-d, IV_3a-f and _IV_4a-d.

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[16] and Good Manufacturing Practice.

4. Conclusions

S. cerevisiae CNCM I-1079 is safe for the target species, the consumer and the environment.

The additive is not a skin or eye irritant, or a skin sensitiser, but should be considered a respiratory sensitiser. However, exposure by inhalation to the encapsulated form is unlikely.

The Panel is not in the position to conclude on the efficacy of the additive for calves, all other ruminant species and camelids for rearing and for fattening.

Documentation provided to EFSA/Chronology

Date	Event
10/05/2021	Dossier received by EFSA. *Saccharomyces cerevisiae* CNCM I-1079 for calves, all other ruminant species (for rearing and for fattening) and camelids (for rearing and for fattening). Submitted by Danstar Ferment AG, represented in the EU by Lallemand SAS
05/08/2021	Reception mandate from the European Commission
08/12/2021	Application validated by EFSA – Start of the scientific assessment
21/03/2022	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation*
09/03/2022	Comments received from Member States
19/04/2022	Reception of supplementary information from the applicant –Scientific assessment re-started
27/09/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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[16] 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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Abbreviations

CFU	colony forming unit
CNCM	Collection Nationale de Cultures De Microorganismes
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
QPS	qualified presumption of safety