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Safety of a tincture derived from *Artemisia vulgaris* L. (Mugwort tincture) when used as a sensory additive in feed for all animal species

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Abstract

The tincture derived from *Artemisia vulgaris* L. (Mugwort tincture) is intended to be used as a sensory additive in feed for all animal species. The product is a water/ethanol solution, with a dry matter content of approximately 1.7% and is specified to contain a minimum of 0.01% hydroxycinnamic acid derivatives (expressed as chlorogenic acid). In a previous assessment, the additive was not characterised in full and about 74% of the dry matter fraction remained uncharacterised (representing 1.24% of the tincture). Therefore, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) could not conclude on the safety of the additive at the proposed use levels of up to 400 mg/kg complete feed for all animal species or for the consumer. The applicant has provided new data which show that the unidentified fraction consists of crude fibre, other carbohydrates, and protein; none of which are considered of concern. Consequently, the Panel concludes that the additive is safe when used at the proposed use level of 400 mg/kg feed for all animal species. No concerns for consumer safety were identified following the application of the additive at the proposed use level in animal nutrition.

Keywords: sensory additives, *Artemisia vulgaris* L., tincture, Mugwort tincture, safety

Requestor: European Commission

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1. Introduction

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

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defined the term of the authorisation by the Commission.

The applicant MANGHEBATI SAS[2] is seeking a Community authorisation of the product Mugwort tincture (MANGHEBATI) to be used as a flavouring additive in feed for all animal species (Table 1).

Table 1: Description of the substances

Category of additive	Sensory additives
Functional group of additive	Flavourings
Description	Mugwort tincture
Target animal category	All animal species
Applicant	MANGHEBATI SAS
Type of request	New opinion

On 4 October 2019, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety and efficacy of the product could not conclude on the safety of the additive at the proposed use levels of up to 400 mg/kg complete feed.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment and to allow a revision of Authority's opinion. The new data have been received on 2 April 2020.

In view of the above, the Commission asks the Authority to deliver a new opinion on the safety of Mugwort tincture (MANGHEBATI) as a feed additive for all animal species based on the additional data submitted by the applicant.

1.2. Additional information

The FEEDAP Panel issued an opinion on the safety and efficacy of a tincture derived from *Artemisia vulgaris* L. when used as a sensory additive in feed for all animal species (EFSA FEEDAP Panel, 2019). Since the 74% of the dry matter fraction of the additive remained uncharacterised, the Panel could not conclude on the safety of the additive at the proposed use levels of up to 400 mg/kg complete feed for all animal species or for the consumer. The applicant has now provided new data to address the issues previously identified regarding the characterisation of the additive.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[3] in support to a previous application on the same product.[4]

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 phytochemical markers in Mugwort tincture in animal feed are valid and applicable for the current application.[5]

[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] Manghebati SAS, zone de la Basse Haye – BP 42133 – 35221 Chateaubourg Cedex.
[3] FEED dossier reference: FAD-2020-0031.
[4] FEED dossier reference: FAD-2010-0401.
[5] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2010-0401-Mugworttincture.pdf

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of Mugwort tincture is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b) and Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c).

3. Assessment

The product under assessment is a tincture produced from the fragmented aerial parts of *A. vulgaris* L. by extended extraction with a water/ethanol mixture. The tincture is specified to contain a minimum of 0.01% hydroxycinnamic derivatives (expressed as chlorogenic acid).

The additive is intended to be used as a sensory additive (functional group: flavouring compounds) in feed for all animal species up to a maximum level of 400 mg tincture/kg complete feed.

3.1. Characterisation of the tincture

The additive was previously shown to contain 98.3% water/ethanol solvent and a dry matter content of about 1.7% (EFSA FEEDAP Panel, 2019). The identified constituents of the dry matter fraction were ash (0.32% of the tincture), polyphenols (0.10%) and a trace amount of 1,8-cineole (0.001%). Some 1.24% of the tincture, corresponding to the 74% of the dry matter fraction and to the 92% of the organic fraction remained uncharacterised.

The applicant has now completed the characterisation of the additive with a proximate analysis of five batches, which show that beside 0.32% ash (range: 0.22–0.45% w/w) and 0.10% polyphenols (range: 0.07–0.16% w/w), the tincture contains on average 0.55% crude fibre (range: 0.44–0.61% w/w), 0.54% other carbohydrates (range: 0.25–0.93% w/w) and 0.12% crude protein (range: 0.04–0.21% w/w).[7] This fully accounts for the dry matter content of the additive. The fraction of polyphenols accounts on average for 6.3% of the dry matter fraction of the tincture (range: 3.9–9.4%) and the other plant constituents for the remaining 93%.

3.2. Safety

In the previous opinion, the FEEDAP Panel concluded that no safety concern would arise from the phenolic fraction and the other identified components when the tincture is used up to the maximum proposed use level of 400 mg tincture/kg feed. However, in the absence of data on the full characterisation of the additive and considering the uncertainty surrounding the composition of 74% of the dry matter fraction of the additive, the FEEDAP Panel could not conclude on the safety of the tincture derived from *A. vulgaris* at the proposed use levels for all animal species or for the consumer.

The additional analytical data provided in response to the previous opinion show that the unidentified fraction (1.21% of the tincture) is composed only of crude fibre, other carbohydrates, and protein. These components identified by the proximate analysis are not of concern. Therefore, the FEEDAP Panel is now able to conclude that the use of the additive up to the maximum proposed use level in feed of 400 mg/kg complete feed is safe for all animal species.

With the full characterisation of the additive the Panel is also in a position to conclude that no safety concern for consumers of animal products would arise from the use of the tincture up to the maximum proposed use level in feed.

4. Conclusions

The additive under assessment, a tincture derived from *A. vulgaris* (Mugwort tincture) is safe for all animal species up to the maximum proposed use level of 400 mg tincture/kg feed.

No concerns for consumer safety were identified following the application of the additive at the proposed use level in animal nutrition.

[6] 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.

[7] Technical dossier/Section II/Supplementary information FAD-2010-0401_SANTE 0010-2011.

5. Documentation as provided to EFSA/Chronology

Date	Event
29/04/2020	Dossier received by EFSA. Mugwort tincture for all animal species. Submitted by Manghebati S.A.S
29/04/2020	Reception mandate from the European Commission
14/05/2020	Application validated by EFSA – Start of the scientific assessment
01/07/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

EURL European Union Reference Laboratory
FEEDAP EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed