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Assessment of the feed additive consisting of thaumatin for all animal species for the renewal of its authorisation (ADISSEO France S.A.S.)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the assessment of the application for the renewal of authorisation of thaumatin as a sensory additive (flavouring compound) for all animal species. The applicant requested a change in the authorising regulation for the minimum content of nitrogen and protein in the specification of the additive. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) confirms that the use of thaumatin under the current authorised conditions of use is safe for the target species, the consumers and the environment. This conclusion can be extended to the newly proposed specification. Due to its proteinaceous nature, the additive is considered to be a respiratory sensitiser. Thaumatin is not irritant to the eyes and the skin. In the absence of data, no conclusion on skin sensitisation could be made. The proposed modification of the specification of the additive is not considered to have an impact on the efficacy of thaumatin.

Keywords: Thaumatin, Talin, sensory additive, sweetener, flavour enhancer, feed additive, *Thaumatococcus daniellii*

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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 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 ADISSEO France S.A.S.[2] for the renewal of the authorisation of the additive consisting of thaumatin, when used as a feed additive for all animal species (category: sensory additive; functional group: flavouring compounds).

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 14(1) (renewal of the authorisation). 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 12 May 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 thaumatin, when used under the proposed conditions of use (see **Section 3.1.3**).

1.2. Additional information

The FEEDAP Panel issued an opinion on the safety and efficacy of thaumatin when used in feed for all animal species (EFSA FEEDAP Panel, 2011).

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) issued a scientific opinion on a proposed extension of use of thaumatin (E 957) in 2015 (EFSA ANS Panel, 2015). Thaumatin has been recently re-evaluated by EFSA Panel on Food Additives and Flavourings (EFSA FAF Panel, 2021).

The additive is currently authorised as a sensory additive (functional group: flavouring compounds) for use in feed for all animal species and categories without a maximum limit (2b957).[3] The additive is also authorised for use as food additive (E957), as a sweetener or flavour enhancer in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives and its specifications are defined in the Commission Regulation (EU) No 231/2012[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 dossier[5] in support of the renewal authorisation request for the use of thaumatin as a feed additive. The dossier was received on 6 December 2021 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2021-00739.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 12 May 2022 to 12 August 2022 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[6] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the

[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] ADISSEO France S.A.S, Immeuble Antony Parc II, 10 place du Général de Gaulle, 92160 Antony, France.
[3] COMMISSION IMPLEMENTING REGULATION (EU) No 869/2012 of 24 September 2012 concerning the authorisation of thaumatin as a feed additive for all animal species. OJ L 257, 25.9.2012, p. 7.
[4] COMMISSION REGULATION (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.
[5] Dossier reference: FEED-2021-1731.
[6] 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.

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 presubmission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 19 April to 10 May 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 thaumatin 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 thaumatin for the renewal of its authorisation 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, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP 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 safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3. Assessment

The feed additive consisting of thaumatin is currently authorised for its use as a sensory additive (functional group: flavouring compounds) in feed for all animal species (2b957). This assessment regards the renewal of the authorisation.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive consists of thaumatin, a natural plant protein material containing two major proteins, thaumatin I and thaumatin II, with molecular mass of 22,209 and 22,293 Da, respectively. It is extracted from the arils of the fruits of *Thaumatococcus daniellii* (Benth). Thaumatin is identified with the single Chemical Abstracts Service (CAS) number 53850-34-3 and the European Inventory of Existing Commercial Chemical Substances (EINECS) number 258-822-2.

The identity of the thaumatin I and II has been confirmed by mass-spectrometry technique.[10]

The applicant stated that the manufacturing of the additive remained unchanged since the previous authorisation.

Regarding the composition of the additive, thaumatin is currently authorised as a feed additive with minimum 16% nitrogen on the dry matter basis, equivalent to not less than 94% protein.[11] The applicant proposed a modification of the specifications for nitrogen and protein in the additive, in order to align them to the specifications for thaumatin when used as a food additive: not less than 15.1% nitrogen (N) on the dried basis and not less than 93% protein (N $\times$ 6.2).[4]

[7] Decision available online: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements
[8] The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0138_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] RFI_Jul_2022_Annex_02.
[11] COMMISSION IMPLEMENTING REGULATION (EU) No 869/2012 of 24 September 2012 concerning the authorisation of thaumatin as a feed additive for all animal species.

Six recent batches of additive[12] were analysed for nitrogen (dry matter basis), showing an average nitrogen content of 15% (range 14.6–15.5%); the Panel notes that three out of six analysed samples showed values of nitrogen below the newly proposed specification of 15.1%; the protein content of the same three samples showed values in the range 91.1–92%, also below the newly proposed specification of minimum 93% protein in the additive. The average protein content of the six samples was 93.4%.[13]

Water content (loss on drying) was provided for six batches and was on average 3.82% (range 2.6–5.15%). Five recent batches of the additive were analysed for impurities. The content of carbohydrates and aluminium[14] was reported to be < 30 g/kg and < 100 mg/kg, respectively; however, no analytical values were provided. Sulfated ash was on average 0.8% (range from 0.4% to 1.3%).[14]

Analytical results for lead, mercury, cadmium and arsenic were reported for three batches. Lead and mercury were below the corresponding limit of quantification (LOQ).[15] Cadmium was on average 0.019 mg/kg, while arsenic was 0.14–0.17 mg/kg. In five other batches of the additive lead and arsenic were reported as 'conform', but no analytical values were provided.[16]

Three batches of the additive were tested for dioxins.[17] Polychlorinated dibenzo-*p*-dioxin (PCDD) and polychlorinated dibenzofuran (PCDF) and the sum of dioxins plus dioxin like polychlorinated biphenyls (PCBs) concentrations/levels were up to 0.125 ng WHO-PCDD/F-TEQ/kg and 0.189–0.192 ng WHO-PCDD/F-PCB-TEQ/kg (upper bound), respectively; sum of six non-dioxin-like PCBs was 0.117 μg/kg in two batches tested and 0.119 μg/kg in one batch (upper bound).

The analysis of mycotoxins was carried out in three batches of the additive. Aflatoxins (B1, G1, B2, G2) and ochratoxin A were found below the corresponding LOQ.[18]

Microbiological contamination was analysed in six batches.[19] Total plate count was 30 CFU/g in one batch and less than 10 CFU/g in the rest of the batches. Yeasts and filamentous fungi count was < 20 CFU/g. *Escherichia coli* and coagulase-positive staphylococci (including *Staphylococcus aureus*) were both non-detectable in 1 g. Lactic acid bacteria and *Pseudomonas* spp. were < 10 CFU/g. *Salmonella* spp. was not detected in 25 g and bile tolerant Gram-negative bacteria were < 100 CFU/g (in five batches tested).

The FEEDAP Panel considers that the microbial contamination and the amounts of the detected impurities do not raise safety concerns.

3.1.2. Physical properties of the additive

The additive appears as odourless, cream to light brown coloured powder. Bulk density[20] was determined for three batches and was on average 170 kg/m^3 (range from 134 to 204 kg/m^3). The solubility[21] of the additive in water at 20 °C was reported to be minimum 330 g/L, but less than 500 g/L based on a visual assessment of the water solubility. The solution of 1% of the additive in water had a pH 2.5–4.0. The additive is insoluble in ethanol.

The dusting potential of one batch of the additive (four replicates) was determined using the Stauber-Heubach method and resulted[22] in a value of 2,165 mg/m^3 (mg airborne dust per m^3 of air). The particle size of the additive was specified to be < 350 μm,[23] but no analytical evidence was provided.

Since the additive is *freely soluble*[24] in water, the Panel concludes that any potential nanoparticles present in the feed additive would be fully solubilised in the gastrointestinal tract and, therefore, a conventional risk assessment should be sufficient.

[12] Annex II_01; Reply_RFI_Jul_2022_Annex_01 and Annex_03.
[13] Annex II_06.
[14] Annex II_1; Reply_RFI_Jul_2022_Annex_01.
[15] Annex II_2; LOQ (Pb) = 0.04 mg/kg, LOQ (Hg) = 0.005 mg/kg, LOQ (Cd) = 0.01 mg/kg and LOQ (As) = 0.03 mg/kg.
[16] Annex II_1 and Reply_RFI_Jul_2022_Annex_01.
[17] Annex II_05. Results were all expressed as wet weight.
[18] Annex II_04: LOQ (aflatoxin B1) = 0.1 μg/kg; LOQ (aflatoxin B2) = 0.1 μg/kg; LOQ (aflatoxin G1) = 0.1 μg/kg; LOQ (aflatoxin G2) = 0.1 μg/kg; LOQ (Ochratoxin A) = 0.5 μg/kg.
[19] Annex II_1 and Reply_RFI_Jul_2022_Annex_01 and Annex 03.
[20] Annex II_8.
[21] Annex II_11.
[22] Annex II_7.
[23] Annex II_6.
[24] The solubility is above the threshold set in Section 2.3.1 of the Guidance on Particle – TR (EFSA Scientific Committee, 2021).

3.1.3. Conditions of use

Thaumatin is currently authorised (2b957) for use in complete feed for all animal species without a withdrawal period.[11] The authorising regulation under other provisions requires that:

1) In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
2) Recommended use up to 5 mg/kg complete feedingstuff.
3) For safety: breathing, eye and skin protection shall be used during handling

The applicant proposes to keep the current conditions of use.

3.2. Safety

The safety of thaumatin for the target species, consumers, users and the environment was evaluated in a previous Panel opinion (EFSA FEEDAP Panel, 2011). The applicant stated that the additive and its purity, manufacturing and conditions of use did not change since the first authorisation in 2012.[25] The applicant provided a statement[26] that in the context of the requirements of the EU Feed Hygiene Regulation,[27] no complaints that required the initiation of procedure and information to the competent authorities have been received since the additive's initial authorisation.

3.2.1. Extensive literature search (ELS)

Following the requirements of the Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021), the applicant provided a literature search on the safety of thaumatin. The applicant carried out an automatic ELS[28] and an independent 'manual' literature search to demonstrate that the additive remains safe for the target species, consumer, user and the environment under the current conditions of use. The ELS covered the period from 2010 to 2021.

Search syntax was developed based on EFSA guidelines and recommendations on conducting an ELS. The substance descriptor words for the automatic ELS were 'thaumatin', 'Talin', 'E957' or its CAS number; these words were used in combination with the 'effects/endpoints' and 'target species' keywords. Specific search words were added in order to target the search for specific areas (such as safety for the different target animals, safety for user/workers, safety for consumers and safety for the environment). A detailed description of the search syntax used, and the inclusion/exclusion criteria applied for the selection were provided. The date of search has been reported.

The automatic ELS was carried out using agricultural, aquacultural, medical and veterinary databases (having access to Elsevier, Springer, Wiley Library, Ingenta and many others).[29] The results from the automatic ELS were screened according to 'inclusion/exclusion criteria' by two independent reviewers. Each reviewer assessed the title, abstract and keywords, for its relevance in a first step. Consequently, full texts of all selected papers were further evaluated for consideration. Results from both of the independent reviewers were combined. Articles that did not receive the same relevance by both reviewers were re-discussed until a common agreement to include or exclude was reached. In total, eight publications were considered relevant in the automatic ELS. Two of the eight matches were EFSA opinions on thaumatin (EFSA FEEDAP Panel, 2011; EFSA ANS Panel, 2015).

The 'manual' literature search was performed by using the Swiss Library Service Platform-Swisscovery and Google scholar. The search was restricted to the years 2010–2021 and peer-reviewed publications; patents were excluded. The search syntax has been provided. For the 'manual' search, the applicant used the same inclusion and exclusion criteria from the automatic ELS. The applicant reported 24 final relevant articles from the 'manual' search.

Articles from both automatic and 'manual' ELS were combined into a final list of 32 publications.

3.2.2. Toxicological profile of thaumatin

Thaumatin was previously assessed by JECFA (Joint FAO/WHO Expert Committee on Food Additive) (JECFA, 1983, 1986) and the SCF (Scientific committee for food) (SCF, 1985; , 1989). In 1986, JECFA

[25] Scientific summary.
[26] Annex III_1.
[27] 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.
[28] Annex III_2.
[29] Annex III-2.

identified a no observed adverse effect level (NOAEL) of 10,000 mg/kg body weight (bw) day in a subchronic toxicity study in dogs. From this NOAEL, the FEEDAP Panel, in its opinion of 2011, calculated the maximum safe feed concentrations for the target species (EFSA FEEDAP Panel, 2011). In 2015, the EFSA ANS Panel (EFSA ANS Panel, 2015) noted that for the above NOAEL, there were errors in the description of the studies in the JECFA opinion, particularly in the transcription of the dose.[30] On the basis of the original study report, the ANS Panel considered that the highest dose tested of 3% of thaumatin in the diet would correspond to a NOAEL of ~ 1,400 mg/kg bw per day in dogs (average of NOAEL for male and female). The EFSA Panel of Food Additives and Flavourings (FAF) has recently published an opinion on the re-evaluation of thaumatin (E 957) when used as food additive (EFSA FAF Panel, 2021). In the opinion, the FAF Panel reconsidered the results of all the animal oral toxicity studies available. The NOAEL identified from the above-mentioned subchronic toxicity study in dogs was confirmed to be 1,305 mg/kg bw per day in male dogs and 1,476 mg/kg bw per day in female dogs. Among all NOAELs identified in different toxicological studies, all corresponding to the highest dose tested, the FAF Panel used the highest NOAEL of 5,200 mg/kg bw per day (the highest dose tested in males), identified in a subchronic toxicity study with rats (Ben-Dyke et al., 1976, as cited by EFSA FAF Panel, 2021), to calculate the Margin of Safety (MOS) for humans. In addition, the FAF Panel concluded that thaumatin does not raise concern for genotoxicity and developmental toxicity.

3.2.3. Safety for the target species

The assessment of scientific papers resulting from the ELS did not reveal any relevant study for the safety for target species. The studies identified were not designed as tolerance studies and were mostly research on sensory and taste perception.[31]

In its previous opinion, the FEEDAP Panel applied the NOAEL of 10,000 mg/kg bw per day, identified in a subchronic toxicity study in dogs, to derive the maximum safe feed concentrations for the target species (ranging from 1,667 to 5,000 mg/kg feed) and concluded that the proposed use levels of 1–5 mg thaumatin/kg feed were safe for all animal species with a large MOS (EFSA FEEDAP Panel, 2011).

In their opinions, the EFSA ANS Panel (EFSA ANS Panel, 2015) and the EFSA FAF Panel (EFSA FAF Panel, 2021) recalculated the NOAEL, from the same subchronic toxicity study in dogs, which resulted in values of 1,305 mg/kg bw per day in male dogs and 1,476 mg/kg bw per day in female dogs. These NOAELs are the lowest among all NOAELs (all corresponding to the highest dose tested) identified by the EFSA FAF Panel from the available toxicological studies. In the current assessment, the FEEDAP Panel considers the lowest NOAEL of 1,305 mg/kg bw per day as the relevant NOAEL to be used to calculate the maximum safe concentration of the additive in feed for all animal species.

The updated maximum safe concentration in complete feed for the target species was re-calculated following the procedure described in the EFSA Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c) and by applying an uncertainty factor of 100 to the NOAEL of 1,305 mg/kg bw per day (Table 1).

Table 1: Maximum safe concentration of thaumatin in feed for different target animals, derived using a NOAEL of 1,305 mg/kg bw per day and applying an uncertainty factor of 100

Animal species/categories	Body weight (kg)	Feed Intake (g (DM)/day)	Maximum safe concentration in feed (mg/kg complete feed)*
Chicken for fattening	2	158	145
Laying hen	2	106	217
Turkey for fattening	3	176	196
Piglet	20	880	261
Pig for fattening	60	2,200	313
Sow lactating	175	5,280	381
Veal calf (milk replacer)	100	1,890	608

[30] The highest dose tested was not 10 g/kg bw per day but 3% in the diet corresponding to a daily dose of ~ 1,400 mg/kg bw per day in dogs (range 1,101–1,600 mg/kg bw per day in male dogs; 1,249 to 1,791 mg/kg bw per day in female dogs) (EFSA ANS Panel, 2015).

[31] Target animal safety/Annex III_32–35.

Animal species/categories	Body weight (kg)	Feed Intake (g (DM)/day)	Maximum safe concentration in feed (mg/kg complete feed)*
Cattle for fattening	400	8,000	574
Dairy cow	650	20,000	373
Sheep/goat	60	1,200	574
Horse	400	8,000	574
Rabbit	2	100	230
Salmon	0.12	2.1	656
Dog**	15	250	6,890
Cat	3	60	574
Ornamental fish	0.012	0.054	2,552

*: Complete feed dry matter (DM) = 88%, milk replacer DM = 94.5%.
**: For dogs an uncertainty factor of 10 was applied, covering for the intraspecies variability, since the NOAEL used was identified in a study with dogs.

Thaumatin is authorised with a recommended use level up to 5 mg/kg complete feedingstuff. Comparing the recommended maximum use level with the maximum safe concentrations in feed calculated from the newly proposed NOAEL (Table 1), the lowest MOS that could be identified is about 30. In the absence of any new evidence that reports on the adverse effects from the use of thaumatin in feed, and based on the updated NOAEL, the FEEDAP Panel retains that previous conclusion on the safety of thaumatin for the target species when used as sensory feed additive at the recommended level (up to 5 mg/kg complete feed) is still valid.

This conclusion is also applicable to the newly proposed specification for thaumatin (min 15.1% nitrogen, equivalent to min 93% of protein).

3.2.4. Safety for the consumer

In its recent opinion, the FAF Panel, considering the available toxicological information and the estimated exposure of consumer to thaumatin used as a food additive, concluded that there is no need for establishing a numerical acceptable daily intake (ADI) for thaumatin (E 957) (EFSA FAF Panel, 2021).

In its previous opinion, the FEEDAP Panel considered that 'no residues of thaumatin in animal tissues or products are to be expected and the use of thaumatin in animal nutrition is considered safe for the consumer' (EFSA FEEDAP Panel, 2011).

No information was found in the literature search submitted that would lead to a modification of the above conclusions.

Considering all of the above, the Panel reiterates its previous conclusion, that the use of thaumatin is considered safe for the consumer when thaumatin is used in animal feed at proposed conditions of use.

3.2.5. Safety for the user

At the time of the original application, no studies on safety for the user were provided (EFSA FEEDAP Panel, 2011). The applicant submitted two new studies, an eye irritation and a skin irritation study in line with the requirements of the Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012).

3.2.5.1. Inhalation toxicity

The reported dusting potential[32] was on average 2,165 mg/m^3 which indicates that exposure by inhalation is likely. Due to its proteinaceous nature, the additive is considered to be a respiratory sensitiser.

The ELS search carried out by the applicant identified a publication on potential respiratory allergenic potential of thaumatin in workers (Tschannen et al., 2017). The same study has been recently assessed by the FAF Panel (EFSA FAF Panel, 2021). The results of the study suggested that occupational exposure to a powder mixture containing thaumatin and gum arabic may cause rhinitis, in particular among susceptible individuals, and nasal mucosa signs of allergy. In its opinion on the re-

[32] Annex II_7.

evaluation of thaumatin (E 957) as food additive, the FAF Panel concluded that 'thaumatin may elicit an allergic response via inhalation' (EFSA FAF Panel, 2021).

3.2.5.2. Eye irritation

The eye irritation potential of the additive was investigated in an *in vitro* eye irritation study according to the Organization for Economic Co-operation and Development (OECD) technical Guideline (TG) 437.[33] Based on the results of the study, the additive should be classified as non-irritant to eyes (UN-GHS[34] 'No Category').

3.2.5.3. Skin irritation

The skin irritation potential of the additive was investigated in an *in vitro* skin irritation study according to OECD TG 439.[35] The results of the study indicated that the additive should be classified as non-irritant to the skin (UN-GHS 'No Category').

In the absence of data, the FEEDAP Panel cannot conclude on the skin sensitisation potential of the additive.

3.2.5.4. Conclusions on user safety

The FEEDAP Panel considered that the exposure of the user to the additive through inhalation is possible. Due to its proteinaceous nature, the additive is considered to be a respiratory sensitiser. The additive is considered non-irritant to skin and eyes. In the absence of data, the FEEDAP Panel cannot conclude on the skin sensitisation potential of the additive.

3.2.6. Safety for the environment

Thaumatin is considered to be 'extensively metabolised' in the digestive tract of the target species. As supporting evidence for the extensive metabolisation of the additive, an *in vitro* digestibility study in which thaumatin was compared to whey protein, a well-known digestibility reference, was provided.[36] The digestibility score for thaumatin was 83% which is higher than the digestibility score of whey protein 79.1%.

The literature search submitted did not identify any relevant paper on the adverse environmental effects due to the use of thaumatin in animal nutrition.

The FEEDAP Panel considers that, based on the information received, the use of thaumatin in animal nutrition at the proposed use level does not raise any concern for the safety of the environment.

3.3. Efficacy

The proposed modifications of the specifications of the additive are not considered to have an impact on the efficacy of thaumatin.

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[37] and good manufacturing practice.

4. Conclusions

The FEEDAP Panel considers that the proposed modification of the specifications would not add any hazard to those already assessed. The Panel concludes that thaumatin remains safe for the target species, the consumer and the environment under the conditions of use currently authorised. Exposure via inhalation is likely. Due to its proteinaceous nature, thaumatin is considered as a respiratory sensitiser. Thaumatin is not a skin or an eye irritant. The FEEDAP Panel cannot conclude on the dermal sensitisation potential of the additive. The proposed modifications of the specification of the additive are not considered to have an impact on the efficacy of thaumatin.

[33] 2023-01-31_Reply to ADR1/Reply_RFI_Jul_2022_Annex_05.
[34] UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
[35] 2023-01-31_Reply to ADR1/Reply_RFI_Jul_2022_Annex_04.
[36] Annex_III_36.
[37] 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.

5. Recommendation

The FEEDAP Panel recommends that the specification for thaumatin as feed additive, regarding the content of nitrogen and protein is aligned to the specification set for thaumatin as a food additive (E 957), i.e. not less than 15.1% nitrogen on a dry matter basis and not less than 93% protein.

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Abbreviations

ADI	acceptable daily intake
ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
BW	body weight
CAS	Chemical Abstracts Service
CFU	colony-forming unit
DM	dry matter
EINECS	European Inventory of Existing Chemical Substances
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOQ	limit of quantification
MOS	Margin of safety
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
SCF	Scientific Committee on Food
WHO	World Health Organization