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EURL Evaluation Report on the Analytical Methods submitted in connection with the Application for the Authorisation of Feed Additives according to Regulation (EC) No 1831/2003

Dossier related to:	FAD-2010-0138 CRL/100089
Product Name:	Thaumatin
Active Substance(s):	Thaumatin
Rapporteur Laboratory:	European Union Reference Laboratory for Feed Additives (EURL-FA) Geel, Belgium
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Report approved by: Date:	Christoph von Holst 15/04/2011

EXECUTIVE SUMMARY

In the current application authorisation is sought under articles 4(1) (new use in water) and 10(2) (re-evaluation of additives already authorised under Directive 70/524/EC) for *Thaumatin* under the category "sensory additives", functional group 2(b) "flavouring compounds", according to the classification system of Annex I of Regulation (EC) No 1831/2003.

Thaumatin belongs to the *Chemically Defined Flavourings 30* (*Miscellaneous substances*), according to the Annex I of Commission Regulation (EC) No 1565/2000. Authorisation is sought for the use of *Thaumatin* for all species and categories.

According to the Commission Directive 2008/60/EC preparations containing *Thaumatin* should have a minimum nitrogen content of 15% related to dry mass, equivalent to a minimum content of 93% protein.

The *feed additive* is intended to be incorporated only into *feedingstuffs* or drinking *water*, in combination with other flavouring substances as constituents of *flavouring mixtures*. The Applicant suggested no minimum or maximum levels for *Thaumatin*, but normal contents of the flavouring compound in *feedingstuffs* range up to from 0.1 to 100 mg/kg.

For the identification of *Thaumatin* in the *feed additive*, the Applicant proposed the internationally recognised FAO JECFA monograph for *Thaumatin* in food additives. For the determination of the *Thaumatin* nitrogen content in the *feed additive*, the Applicant submitted the Kjeldhal method, described in the above mention JECFA monograph. Even though no performance characteristics are provided, the EURL recommends for official control the JECFA monograph based on the Kjeldhal method, for the quantification of the *Thaumatin* nitrogen content in the *feed additive*.

As no experimental data were provided by the Applicant for the determination of the product in *feedingstuffs* and *water*, the EURL could not evaluate nor recommend the method for official control to determine *Thaumatin* in *feedingstuffs* and *water*.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.

KEYWORDS

Thaumatin, Chemically Defined Flavourings, flavouring mixtures, sensory additives, all species and categories.

1. BACKGROUND

In the current application authorisation is sought under articles 4(1) (new use in water) and 10(2) (re-evaluation of additives already authorised under Directive 70/524/EC) for *Thaumatin* under the category "sensory additives", functional group 2(b) "flavouring compounds" [1], according to the classification system of Annex I of Regulation (EC) No 1831/2003.

Thaumatin belongs to the *Chemically Defined Flavourings 30* (*Miscellaneous substances*), according to the Annex I of Commission Regulation (EC) No 1565/2000. Authorisation is sought for the use of *Thaumatin* for all species and categories [2].

The additive is a well characterised protein, obtained by aqueous extraction (pH 2.5-4) of the arils of the fruit r from the katemfe plant, *Thaumatococcus daniellii* (Benth), a plant species that is a member of the order Zingiberales and Marantaceae family. [3].

According to the Commission Directive 2008/60/EC preparations containing thaumatin should have a minimum nitrogen content of 15% related to dry mass, equivalent to a minimum content of 93% protein (N × 6.2).

The *feed additive* is intended to be incorporated only into *feedingstuffs* or drinking *water*, in combination with other flavouring substances as constituents of *flavouring mixtures* [3]. The Applicant suggested no minimum or maximum levels for *Thaumatin* [2], but normal contents of the flavouring compound in *feedingstuffs* range up to from 0.1 to 100 mg/kg [3].

2. TERMS OF REFERENCE

In accordance with Article 5 of Regulation (EC) No 378/2005, as last amended by Regulation (EC) No 885/2009, on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and the tasks of the European Union Reference Laboratory concerning applications for authorisations of feed additives, the EURL is requested to submit a full evaluation report to the European Food Safety Authority for each application or group of applications. For this particular dossier, the methods of analysis submitted in connection with *Thaumatin*, and their suitability to be used for official controls in the frame of the authorisation, were evaluated.

3. EVALUATION

Qualitative and quantitative composition of impurities in the additive

When required by EU legislation, analytical methods for official control of undesirable substances in the additive (e.g. arsenic, cadmium, lead, mercury, and dioxins) are available from the respective European Union Reference Laboratories [4].

Description of the analytical methods for the determination of the active substance in feed additive, premixtures and feedingstuffs

For the identification of *Thaumatin* in the *feed additive,* the Applicant proposed the internationally recognised FAO JECFA monograph for *Thaumatin* in food additives [5].

For the determination of the *Thaumatin* nitrogen content in the *feed additive*, the Applicant submitted the Kjeldhal method, described in the above mention JECFA monograph [6].

Even though no performance characteristics are provided, the EURL recommends for official control the JECFA monograph based on the Kjeldhal method, for the quantification of the *Thaumatin* nitrogen content in the *feed additive*.

For the determination of *Thaumatin* in *water* the Applicant submitted an ion chromatography method coupled to UV detection using external calibration (HPLC-UV) [7] developed for the determination of the active substance in beverages and powder extracts. However, the Applicant did not provide any performance characteristics such as limits of detection and quantification. Furthermore, no experimental data were provided by the Applicant for the determination of the product in *feedingstuffs*. Therefore, the EURL cannot evaluate nor recommend a method for official control to determine *Thaumatin* in *feedingstuffs* and *water*.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.

4. CONCLUSIONS AND RECOMMENDATIONS

In the frame of this authorisation the EURL recommends for official control of the *feed additive* the identification tests and the quantification assay described in the JECFA monograph on *Thaumatin*.

The Applicant provided no experimental data for *feedingstuffs* and *water*, therefore the EURL is unable to recommend a method for the determination of *Thaumatin* in *feedingstuffs* and *water*.

Recommended text for the register entry (analytical method)

For the quantification of *Thaumatin* nitrogen content in the *feed additive*:

- Kjeldhal method (JECFA monograph on *Thaumatin*)

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Thaumatin* have been sent to the European Union Reference Laboratory for Feed Additives. The dossier has been made available to the EURL by EFSA.

6. REFERENCES

[1] *Application, Reference SANCO/D/2 Forw. Appl. 1831/0084-2010

[2] *Application, Proposal for Register Entry – Annex A

[3] *Technical dossier, Section II – Sect_II_Identity.pdf: 2.1. Identity of the additives - 2.5. Conditions of use of the additive – 2.6. Method of analysis and reference samples

[4] Commission Regulation (EC) No 776/2006 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards to Community Reference Laboratories

[5] *Technical dossier, Section II – Annex_II_8_FAO 2006b

[6] *Technical dossier, Section II – Annex_II_9_FAO 2006a

[7] *Technical dossier, Section II – Annex_II_12_HPLC method

* Refers to Dossier No. FAD-2010-0138

7. RAPPORTEUR LABORATORY & NATIONAL REFERENCE LABORATORIES

The Rapporteur Laboratory for this evaluation was European Union Reference Laboratory for Feed Additives, IRMM, Geel, Belgium. This report is in accordance with the opinion of the consortium of National Reference Laboratories as referred to in Article 6(2) of Commission Regulation (EC) No 378/2005, as last amended by Regulation (EC) No 885/2009.

8. ACKNOWLEDGEMENTS

The following National Reference Laboratories contributed to this report:

- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)