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European Union Reference Laboratory for Feed Additives

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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-2010-0129 CRL/100088
Product Name:	Naringin)
Active Substance(s):	Naringin
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) and 10(2) for *Naringin* 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. *Naringin* belongs to the *Chemically Defined Flavourings 25* (*Phenol derivatives containing ring-alkyl, ring-alkoxy, and side-chains with oxygenated functional group*), according to the Annex I of Commission Regulation (EC) No 1565/2000. Authorisation is sought for the use of the *feed additive* for all species and categories. According to the Applicant *Naringin* should have a minimum content of 90%. 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 the *Naringin*, but normal contents of the flavouring compound in *feedingstuffs* range up to from 0.1 to 100 mg/kg.

For the determination of *Naringin* in the *feed additive*, the Applicant submitted a single-laboratory validated High Performance Liquid Chromatography (HPLC) method coupled to an UV detector [6], applying the assay procedure described in the European Pharmacopeae monograph 2.2.29 where an external calibration is applied. The EURL considers the HPLC-UV method submitted by the Applicant suitable for official control of *Naringin* in the *feed additive*.

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

Naringin, 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 *Naringin* 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. *Naringin* (Flavis No 16.058) belongs to the *Chemically Defined Flavourings 25* (*Phenol derivatives containing ring-alkyl, ring-alkoxy, and side-chains with oxygenated functional group*), according to the Annex I of Commission Regulation (EC) No 1565/2000 [2]. Authorisation is sought for the use of the *feed additive* for all species and categories [3].

According to the Applicant *Naringin* should have a minimum content of 90% [3]. 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* [4]. The Applicant suggested no minimum or maximum levels for the *Naringin* [3], but normal contents of the flavouring compound in *feedingstuffs* range up to from 0.1 to 100 mg/kg [4].

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 *Naringin*, 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 [5].

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

For the determination of *Naringin* in the *feed additive,* the Applicant submitted a single-laboratory validated High Performance Liquid Chromatography (HPLC) method coupled to an UV detector [6], applying the assay procedure described in the European Pharmacopeae monograph 2.2.29 where an external calibration is applied. The sample to be analysed (50 mg) is dissolved in 50 mL dimethyl sulphoxide, homogenised and placed in an injection vial for analysis (at 284 nm). The following performance characteristics, derived from the study on the *Naringin* purity [7], were reported: - a relative standard deviation for *repeatability* (RSD_r) and *intermediate precision* (RSD_{ip}) of 0.3%.

The EURL considers the HPLC-UV method submitted by the Applicant suitable for official control of *Naringin* in the *feed additive*.

As no experimental data were provided by the Applicant for the determination of the product in *feedingstuffs* or *water*, the EURL could not evaluate nor recommend the method for official control to determine *Naringin* in *feedingstuffs* or *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 the High Performance Liquid Chromatography method coupled to an UV detector (HPLC-UV) for the determination of *Naringin* in the *feed additive.*

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

Recommended text for the register entry (analytical method)

For the determination of the *Naringin* in the *feed additive*:

- High Performance Liquid Chromatography coupled to an UV detector (HPLC-UV)

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Naringin* 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. 1831/0095-2010

[2] Commission Regulation (EC) No 1565/2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council

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

[4] *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

[5] 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

[6] *Technical dossier, Section II – Annex_II_11_Naringin HPLC method

[7] *Technical dossier, Section II – Annex_II_13_Naringin validated method of analysis

* Refers to Dossier No. FAD-2010-0129

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)