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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-2010-0352 CRL/100338
Feed additive:	Brown HT (E 155)
Active Substance(s):	Brown HT
Rapporteur Laboratory:	European Union Reference Laboratory for Feed Additives (EURL-FA) Geel, Belgium
Report prepared by:	Roberto Molteni (EURL-FA)
Report revised by:	Piotr Robouch (EURL-FA)
Date:	08/08/2011
Report approved by:	Christoph von Holst
Date:	08/08/2011

EXECUTIVE SUMMARY

In the current application authorisation is sought under articles 4(1) and 10(2) for *Brown HT* under the "sensory additives", functional group 2(a) "colourants", according to the classification system of Annex I of Regulation (EC) No 1831/2003. Authorisation is sought for the use of the *feed additive* for cats and dogs.

Brown HT is a synthesized reddish-brown powder or granules, soluble in water, consisting of a minimum of 70 % total colouring matters calculated as sodium salt. *Brown HT* is intended to be incorporated directly in *feedingstuffs* as a solution in *water* (either added directly as a solid to the feedingstuffs in the presence of water or by addition of an aqueous solution), with no recommended minimum or maximum levels.

For the determination of *Brown HT* in the *feed additive*, the Applicant proposed the internationally recognised FAO JECFA monograph in food additives. Identification is based on spectrophotometry and Thin Layer Chromatography (TLC), while quantification of *Brown HT* in the *feed additive* is based on spectrophotometry at 460 nm in aqueous solution at pH 7, as recommended by Commission Directive 2008/128/EC laying down specific purity criteria concerning colours for use in foodstuffs. Even though no performance characteristics are provided, the EURL recommends for official control the JECFA monograph based on spectrophotometry for the quantification of the *Brown HT* in the *feed additive*.

The Applicant did not provide any experimental method or data for the determination of *Brown HT* in *premixtures*, *feedingstuffs* and *water*. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Brown HT* in *premixtures*, *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

Brown HT, sensory additive, colourants, cats and dogs

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 the provisions of the Council Directive 70/524/EEC) for *Brown HT* under the "sensory additives", functional group 2(a) "colourants" [1], according to the classification system of Annex I of Regulation (EC) No 1831/2003. Authorisation is sought for the use of the *feed additive* for cats and dogs [2].

Brown HT is a synthesized reddish-brown powder or granules, soluble in water (200 g/L at 20°C) [3], consisting of a minimum of 70 % total colouring matters calculated as sodium salt [2]. The Applicant states that the purity criteria set in the Commission Directive 2008/128/EC for the food additive apply to the requirement for the *feed additive* [3]. *Brown HT* is intended to be incorporated directly in *feedingstuffs* as a solution in *water* (either added directly as a solid to the feedingstuffs in the presence of water or by addition of an aqueous solution), with no recommended minimum or maximum levels [2]. However, a typical maximum concentration of 500 mg/kg *feedingstuffs* is suggested by the Applicant [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 *Brown HT*, and their suitability to be used for official controls in the frame of the authorisation, were evaluated.

3. EVALUATION

Identification /Characterisation of the feed additive

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, mycotoxins, 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 determination of *Brown HT* in the *feed additive*, the Applicant proposed the internationally recognised FAO JECFA monograph for food additives [5]:

- Identification of *Brown HT* in the *feed additive* is based on - spectrophotometry at 460 nm in water of pH 7 and - Thin Layer Chromatography (TLC), with Retention factors (R_f) determined using several chromatographic conditions for confirmation.
- Quantification of *Brown HT* in the *feed additive* is based on spectrophotometry at 460 nm in aqueous solution at pH 7, as recommended by Commission Directive 2008/128/EC. Total colouring matters are quantified using Procedure 1 described in the JECFA monographs n. 1 (Vol. 4) [5].

Even though no performance characteristics are provided, the EURL recommends for official control the JECFA monograph based on spectrophotometry for the quantification of the *Brown HT* in the *feed additive*.

The Applicant did not provide any experimental method or data for the determination of *Brown HT* in *premixtures*, *feedingstuffs* and *water*. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Brown HT* in *premixtures*, *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 recommended by Commission Directive 2008/128/EC and described in the JECFA monographs n. 1 (Vol. 4), Combined Compendium for Food Additive Specifications.

The Applicant did not provide any experimental method or data for the determination of *Brown HT* in *premixtures*, *feedingstuffs* and *water*. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Brown HT* in *premixtures*, *feedingstuffs* and *water*.

Recommended text for the register entry (analytical method)

For the quantification of *Brown HT* in the *feed additive*:

- spectrophotometry at 460 nm (Commission Directive 2008/128/EC referring to FAO JECFA monographs n. 1 (Vol. 4))

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Brown HT* 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. 1831/00192/(10335)-2010
- [2] *Application, Proposal for Register Entry – Annex A
- [3] *Technical dossier, Section II: Identity, characterisation and conditions of use of the additive; Methods of analysis
- [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] FAO JECFA monographs n. 1 (Vol. 4), Combined Compendium for Food Additive Specifications

* Refers to Dossier No. FAD-2010-0352

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:

- Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUFA) Speyer (DE)
- Plantedirektoratet, Laboratorium for Foder og Gødning, Lyngby (DK)
- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Thüringer Landesanstalt für Landwirtschaft (TLL), Abteilung Untersuchungswesen. Jena (DE)
- Instytut Zootechniki w Krakowie, Krajowe Laboratorium Pasz, Lublin (PL)
- Państwowy Instytut Weterynaryjny, Puławy (PL)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)