



JRC.DG.D.5/CvH/ZE/AG/ARES(2012)350467

**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-2011-0024 - CRL/100349

Feed Additive Name: Cellulose powder, E460 (ii)

Active Substance(s): -

Rapporteur Laboratory: European Union Reference Laboratory
for Feed Additives (EURL-FA)
Geel, Belgium

Report prepared by: Zigmas Ezerskis(EURL-FA)

Report revised by: Piotr Robouch (EURL-FA)
Date: 26/03/2012

Report approved by: Christoph von Holst
Date: 26/03/2012

EXECUTIVE SUMMARY

In the current application authorisation is sought under articles 4(1) and 10(2) for *Cellulose powder (E 460ii)* under the category/functional group 1 (c, d, e, f, g) 'technological additives'/'emulsifiers', 'stabilisers', 'thickeners', 'gelling agents' and 'binders' according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the *feed additive* for all animal species and categories.

Cellulose powder (E 460ii) is purified cellulose, prepared as a pulp from fibrous plant material and mechanically disintegrated. It is insoluble in water, ethanol, ether and diluted mineral acids but slightly soluble in sodium hydroxide solution. Furthermore, the purity criteria set in the Commission Directive 2008/84/EC for the food additive are applicable to the *feed additive*.

The *feed additive* is intended to be incorporated directly into *feedingstuffs* or through *premixtures*, with no proposed minimum or maximum levels. However, a typical range of concentration ranging from 3.5 to 20 g/kg *feedingstuffs* is suggested by the Applicant.

For the identification of *cellulose powder* in the *feed additive* the Applicant proposed official VDLUFA method (6.5.1) based on gravimetric assay of neutral detergent fibre (NDF). The Applicant applied the VDLUFA method and reported an NDF value of 92.6 %, thus complying with the specifications set in Commission Directive 2008/84/EC for *cellulose powder*. Furthermore, the EURL identified the dedicated internationally recognised Food Chemical Codex monograph "*cellulose, powdered*" based on: - suspension formation test; and - assay with potassium dichromate and further titration with ferrous ammonium sulphate for determination of a carbohydrate, expressed as cellulose content. These methods comply with the recommendations set in Commission Directive 2008/84/EC and are described in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for *cellulose powder*.

Even though no performance characteristics are provided, the EURL recommends for official control the VDLUFA method (6.5.1) and the dedicated internationally recognised Food Chemical Codex monograph to identify *cellulose powder* in the *feed additive*.

During the review process, NRL experts suggested to monitor - instead of the "Neutral Detergent Fibre" suggested by the Applicant - the "Crude Fibre" content using the Community method (R 152/2009 - Annex III, Part I). This suggestion complies with the information provided by the Applicant in a certificate of analysis of his product, which indicates a crude fibre value of 68 %. However, the proposed registry entry specifying the composition of the additive does not contain at present such a criterion.

The Applicant provided no experimental data or any analytical methods for the determination of *cellulose powder* in *premixtures* and *feedingstuffs*, as the accurate determination of the *cellulose powder* in these matrices is not achievable experimentally. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *cellulose powder* in *premixtures* and *feedingstuffs*.

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

Cellulose powder, technological additives, emulsifiers, stabilisers, thickeners, gelling agents, binders, all animal species and categories

1. BACKGROUND

In the current application authorisation is sought under articles 4(1) (new use) and 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) for *Cellulose powder (E 460ii)* under the category/functional group 1 (c, d, e, f, g) [1] 'technological additives'/emulsifiers', 'stabilisers', 'thickeners', 'gelling agents' and 'binders' according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the *feed additive* for all animal species and categories [2].

Cellulose powder (E 460ii) is purified cellulose, prepared as a pulp from fibrous plant material and mechanically disintegrated [3]. It is insoluble in water, ethanol, ether and diluted mineral acids but slightly soluble in sodium hydroxide solution. Furthermore, the purity criteria set in the Commission Directive 2008/84/EC for the food additive are applicable to the *feed additive* [2].

The *feed additive* is intended to be incorporated directly into *feedingstuffs* or through *premixtures* [3], with no proposed minimum or maximum levels [2]. However, a typical range of concentration ranging from 3.5 to 20 g/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 *cellulose powder* 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, aflatoxin B1 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, feedingstuffs and water

For the identification of *cellulose powder* in the *feed additive* the Applicant proposed official VDLUFA method (6.5.1) based on gravimetric assay of neutral detergent fibre (NDF) [5]. The Applicant applied the VDLUFA method and reported an NDF value of 92.6 % [3], thus complying with the specifications set in Commission Directive 2008/84/EC for *cellulose powder*. Furthermore, the EURL identified the dedicated internationally recognised Food Chemical Codex (FCC) monograph “*cellulose, powdered*” [6] describing:

- the suspension formation test;
- the assay with potassium dichromate and further titration with ferrous ammonium sulphate for determination of a carbohydrate, expressed as cellulose content; and
- the following purity tests: - loss on drying; - water soluble matter; - sulphated ash; -pH of 10 % suspension in water; - absence of starch; and - particle size.

These methods comply with the recommendations set in Commission Directive 2008/84/EC and are described in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for *cellulose powder*.

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned official VDLUFA method (6.5.1) and the dedicated

internationally recognised Food Chemical Codex monograph to identify *cellulose powder* in the *feed additive*.

During the review process, NRL experts suggested to monitor - instead of the “Neutral Detergent Fibre” suggested by the Applicant - the “Crude Fibre” content using the Community method (R 152/2009 - Annex III, Part I). This suggestion complies with the information provided by the Applicant in a certificate of analysis of his product [7], indicating a crude fibre value of 68 %. However, the proposed registry entry specifying the composition of the additive does not contain at present such a criterion. This criterion maybe included in the registry entry.

The Applicant provided no experimental data or any analytical methods for the determination of *cellulose powder* in *premixtures* and *feedingstuffs*, as the accurate determination of the *cellulose powder* in these matrices is not achievable experimentally. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *cellulose powder* in *premixtures* and *feedingstuffs*.

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 *cellulose powder* in the *feed additive*, the official VDLUFA method (6.5.1) based on: - gravimetric assay of neutral detergent fibre (NDF); and the dedicated Food Chemical Codex monograph based on: - suspension formation test; and - assay with potassium dichromate and further titration with ferrous ammonium sulphate for determination of a carbohydrate, expressed as cellulose content. These methods comply with the recommendations set in Commission Directive 2008/84/EC and are described in the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Alternatively, the feed additive may be characterised determining the crude fibre content and applying the Community method (R 152/2009 - Annex III, Part I).

The Applicant provided no experimental data or any analytical methods for the determination of *powder cellulose* in *premixtures* and *feedingstuffs*, as the accurate determination of the *powder cellulose* in these matrices is not achievable experimentally. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *cellulose powder* in *premixtures* and *feedingstuffs*.

Recommended text for the register entry (analytical method)

For the identification of *cellulose powder* in the *feed additive*:

- Official VDLUFA method (6.5.1) - gravimetric assay of neutral detergent fibre (NDF); and
- Food Chemical Codex monograph “*cellulose, powdered*” - suspension formation test; and - assay of titration with ferrous ammonium sulphate.

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *cellulose powder* 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/(00172) (10135)-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] VDLUFA Methodenbuch III, 6.5.1. Neutral-Detergentien-Faser (NDF)
 - [6] Food Chemicals Codex monograph “*cellulose, powdered*”, FCC 7 (2010), p. 206 - 208.
 - [7] *Technical dossier, Section II – Annex II_8
- *Refers to Dossier No. FAD-2011-0024

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:

- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Plantedirektoratet, Laboratorium for Foder og Gødning, Lyngby (DK)
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Thüringer Landesanstalt für Landwirtschaft (TLL), Abteilung Untersuchungswesen, Jena, DE
- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Univerza v Ljubljani, Veterinarska fakulteta. Nacionalni veterinarski inštitut, Enota za patologijo prehrane in higieno okolja, Ljubljana (SI)
- Sächsische Landesanstalt für Landwirtschaft, Fachbereich 8 - Landwirtschaftliches Untersuchungswesen, Leipzig (DE)
- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes (FR)