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

Lecithins
(FAD-2010-0364; CRL/100261)



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in connection with the Application for Authorisation of a
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Dossier related to: **FAD-2010-0364 - CRL/100261**

Name of Product: ***Lecithins E322***

Active Agent (s): **Lecithins**

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

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Report checked by: **Piotr Robouch (EURL-FA)**
Date: **10/02/2015**

Report approved by: **Christoph von Holst**
Date: **11/02/2015**

EXECUTIVE SUMMARY

In the current applications authorisation is sought under article 10(2) for *Lecithins* under the 'category' / 'functional groups' 1(c), 1(d), 1(e) and 1(f) 'technological additives' / 'emulsifiers', 'stabilisers', 'thickeners' and 'gelling agents' according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, authorisation is sought for the use of the *feed additive* for all animal species. *Lecithins* are mixtures or fractions of phosphatides obtained from animal or vegetable foodstuffs; including hydrolysed products produced by enzymatic reaction with suitable phospholipase. *Lecithins* are extracted from eggs and oil-bearing seeds and they appear as a brownish viscous liquid, paste or powder. The Applicant stated that the purity criteria/specification set in Directive 2008/84/EC for the food additive are applicable also for the feed additive. *Lecithins* are used as emulsifying agents to homogenize feed matrixes consisting of oily and aqueous phases. The Applicant did not specify the minimum or maximum inclusion levels, but stated that *lecithins* are used *quantum satis* in feed corresponding to concentrations up to 5 % w/w.

For the characterisation of *lecithins* the Applicant submitted internationally recognised monograph 'Lecitin' from the FAO JECFA Compendium, cited in the Commission Regulation (EU) 231/2012. Identification is based on the qualitative tests for - acetone-insoluble matter; - solubility in water; - choline; - phosphorus; - fatty acid; and hydrolysed lecithins. The *feed additive* is further characterised using the following quantitative assays: - loss on drying; - acid value; - peroxide value; and - toluene-insoluble matter.

For the quantification of *lecithins* in *feedingstuffs* the Applicant submitted a two-step indirect method based on (1) lipid extraction from the *feedingstuffs* followed by (2) phosphorus quantification in the lipid fraction by the colorimetric determination of the formed phosphomolybdate complex. According to the Applicant the results correlate with the content of *lecithins* in *feedingstuffs*. The Applicant provided few experimental results obtained in the frame of the stability study of the additive in *feedingstuffs*. However, the EURL considers that these results are not sufficient to demonstrate the accurate and unambiguous quantification of *lecithins* in *feedingstuffs*. Therefore, the EURL cannot recommend any method for official control to quantify *lecithins* in *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

Lecithins, technological additives, emulsifiers, stabilisers, thickeners, gelling agents, all animal species

1. BACKGROUND

In the current applications authorisation is sought under article 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) for *Lecithins* under the 'category' / 'functional groups' 1(c), 1(d), 1(e) and 1(f) 'technological additives' / 'emulsifiers', 'stabilisers', 'thickeners' and 'gelling agents' according to the classification system of Annex I of Regulation (EC) No 1831/2003 [1,2]. Specifically, authorisation is sought for the use of the *feed additive* for all animal species [1,2].

Lecithins are mixtures or fractions of phosphatides obtained from animal or vegetable foodstuffs; including hydrolysed products produced by enzymatic reaction with suitable phospholipase. *Lecithins* are extracted from eggs and oil-bearing seeds (e.g. soybeans, rape seeds and sunflower seeds) and they appear as a brownish viscous liquid, paste or powder [3].

The Applicant stated that the purity criteria/specification set in Directive 2008/84/EC for the food additive are applicable also for the feed additive [3].

Lecithins are used as emulsifying agents to homogenize feed matrixes consisting of oily and aqueous phases. The Applicant did not specify the minimum or maximum inclusion levels, but stated that *lecithins* are used *quantum satis* in feed corresponding to concentrations up to 5 % w/w.

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 *Lecithins* 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 and feedingstuffs

For the characterisation of *lecithins* the Applicant submitted internationally recognised monograph 'Lecitin' from the FAO JECFA Compendium [5], which is cited in Commission Regulation (EU) 231/2012.

Identification is based on the qualitative tests for - acetone-insoluble matter; - solubility in water; - choline; - phosphorus; - fatty acid; and hydrolysed lecithins. The *feed additive* is further characterised using the following quantitative assays: - loss on drying; - acid value; - peroxide value; and - toluene-insoluble matter. Most experimental protocols for the tests are provided in the FAO JECFA monograph 'Lecithin' [5] while the generic tests for the solubility and loss on drying are provided in the FAO JECFA Compendium of methods [6].

Even though no performance characteristics are provided, the EURL recommends for official control the FAO JECFA monograph 'Lecithin', cited in the Commission Regulation (EU) 231/2012 for the characterisation of *lecithins (feed additive)*.

For the quantification of *lecithins* in *feedingstuffs* the Applicant submitted a two-step indirect method based on (1) lipid extraction from the *feedingstuffs* [7] followed by (2) phosphorus quantification in the lipid fraction by the colorimetric determination of the formed phosphomolybdate complex [8]. According to the Applicant the results correlate with the content of *lecithins* in *feedingstuffs*. The Applicant provided few experimental results obtained in the frame of the stability study of the additive in *feedingstuffs* [9]. However, the EURL considers that these results are not sufficient to demonstrate the accurate and unambiguous quantification of *lecithins* in *feedingstuffs*. Therefore, the EURL cannot recommend any method for official control to quantify *lecithins* in *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 the characterisation tests described in the FAO JECFA monograph as cited Commission Regulation (EU) 231/2012 for the characterisation of *lecithins (feed additive)*.

Since the accurate quantification of *lecithins* added to *premixtures* or *feedingstuffs* is not achievable experimentally, the EURL cannot evaluate nor recommend any method for official control to quantify *lecithins* in *premixtures* or *feedingstuffs*.

Recommended text for the register entry (analytical method)

For the characterisation of *lecithins* (feed additive):

- Commission Regulation (EU) No 231/2012 and the corresponding tests in the FAO JECFA monograph '*Lecithins*'

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *lecithins* 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/G1: Forw. Appl. 1831/0035-2014
- [2] *Application, Proposal for Register Entry
- [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 Combined Compendium of Food Additive Specifications, ' Lecithins', Monograph No. 4 (2007)
<http://www.fao.org/ag/agn/jecfa-additives/specs/monograph4/additive-250-m4.pdf>
(last visited on 27/01/2015)
- [6] FAO JECFA Combined Compendium for Food Additive Specifications - Analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications, Vol. 4
<http://www.fao.org/docrep/009/a0691e/a0691e00.htm> (last visited on 27/01/2015)
- [7] *Technical dossier, Section II – Annex 10b
- [8] *Technical dossier, Section II – Annex 10a
- [9] *Technical dossier, Section II – Annex 8c
*Refers to Dossier no: FAD-2010-0364

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:

- Plantedirektoratet, Laboratorium for Foder og Gødning, Lyngby Fødevarestyrelsen, Ringsted¹ DK
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Państwowy Instytut Weterynaryjny, Puławy (PL)
- Thüringer Landesanstalt für Landwirtschaft (TLL), Abteilung Untersuchungswesen, Jena (DE)
- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes (FR)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft, Freistaat Sachsen, Nossen² (DE)

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