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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-2011-0006 - CRL/100297

Feed additive: Sodium hydroxide (E524)

Active Substance(s): Sodium hydroxide

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EXECUTIVE SUMMARY

In the current application authorisation is sought under articles 4(1) and 10(2) for *sodium hydroxide* (E524) under the category/functional group 1(j) 'technological additives' / 'acidity regulators: substances which adjust the pH of feedingstuffs', according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, the authorisation is sought for the use of the *feed additive* for cats, dogs and ornamental fish.

The *feed additive* is a white solid substance, containing a minimum of 98% of *sodium hydroxide*. The Applicant states that the purity criteria set in Commission Directive 2008/84/EC and in Commission Regulation EU/231/2012 for the food additive are applicable for the *feed additive*.

The *feed additive* is intended to be incorporated to *feedingstuffs* through *premixtures*, with no recommended minimum or maximum concentration levels. However, the Applicant suggested a typical inclusion level varying from 50 to 1000 mg sodium /kg *feedingstuffs*.

For the determination of *sodium hydroxide* in the *feed additive*, the Applicant proposed the internationally recognised FAO JECFA monographs for food additives, where: identification is based on the following tests: alkalinity, sodium and solubility in water/ethanol, while quantification is based on a titrimetric method. Even though no performance characteristics are provided, the EURL recommends for official control the methods described in the FAO JECFA monographs - as recommended by Commission Directive 2008/84/EC and by Commission Regulation EU/231/2012 - to determine *sodium hydroxide* in the *feed additive*.

The Applicant did not provide any analytical method for the determination of *sodium hydroxide* in *premixtures* and *feedingstuffs* as the unambiguous determination of *sodium hydroxide* in these matrices is not achievable experimentally. Therefore, the EURL could not evaluate nor recommend any method for official control to determine *sodium hydroxide* 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

Sodium hydroxide, E524, technological additives, acidity regulators, cats, dogs, ornamental fish

1. BACKGROUND

In the current application authorisation is sought under articles 4(1) (new use in ornamental fish) and 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) for *sodium hydroxide (E524)* under the category/functional group 1(j) 'technological additives' / 'acidity regulators: substances which adjust the pH of feedingstuffs', according to the classification system of Annex I of Regulation (EC) No 1831/2003 [1]. Specifically, the authorisation is sought for the use of the *feed additive* for cats, dogs and ornamental fish [2].

The *feed additive* is a white solid substance, containing a minimum of 98% of *sodium hydroxide* [2]. The Applicant states that the purity criteria set in Commission Directive 2008/84/EC and in Commission Regulation EU/231/2012 for the food additive are applicable for the *feed additive* [3].

The *feed additive* is intended to be incorporated to *feedingstuffs* through *premixtures* [3], with no recommended minimum or maximum concentration levels [2]. However, the Applicant suggested a typical inclusion level ranging from 50 to 1000 mg sodium /kg *feedingstuffs*.

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 (EFSA) for each application or group of applications. For this dossier, the method of analysis submitted in connection with the *sodium hydroxide (E524)* and its 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) are available from the respective European Union Reference Laboratories [4].

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

For the determination of *sodium hydroxide* in the *feed additive*, the Applicant proposed the internationally recognised FAO JECFA monographs for food additives [5, 6], where:

- identification is based on tests for alkalinity, sodium and solubility in water and ethanol, while
- quantification is based on titrimetric method. The aliquot of 1.5 g is dissolved in 40 ml of water and phenolphthalein is added. Solution is titrated with 1 N sulphuric acid. At the point of disappearance of the pink colour the volume of the acid is recorded, then methyl orange is added and solution is titrated to a persistent pink colour. Total volume of the acid required for the titration is recorded. One ml of 1 N sulphuric acid is equivalent to 40.00 mg of total alkali, calculated as sodium hydroxide.

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods described in the FAO JECFA monographs - as recommended by Commission Directive 2008/84/EC and by Commission Regulation EU/231/2012 - to determine *sodium hydroxide* in the *feed additive*.

The Applicant did not provide any analytical method for the determination of *sodium hydroxide* in *premixtures* and *feedingstuffs* as the unambiguous determination of *sodium hydroxide* in these matrices is not achievable experimentally. Therefore, the EURL could not evaluate nor recommend any method for official control to determine *sodium hydroxide* 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:

- the methods recommended by Commission Directive 2008/84/EC and by Commission Regulation EU/231/2012, described in FAO JECFA monographs (No. 1, Vol. 4) and 'sodium hydroxide' monograph No. 1 (2006), Combined Compendium for Food Additive Specifications, for the determination of *sodium hydroxide* in *feed additive*.

The Applicant did not provide any analytical method for the determination of *sodium hydroxide* in *premixtures* and *feedingstuffs* as the unambiguous determination of *sodium hydroxide* in these matrices is not achievable experimentally. Therefore, the EURL could not evaluate nor recommend any method for official control to determine *sodium hydroxide* in *premixtures* and *feedingstuffs*.

Recommended text for the register entry (analytical method)

For the determination of *sodium hydroxide* in the *feed additive*:

- Titrimetry - FAO JECFA Combined Compendium for Food Additive Specifications, Monograph No. 1 (2006) '*sodium hydroxide*'

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *sodium hydroxide* 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/(00194) (10499)-2010
- [2] *Application, Proposal for Register Entry – Annex A
- [3] *Technical dossier, Section II: Identity, characterisation and conditions of use; 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 for Food Additive Specifications - *Analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications*, Monographs No. 1, Vol. 4
<http://www.fao.org/docrep/009/a0691e/a0691e00.htm>
(last visited on 13/08/2012)
- [6] FAO JECFA Combined Compendium of Food Additive Specifications, '*sodium hydroxide*', Monograph No. 1 (2006)
<http://www.fao.org/ag/agn/jecfa-additives/details.html?id=400>
(last visited on 13/08/2012)

*Refers to Dossier No. FAD-2011-0006

7. RAPPORTEUR LABORATORY & NATIONAL REFERENCE LABORATORIES

The Rapporteur Laboratory for this evaluation was National Veterinary Research Institute (NVRI), Poland. 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 (DK)
- Instytut Zootechniki w Krakowie, Krajowe Laboratorium Pasz, Lublin (PL)
- Schwerpunktlabor Futtermittel des Bayerischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim (DE)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)