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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**

Sodium Ferrocyanide (E 535)

(FAD-2011-0047; CRL/090036)

Potassium Ferrocyanide (E 536)

(FAD-2011-0048; CRL/090035)

(FAD-2013-0016; CRL/130005)



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

Dossier related to: **FAD-2011-0047 - CRL/090036**
FAD-2011-0048 - CRL/090035
FAD-2013-0016 - CRL/130005

Name of feed additive: **Sodium Ferrocyanide (E 535)**
Potassium ferrocyanide (E536)

Active Substance(s): **Sodium Ferrocyanide**
Potassium ferrocyanide

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

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Date: **24/02/2014**

EXECUTIVE SUMMARY

In the current application authorisation is sought for *sodium ferrocyanide* (FAD-2011-0047) under article 10(2) and for *potassium ferrocyanide* under articles 10(2) and 4(1) (FAD-2011-0048 and FAD-2013-0016, respectively), under the category/functional group 1(i) "technological additives"/"anticaking agents" according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of *sodium ferrocyanide* ($\text{Na}_4(\text{Fe}(\text{CN})_6) \cdot 10\text{H}_2\text{O}$) and *potassium ferrocyanide* ($\text{K}_4(\text{Fe}(\text{CN})_6) \cdot 3\text{H}_2\text{O}$) for all animal species and categories. According to the Applicants both *feed additives* are lemon yellow crystalline powders with a minimum purity of 99%, similar to that set by the Commission Directive 2008/84/EC for food additives. While both *feed additives* are intended to be sprayed on sodium chloride salt, *potassium ferrocyanide* is also intended to be sprayed on potassium chloride salt. The Applicants proposed a maximum concentration of 80 mg $\text{Fe}(\text{CN})_6$ / kg NaCl and 200 mg $\text{Fe}(\text{CN})_6$ / kg KCl. These maximum concentrations are expressed in NaCl and KCl salts and not in complete *feedingstuffs*.

Applicant (FAD-2013-0016) submitted the internationally recognised FAO JECFA monograph "Ferrocyanides of Calcium, potassium and sodium", recommended in Commission Directive 2008/84/EC, where: - identification of the two *feed additives* is based on (a) the precipitation of the Prussian Blue complex; and (b) the specific sodium and potassium generic tests described in the FAO JECFA "Combined compendium of food additive specifications"; while - quantification of *ferrocyanides* in the two *feed additives* is based on titration with ceric sulfate.

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods recommended by Commission Directive 2008/84/EC and described in the FAO JECFA monographs for the characterisation of the two *feed additives*.

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 Ferrocyanide (E 535), *Potassium Ferrocyanide* (E 536), technological additives, anticaking agents, all animal species

1. BACKGROUND

In the current application authorisation is sought for *sodium ferrocyanide* (FAD-2011-0047) under article 10(2) (re-evaluation of the already authorised additives) and for *potassium ferrocyanide* under articles 10(2) and 4(1) (new use of the feed additive) (cf. FAD-2011-0048 and FAD-2013-0016 respectively), under the category/functional group 1(i) "technological additives"/"anticaking agents" according to Annex I of Regulation (EC) No 1831/2003 [1,2].

The authorisation is sought for the use of *sodium ferrocyanide* ($\text{Na}_4(\text{Fe}(\text{CN})_6) \cdot 10\text{H}_2\text{O}$) and *potassium ferrocyanide* ($\text{K}_4(\text{Fe}(\text{CN})_6) \cdot 3\text{H}_2\text{O}$) for all animal species and categories [1,2]. According to the Applicants both *feed additives* are lemon yellow crystalline powders with a minimum purity of 99%, similar to that set by the Commission Directive 2008/84/EC for food additives.

While the two anticaking *feed additives* are intended to be sprayed on sodium chloride salt [2a,2b], *potassium ferrocyanide* is also intended to be sprayed on potassium chloride salt [2c]. The Applicants proposed a maximum concentration of 80 mg $\text{Fe}(\text{CN})_6$ / kg NaCl [2a,2b] and 200 mg $\text{Fe}(\text{CN})_6$ / kg KCl [3c]. Please note that these maximum concentrations are expressed in NaCl and KCl salts and not in complete *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 for each application or group of applications. For this particular dossier, the methods of analysis submitted in connection with *Sodium Ferrocyanide (E 535)*, *Potassium Ferrocyanide (E 536)*, 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 feed additive

When required by EU legislation, analytical methods for official control of undesirable substances in the additive such as heavy metals (arsenic, cadmium, lead and mercury),

dioxins, microbiological agents and mycotoxins are available from the respective European Union Reference Laboratories [4].

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

For the determination of the *sodium* and *potassium ferrocyanides*, the Applicants refer to the same identification test, based on the oxidation of *ferrocyanides* and further precipitation of Prussian Blue complex ($\text{Fe}_4(\text{Fe}(\text{CN})_6)_3$) in the presence of ferric chloride [3]. Furthermore, Applicant (FAD-2013-0016) submitted the internationally recognised FAO JECFA monograph "Ferrocyanides of Calcium, potassium and sodium" [5], recommended in Commission Directive 2008/84/EC, where:

- Identification of the two *feed additives* is based on (a) the *ferrocyanide* test based on the precipitation of the Prussian Blue complex; and (b) the dedicated sodium and potassium generic tests described in the FAO JECFA "Combined compendium of food additive specifications" [6];
- Quantification of *ferrocyanides* in the two *feed additives* is based on titration with ceric sulphate [5].

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods recommended by Commission Directive 2008/84/EC and described in the FAO JECFA monographs for the characterisation of the two *feed additives*.

Furthermore, Applicant (FAD-2013-0016) informed the EURL [7] that the content of potassium, sodium, magnesium, calcium and iron in the treated salt (containing the anti-caking feed additive) are monitored using Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES).

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

For the characterisation of the *sodium* and *potassium ferrocyanides*, the EURL recommends for official control the identification and quantification methods described in FAO JECFA Combined Compendium for Food Additive Specifications and in the specific monograph

"*Ferrocyanides of calcium, potassium and sodium*" as recommended in Commission Directive 2008/84/EC.

Recommended text for the register entry (analytical method)

For the characterisation of the *sodium* and *potassium ferrocyanides* in the *feed additive*:

- FAO JECFA monograph "*Ferrocyanides of calcium, potassium and sodium*"

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference sample of *Sodium Ferrocyanide* and *Potassium Ferrocyanide* 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] ^aReference SANCO/D/2 Forw. Appl. 1831/0024-2013
- [1] ^bReference SANCO/D/2 Forw. Appl. 1831/0023-2013
- [1] ^cReference SANCO/D/2 Forw. Appl. 1831/0011-2013
- [2] ^{a,b,c}Application, Proposal for Register Entry – Annex A
- [3] ^{a,b,c}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 Monograph "Ferrocyanides of calcium, potassium and sodium"
<http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-190.pdf>
- [6] FAO JECFA combined compendium of food additive specifications
<http://www.fao.org/docrep/009/a0691e/a0691e00.htm>
- [7] ^cSupplementary information. SIN-Kali-ICPAES

^aRefers to Dossier no: FAD-2011-0047

^bRefers to Dossier no: FAD-2011-0048

^cRefers to Dossier no: FAD-2013-0016

7. RAPPORTEUR LABORATORY

The Rapporteur Laboratory for this evaluation was the 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

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- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Instytut Zootechniki w Krakowie, Krajowe Laboratorium Pasz, Lublin (PL)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft, Freistaat Sachsen, Nossen (DE)¹
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