



RIKILT

WAGENINGEN UR



Feed additives

Annual Report 2011 of the National Reference Laboratory

RIKILT Report 2012.006

J.J.M. Driessen, W.M.J. Beek and J. de Jong



Feed additives

Annual Report 2011 of the National Reference Laboratory

J.J.M. Driessen, W.M.J. Beek and J. de Jong

Report 2012.006

May 2012

Project number:	121.71.111.01
BAS-code:	WOT-02-438-IV
Project title:	Assessment of dossiers on animal feed additives for registration purposes: NRL-tasks and national activities
Project leader:	J.J.M. Driessen

RIKILT – Institute of Food Safety

Wageningen UR (University & Research centre)
Akkermaalsbos 2, 6708 WB Wageningen, The Netherlands
P.O. Box 230, 6700 AE Wageningen, The Netherlands
Tel. +31 317 480 256
Internet: www.rikilt.wur.nl

Copyright 2012, RIKILT – Institute of Food Safety.

The client is allowed to publish or distribute the full report to third parties. Without prior written permission from RIKILT – Institute of Food Safety it is not allowed to:

- a) *publish parts of this report;*
- b) *use this report or title of this report in conducting legal procedures, for advertising, acquisition or other commercial purposes;*
- c) *use the name of RIKILT – Institute of Food Safety other than as author of this report.*

This research was funded by the Dutch Ministry of Economic Affairs, Agriculture and Innovation and has been performed in the WOT-program Food Safety, Theme: Animal feed.

Distribution list:

- Ministry of Economic Affairs, Agriculture and Innovation, Department 'Plantaardige Agroketens en Voedselkwaliteit' (EL&I-PAV; E.R. Deckers)
- Ministry of Economic Affairs, Agriculture and Innovation, Department 'Agrokennis' (EL&I-AK; T. Greutink)
- Ministry of Economic Affairs, Agriculture and Innovation, Dutch Food and Consumer Product Safety Authority (EL&I-NVWA; R. Herbes, M. Pelk, H.A. van der Schee, R.M.C. Theelen)
- Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (JRC-IRMM; C. von Holst)
- Central Veterinary Institute (CVI; N.P. Lenis)
- Medicines Evaluation Board (CBG-MEB; D.G. Vreeswijk, E. Top, B. Schat)

<p>This report from RIKILT – Institute of Food Safety has been produced with the utmost care. However, RIKILT does not accept liability for any claims based on the contents of this report.</p>
--

Summary

This report of the National Reference Laboratory (NRL) for feed additives describes the activities employed in 2011. The main tasks of the NRL are: providing assistance to the European Union Reference Laboratory (EURL) on their request, as well as providing advice and support to the competent authority, which is the Dutch Ministry of Economic Affairs, Agriculture and Innovation - Department 'Plantaardige Agroketens en Voedselkwaliteit'.

NRL activities on request of the EURL

In 2011 the NRL commented on three initial evaluation reports prepared by the rapporteur laboratory. It concerned one detoxication product, one preservative and one antioxidant.

In October 2011 an employee of RIKILT participated and actively contributed to a workshop in discussions regarding the experiences in daily practice with the implementation of the verification-concept as laid down in Regulation (EC) No 429/2008. One presentation concerned clustered assessment of several dossiers concerning the same additive. Furthermore, another presentation focussed on improvement of some CEN methods of analysis for probiotics. These improvements can be implemented after an international ring test of the CEN methods of concern.

It was announced that in 2012 approximately 80 dossiers will be assessed for re-evaluation purposes. During the workshop ideas have been exchanged about how to enlarge the involvement of the NRLs so that the large number of dossiers will be assessed in due time.

The EURL announced a proficiency test for coccidiostats on a carry-over level in order to get information about the quality of the official control by the NRLs. RIKILT will participate in this proficiency test.

Advice and support

With respect to 31 requests the NRL advised the competent authority regarding temporary use exemptions of feed additives in the Netherlands. The requests concerned among others enzymes, probiotics and amino acids.

Furthermore the Dutch 'Bureau Diergeneesmiddelen' was advised about storage, stability and homogeneity of feed additives.

Contents

Summary	3
1 Introduction	7
2 NRL activities.....	9
2.1 Dossier evaluation.....	9
2.2 EURL workshop.....	9
3 Advice on temporary use exemptions.....	11
4 Communications and advice.....	12
5 Publications, presentations and posters	13
6 Plan for NRL activities 2012	14
7 References.....	15

1 Introduction

Within the EU livestock production occupies a very important place in the agriculture. Satisfactory results depend to a large extent on the use of safe and good-quality feedingstuffs. In order to protect human health, animal health and the environment, feed additives should undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community. The applicant (producer of the additive) has to submit a dossier containing all relevant information regarding safety of the product. The details of the application procedure are described in Regulation (EC) 1831/2003. The European Food Safety Authority, established by Regulation (EC) no. 178/2002 carries out scientific assessment of feed additives (including premixes).

Within the EU, the European Union Reference Laboratory (EURL) and a consortium of National Reference Laboratories (NRLs) play an important role in the evaluation and authorisation process to place a feed additive in the market. The Joint Research Centre (JRC in Geel, Belgium) is the EURL. Within the Netherlands RIKILT Wageningen UR is the NRL for feed additives (Commission Regulation (EC) No 378/2005).

In EU regulation 1831/2003 the tasks and duties of the EURL are defined. It is also described in this regulation that for all tasks and duties of the EURL the NRLs may be asked by the EURL for assistance.

The EURL is responsible for:

- The reception, preparation, storage and maintenance of the reference samples;
- The testing and evaluation or validation of the method for detection;
- Evaluating the data provided by the applicant for authorisation to place the feed additive on the market, for the purpose of testing and evaluation or validation of the method for detection;
- Submitting full evaluation reports to the Authority.

Next to these tasks the EURL shall play a role in dispute settlements between Member States concerning the analytical results of testing additives for use in animal nutrition.

Commission regulation (EC) 378/2005 describes in more detail the activities and organisation of EURL and NRLs. During an application evaluation process it is possible that an NRL is requested to act as the rapporteur of the application (the rapporteur laboratory) or to participate in the consortium. The rapporteur laboratory has to :

- Draft an initial evaluation report concerning the data submitted in each application and submitting it for comments to the other laboratories;
- Compile the comments received from the other laboratories and prepare a revised evaluation report;
- Submit the revised evaluation report to the EURL. The EURL submits the full evaluation report to the Authority.

For carrying out research on the use of a feed additive that has not yet been registered as such or for a specific application, the applicant needs a 'temporary use exemption' for the particular feed

additive. These permissions are obtained from the Dutch 'Bureau Diergeneesmiddelen' under supervision of the Ministry of Economic Affairs, Agriculture and Innovation - Department 'Plantaardige Agroketens en Voedselkwaliteit' (EL&I-PAV). EL&I-PAV is the competent authority in the Netherlands for authorisation of feed additives. RIKILT advises the Dutch government regarding the temporary use exemption of specific feed additives, more specific about issues related to the application of feed additives in feed, e.g. cross-contamination, stability and homogeneity. Furthermore on request RIKILT as a NRL advises EL&I regarding other issues concerning feed additives.

This report describes the activities employed in 2011 by RIKILT regarding the functions as described above namely:

- As the NRL for feed additives;
- Advice regarding temporary use exemptions, other advice and support of EL&I.

This report also presents the activities performed by the NRL to keep up expertise on the analysis of feed additives like participation in proficiency tests and presenting (posters, abstracts, publications) analytical research.

2 NRL activities

2.1 Dossier evaluation

In 2011 the NRL commented on three initial evaluation reports prepared by the rapporteur laboratory. The advice was presented in three evaluation reports and included the following additives:

- ToxfinDry: authorisation was sought to use as a feed additive for reduction of the contamination of feed by mycotoxins; evaluation of X-Ray diffraction together with X-Ray fluorescence for the characterisation of the preparation bentonite-montmorillonite / sepiolite in the feed additives. A notification has been made regarding to potential presence of dioxins in binders such as bentonite.
- Formate (ammonium formate, sodium formate, potassium diformate, calcium formate): authorisation as feed additive (as preservative and/or silage additive) for all animal species and categories was sought; evaluation of methods based on atomic absorption spectrometry, complexometric titration, HPLC-UV and HPLC-UV/RI in the additive, premixtures and in feedingstuffs, respectively.
- Propyl Gallate: authorisation is sought for the use of the feed additive as an anti-oxidant for all animal species and categories. The feed additive is intended to be mixed in premixtures or added directly in complete feedingstuffs or water. Evaluation of the official European Pharmacopoeia method (Ultraviolet-visible spectrophotometry) for propyl gallate in the feed additive, and RP-HPLC with UV-DAD methods for propyl gallate in premixtures and feedingstuffs.

2.2 EURL workshop

In October 2011 an employee of RIKILT (Dr. J. de Jong) participated in the Annual Workshop in Brussels (Belgium) organised by the European Union Reference Laboratory (EURL), JRC-IRMM.

During this workshop recent developments with regards to feed additives have been explained by a representative of the European Commission, DG SANCO (J. Moynagh). An explanation has been given by a representative of the EURL about how the clustered assessment of several dossiers concerning the same additive will be dealt with.

Another presentation has been given by a representative of the German organisation of laboratories for official control of feedingstuffs (VDLUFA) about advisable improvements of some CEN methods for analysis of probiotics. VDLUFA has developed alternative methods of analysis which will yield better results for certain products (e.g. encapsulated probiotics). Initiatives are undertaken to ring test these methods internationally after which the improvements will be implemented in the CEN methods of concern.

It was announced that in 2012 approximately 80 dossiers will be assessed for re-evaluation purposes. During the workshop ideas have been exchanged about how to enlarge the involvement of the NRLs so that the large number of dossiers will be assessed in due time.

The EURL announced a proficiency test for coccidiostats on a carry-over level in order to get information about the quality of the official control by the NRLs. RIKILT will participate in this proficiency test.

3 Advice on temporary use exemptions

In 2011 31 national requests for permission to use substances - which are not authorised at Community level - as additives for experiments for scientific purposes (according to Regulation (EC) No 1831/2003, article 3.2, handled by EL&I-PAV / Bureau Diergeneesmiddelen) have been assessed. The requests concerned among others enzymes, probiotics and amino acids.

4 Communications and advice

One of the tasks of the NRL is to communicate with the Competent Authority on issues regarding the labelling, and control of feed additives. In 2011 the Competent Authority was advised about issues related to the registration or use of feed additives.

Other advice concerned the storage, stability and homogeneity of additives in feedingstuffs. The advice was based on the documents 'Commission Regulation EC No. 429/2008 of 25 April 2008' and 'Additional quality requirements for products intended for incorporation into animal feedingstuffs – EMEA/CVMP/080/95-final'. The first document sets rules for stability (studies) while in the second document storage and homogeneity requirements are described.

Another advice was given to EL&I-PAV regarding proposals from the European Commission for the labelling of the hydroxy analogue of methonine.

5 Publications, presentations and posters

Publications

- J.J.M. Driessen, W.M.J. Beek and J. de Jong. Feed Additives; Annual Report 2010 of the Dutch National Reference Laboratory, RIKILT-report 2011.010

Presentations

The following presentations are related to but have not been produced within this NRL project:

- J. de Jong, S. Weigel and M. Nielen; Rapid methods for chemical contaminants in food and feed; the CONFIDENCE research project; Food Integrity and Traceability Conference, Belfast, 21-24 March 2011
- Jacob de Jong and Hans van den Heuvel; Rapid methods for chemical contaminants in feed: industrial needs and scientific perspectives; FIAAP Conference, Köln, 4 May 2011
- Jacob de Jong, Stefan Weigel and Michel Nielen; Recent progress in rapid methods for food quality and safety control; Recent Advances in Food Analysis (RAFA), 1-4 November 2011, Prague (CZ)

Posters

The following posters are related to but have not been produced within this NRL project:

- Monique Bienenmann-Ploum, Anne-Catherine Huet, Katrina Campbell, Terence Fodey, Willem Haasnoot, Philippe Delahaut, Chris Elliott, Ursula Vincent, Jacob de Jong and Michel Nielen; Multiplex flow cytometric immunoassay for the simultaneous detection of 6 coccidiostats in feed and egg; Food Integrity and Traceability Conference, Belfast, March 2011
- Monique Bienenmann-Ploum, Anne-Catherine Huet, Katrina Campbell, Terence Fodey, Willem Haasnoot, Philippe Delahaut, Chris Elliott, Ursula Vincent, Jacob de Jong and Michel Nielen; Fiveplex flow cytometric immunoassay for the simultaneous detection of 6 coccidiostats in feed and egg; Recent Advances in Food Analysis (RAFA), 1-4 November 2011, Prague (CZ)

6 Plan for NRL activities 2012

The participation of the NRL in the dossier evaluation procedure will be continued for the coming year. The NRL will also advise the competent authority regarding all kind of upcoming questions and temporary use exemptions.

Furthermore the annual EURL meeting will be attended.

RIKILT Wageningen UR will participate in the proficiency test for coccidiostats on a carry-over level in order to get information about the quality of the official control by the NRLs.

7 References

- Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003. On additives for use in animal nutrition, L 268 page 29-43.
- Commission Regulation (EC) No 378/2005 of 4 March 2005 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 tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives.
- Commission Directive 2009/8/EC of 10 February 2009 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels of unavoidable carry-over of coccidiostats or histomonostats in nontarget feed, L 40 page 19-25.
- Commission Regulation (EC) No 386/2009 of 12 May 2009 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives.

RIKILT - Institute of Food Safety is part of the international knowledge organisation Wageningen UR (University & Research centre). RIKILT conducts independent research into the safety and quality of food. The institute is specialised in detecting and identifying substances in food and animal feed and determining the functionality and effect of those substances.

RIKILT advises national and international governments on establishing standards and methods of analysis. RIKILT is available 24 hours a day and seven days a week in cases of incidents and food crises.

The research institute in Wageningen is the National Reference Laboratory (NRL) for milk, genetically modified organisms, and nearly all chemical substances, and is also the European Union Reference Laboratory (EU-RL) for substances with hormonal effects.

RIKILT is a member of various national and international expertise centres and networks. Most of our work is commissioned by the Dutch Ministry of Economic Affairs, Agriculture and Innovation and the new Dutch Food and Consumer Product Safety Authority. Other parties commissioning our work include the European Union, the European Food Safety Authority (EFSA), foreign governments, social organisations, and businesses.

More information: www.rikilt.wur.nl

