



Feed additives

Annual Report 2010 of the National Reference Laboratory

RIKILT Report 2011.010

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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

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Summary

This report of the National Reference Laboratory (NRL) for feed additives describes the activities employed in 2010. The main tasks of the NRL are: giving assistance to the European Union Reference Laboratory (EU-RL) on their request and advice and support the competent authority, the Dutch Ministry of Economic Affairs, Agriculture and Innovation - Department of Food, Animal and Consumer (EL&I-VDC).

NRL activities on request of the EU-RL

In 2010 the NRL commented on six initial evaluation reports prepared by the rapporteur laboratory. This concerned mainly coccidiostats as well as one vitamin and one detoxication product.

In December 2010 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. Furthermore presentations were attended focussed on methods of analysis for the coccidiostats semduramycin and decoquinate that are under development within the CEN-Technical Committee 327 'Animal Feedingstuffs' as well as practical experiences with the CEN-method for phytase.

By EU-RL a questionnaire has been sent to all the NRLs about the needs of the NRLs with regards to official control on additives in feed. RIKILT indicated that there is a need for the organisation of proficiency testing schemes for coccidiostatics (both cross-contamination and additive levels), copper, zinc and iron.

Furthermore RIKILT indicated that there is a need for arbitration in the framework of official control and for practical training on methods for vitamins.

Advices and support

The NRL gave 27 advices to the competent authority regarding temporary use exemptions of feed additives in the Netherlands. The requests concerned among others enzymes, probiotics and amino acids.

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

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

The EU-RL 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 EU-RL 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 details the activities and organisation of EU-RL 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 EU-RL. The EU-RL submits the full evaluation report to the Authority.

For doing research on the use of a feed additive that has not yet been registered as such or for a specific application, the applicant needs to have a 'temporary use exemption' for the feed additive. These permissions are obtained by the Dutch 'Bureau Diergeneesmiddelen' under supervision of the Dutch Ministry of Economic Affairs, Agriculture and Innovation - Department of Food, Animal and Consumer (EL&I-VDC). EL&I-VDC 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 2010 by RIKILT regarding the functions as described above viz:

- as the NRL for feed additives,
- advices given regarding temporary use exemptions, other advices 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 2010 the NRL commented on six initial evaluation reports prepared by the rapporteur laboratory. The advices were described in evaluation reports and included the following additives:

- Vitamin E: authorisation as feed additive for all animal species and categories is sought; evaluation of the official European Pharmacopoeia method (GC) for vitamin E in the feed additive and a Community method (HPLC) for the determination of Vitamin E in premixtures and in feedingstuffs respectively.
- Avatec 150 G: re-evaluation as feed additive for turkeys is sought; evaluation of HPLC-methods for the determination of the active substance lasalocid sodium A in the additive, premixtures and in feedingstuffs respectively.
- Cygro 10G: re-evaluation of the use as feed additive for chickens for fattening and turkeys is sought; evaluation of HPLC-methods for the determination of the active substance maduramicin ammonium alpha in premixtures and feedingstuffs and the residues in tissues.
- Mycofix secure: authorisation as feed additive for reduction of the contamination of feed by mycotoxins; evaluation of X-ray diffraction method for the determination of dioctahedral montmorillonite (bentonite) in the feed additive. A notification has been made regarding to possible presence of dioxins in binder and anti-caking agent feed additives such as bentonite.
- Coxidin: authorisation as feed additive for use in compound feedingstuffs for chickens- and turkeys for fattening; evaluation of HPLC-methods for the determination of the active substance monensin sodium in the feed additive, premixtures and in feedingstuffs respectively.
- Clinacox 0.5%: authorisation for the feed additive is sought for turkeys for fattening; evaluation of HPLC-methods for the determination of the active substance diclazuril in the feed additive, premixtures and feedingstuffs and the residues in food.

2.2 EU-RL workshop

In 2010 an employee of RIKILT (J. de Jong) participated to the Annual Workshop of the European Union Reference Laboratory (EU-RL), 2-3 December 2010, JRC-IRMM in Geel, Belgium.

During this workshop the status with regards to the re-evaluation of additives has been explained by a representative of the European Commission, DG SANCO. A preview has been given by a representative of the EU-RL about how the large number of dossiers that have been submitted during the re-evaluation procedure will be dealt with.

The experiences in daily practice with the implementation of the verification-concept were discussed. The verification-concept, as laid down in Regulation (EC) No 429/2008, means that the performance of methods of analysis, developed and validated in one laboratory must be checked by a second accredited and independent laboratory and that the results of this check must be included in the dossier.

Another presentation focussed on methods of analysis for the coccidiostats semduramycin and decoquinate that are under development within the CEN-Technical Committee 327 'Animal Feedingstuffs'. Finally there was a presentation about the practical experiences with the CEN-method for phytase.

2.3 Questionnaire to NRLs

In 2010 the EU-RL has sent a questionnaire to all the NRLs about the needs of the NRLs with regards to official control on additives in feed. The questionnaire related to which methods of analysis for additives are applied by RIKILT and for which areas there is a need for support by the EU-RL. RIKILT indicated that there is a need for the organisation of proficiency testing schemes for coccidiostatics (both cross-contamination and additive levels) copper, zinc and iron.

Furthermore RIKILT indicated that there is a need for arbitration in the framework of official control and for practical training on methods for vitamins.

3 Advices on temporary use exemptions

In 2010 a number of 27 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-VDC / Bureau Diergeneesmiddelen) have been assessed. The requests concerned among others enzymes, probiotics and amino acids.

4 Communications and advices

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 2010 the Competent Authority was advised about the way of labelling of the hydroxy-analogue of methionine and about the method of analysis that should be applied to quantify the content of the hydroxy-analogue of methionine.

5 Participation in collaborative studies

Due to the scope of the NRL task assigned, in 2009 RIKILT participated in two collaborative studies organised by CEN/TC 327 'Animal Feedingstuffs' Working group 3 (Feed Additives and Drugs) as part of harmonisation of methods of analysis.

1. Animal feeding stuffs - Determination of Decoquinat by HPLC-fluorescence
2. Animal feedingstuffs - Determination of semduramicin content - Liquid chromatographic method using mass spectrometry detection

The results were evaluated and discussed in 2010 in the working group. It was concluded that both methods were fit for purpose. With some small modifications to the protocols the process to standardise the methods proceeds.

6 Publications, presentations and posters

Publications

J.J.M. Driessen, W.M.J. Beek and J. de Jong. Feed Additives; Annual Report 2009 of the Dutch National Reference Laboratory, RIKILT-report 2010.013

Presentations

The following presentation is related to but has not been produced within the NRL project:

J. de Jong; Rapid methods for food and feed safety; the CONffIDENCE project (General Introduction); CONffIDENCE Open Day; 27 January 2010, Noordwijkerhout

Posters

The following poster is related to but has not been produced within the NRL project:

Tina Zuidema, Efraim Oosterink, Wim Schutte, Linda Stolker, Harry van Egmond and Jacob de Jong, Carry-over of coccidiostats in animal feed, 1 – 4 June, 2010, 6th International Symposium on Hormone and Veterinary Drug Residue Analysis, Ghent, Belgium

7 Plan for NRL activities 2011

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 yearly EURL meeting will be attended.

8 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.

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