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Activity Report 2015

European Union Reference Laboratory for Feed Additives (EURL-FA) Authorisation

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Activity Report 2015

of the
European Union Reference Laboratory
for Feed Additives Authorisation

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Executive summary

This report presents the main achievements of the European Union Reference Laboratory for feed additives authorisation (later referred as EURL) in 2015. The tasks of the EURL regarding the authorisation of feed additives are specified in Regulation (EC) No 378/2005, last amended by Commission Implementing Regulation (EU) 2015/1761.

The main achievements of the EURL are:

- The sample registration and maintenance of the sample bank of reference feed additives;
- The scientific evaluation of analytical methods submitted by the applicants; and
- The organisation of 15th annual EURL workshop with National Reference Laboratories (NRLs), to discuss topics related to the authorisation of feed additives.

In addition, the EURL:

- Updated two administrative documents: the Declaration Form and the Guidance for Applicants;
- Contributed to the amendment of Commission Regulation (EC) No 378/2005 by Commission Implementing Regulation (EU) 2015/1761;
- Contributed to the organisation of a collaborative trial to improve the Community method for determination of Diclazuril.

Declaration forms and sample management

When applying for the authorisation of a feed additive, Applicants send a Declaration Form (DF) to the EURL. The details included allow the establishment of the fee to be paid. In 2015, a total of 42 DF were processed. As for reference samples a total of 317 samples were processed by EURL, to include 40 new samples, 132 replacement samples and 145 shelf-life extensions.

Evaluation of Dossiers

In 2015 the EURL evaluated 50 applications and issued a total of 47 reports (including the amendment of a 2011 report) with the support of the National Reference Laboratories (NRLs). Table 1 presents the number of applications submitted by the Applicants and the number of reports evaluated by the EURL since 2009. Since 2013 the number of the applications and reports is similar, indicating the end of the "grouping" of applications. Twelve (out of 47) reports - mainly related to micro-organisms - were evaluated and drafted by the following four NRLs: CRA-W,BE (6), CReAA,IT (2), AGES,AT and PIWET,PL. The evaluation process was co-ordinated by the EURL.

Table 1 also includes the number of corresponding EFSA opinions and Commission Implementing Regulations, CIR (Table 1) published in 2009 to 2015 based on the EURL recommendations. The list of all the EURL report issued in 2015 is provided in Annex II and the reports are available from the EURL webpage:

https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports.

Tables 2 and 3 list the EFSA opinions and the CIR published in 2015 based on or including the EURL recommendations.

Table 1. Number of applications evaluated, evaluation reports, EFSA opinions and CIR issued since 2009

	2009	2010	2011	2012	2013	2014	**2015**
Applications	24	70	124	92	36	51	**50**
EURL Reports	24	68	87	59	32	44	**47**
EFSA opinions	24	22	54	74	50	34	**35**
CIR	18	20	46	36	39	26	**38**

Table 2. EURL executive summaries included in EFSA opinions published in 2015

	EFSA Journal reference	Feed additives/Active substances	Dossier number
1	2015;13(12):4198	Lactic acid and calcium lactate	2010-0133
2	2015;13(11):4272	Ethoxyquin (6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline)	2010-0141
3	2015;13(11):4275	Axtra® PHY 15 000 L (6-phytase)	2013-0049
4	2015;13(11):4274	Calsporin® (Bacillus subtilis DSM 15544)	2009-0013
5	2015;13(11):4273	Liderfeed® (eugenol)	2010-0396
6	2015;13(11):4267	Zinc chelate of L-lysinate-HCl	2014-0021
7	2015;13(11):4271	Sodium selenite (coated granulated preparation)	2010-0369
8	2015;13(11):4268	Saturated and unsaturated aliphatic secondary alcohols, ketones and esters with esters containing secondary alcohols belonging to chemical group 5	2010-0074
9	2015;13(9):4238	L-tryptophan, technically pure, produced by *Escherichia coli* strains DSM 25084, KCCM 11132P or SARI12091203	2010-0056
10	2015;13(9):4236	L-threonine produced by *Escherichia coli* strains NRRL B-30843, DSM 26131, KCCM11133P or DSM 25085	2010-0058
11	2015;13(9):4239	Sorbic acid and potassium sorbate	2010-0145 2010-0193
12	2015;13(9):4230	*Bacillus subtilis* KCCM 10673P and *Aspergillus oryzae* KCTC 10258BP	2009-0007
13	2015;13(7):4155	L-lysine sulphate produced by fermentation with *Escherichia coli* CGMCC 3705	2013-0045
14	2015;13(7):4160	Lignosulphonate	2010-0209
15	2015;13(7):4159	ENZY PHOSTAR® (6-phytase)	2012-0044
16	2015;13(7):4158	Cylactin® (*Enterococcus faecium* NCIMB 10415)	2010-0269
17	2015;13(5):4113	Formic acid, ammonium formate and sodium formate	2009-0027 2010-0188 2010-0303 2010-0312
18	2015;13(5):4110	L-valine (L-valine, feed grade) produced by *Escherichia coli* NITE BP-01755	2014-0015
19	2015;13(5):4109	Ferrous carbonate	2010-0380
20	2015;13(5):4114	Complexation products of sodium tartrates with iron(III) chloride	2012-0035
21	2015;13(5):4108	Indigo carmine (E 132)	2010-0346
22	2015;13(5):4056	Ammonium formate, calcium formate and sodium formate	2010-0312
23	2015;13(5):3794	AviMatrix® (benzoic acid, calcium formate and fumaric acid)	2012-0037
24	2015;13(4):4057	Cupric acetate, monohydrate; basic cupric carbonate, monohydrate; cupric chloride, dihydrate; cupric oxide; cupric sulphate, pentahydrate; cupric chelate of amino acids, hydrate; cupric chelate of glycine, hydrate	2010-0031
25	2015;13(3):4055	Cibenza® EP150 (a preparation of *Bacillus licheniformis* (ATCC 53757)	2013-0017
26	2015;13(3):4053	Aliphatic and aromatic hydrocarbons (chemical group 31)	2010-0022
27	2015;13(2):4014	Hexamethylene tetramine	2010-0377
28	2015;13(2):4011	XTRACT® Evolution-B, Code X60-6930 (carvacrol, cinnamaldehyde and capsicum oleoresin)	2013-0010
29	2015;13(2):4012	L-methionyl-DL-methionine	2012-0034
30	2015;13(2):4009	Citric acid	2010-0357
31	2015;13(2):4010	Citric acid	2010-0154 2010-0187 2010-0357
32	2015;13(1):3968	Coxiril® (diclazuril)	2013-0042
33	2015;13(1):3971	Glycyrrhizic acid ammoniated (chemical group 30, miscellaneous substances)	2010-0115
34	2015;13(1):3903	Suilectin™ (*Phaseolus vulgaris* lectins)	2010-0079
35	2015;13(1):3965	L-valine produced by *Escherichia coli* NITE SD 00066	2012-0023

EFSA opinions on: http://www.efsa.europa.eu/en/publications/efsajournal.htm;

EURL reports on: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

Table 3. Commission Implementing Regulations published in 2015 and supported by the EURL recommendations

	Commission Implementing Regulation (EU) No	Feed additives/active substance	Dossier number
1	2015/38 of 13 January 2015	Lactobacillus acidophilus CECT 4529	2010-0394
2	2015/46 of 14 January 2015	Diclazuril	2012-0017 2013-0014
3	2015/47 of 14 January 2015	Alpha-amylase produced by Bacillus licheniformis (DSM 21564)	2010-0009
4	2015/244 of 16 February 2015	Quinoline Yellow	2010-0345
5	2015/264 of 18 February 2015	Neohesperidine dihydrochalcone	2010-0158
6	2015/489 of 23 March 2015	Selenomethionine produced by Saccharomyces cerevisiae NCYC R645	2009-0010
7	2015/502 of 24 March 2015	Saccharomyces cerevisiae NCYC R404	2012-0038
8	2015/518 of 26 March 2015	Enterococcus faecium NCIMB 10415	2008-0021
9	2015/661 of 28 April 2015	Endo-1,4-beta-xylanase and endo-1,3(4)-beta- glucanase produced by Talaromyces versatilis sp. nov. IMI CC 378536 and Talaromyces versatilis sp. nov. DSM 26702	2013-0030
10	2015/662 of 28 April 2015	L-carnitine and L-carnitine L-tartrate	2010-0225 2010-0144
11	2015/722 of 5 May 2015	Taurine	2010-0215
12	2015/723 of 5 May 2015	Biotin	2010-0100
13	2015/724 of 5 May 2015	Retinyl acetate, retinyl palmitate and retinyl propionate	2010-0200
14	2015/861 of 3 June 2015	Potassium iodide, calcium iodate anhydrous and coated granulated calcium iodate anhydrous	2010-0148 2010-0223 2010-0231 2010-0370
15	2015/897 of 11 June 2015	Thiamine hydrochloride and thiamine mononitrate	2010-0040 2010-0052 2010-0140
16	2015/1020 of 29 June 2015	Bacillus subtilis (ATCC PTA-6737)	2008-0039
17	2015/1043 of 30 June 2015	Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma citrinoviride Bisset (IM SD135)	2010-0001
18	2015/1053 of 1 July 2015	Enterococcus faecium DSM 10663/NCIMB 10415	2012-0001 2010-0150
19	2015/1060 of 2 July 2015	Betaine anhydrous and betaine hydrochloride	2010-0174 2010-0216 2010-0253
20	2015/1061 of 2 July 2015	Ascorbic acid, sodium ascorbyl phosphate, sodium calcium ascorbyl phosphate, sodium ascorbate, calcium ascorbate and ascorbyl palmitate	2010-0214 2010-0185
21	2015/1103 of 8 July 2015	Beta-carotene	2009-0046
22	2015/1104 of 8 July 2015	Alpha- galactosidase (EC 3.2.1.22) produced by Saccharomyces cerevisiae (CBS 615.94) and endo-1,4-beta- glucanase (EC 3.2.1.4) produced by Aspergillus niger (CBS 120604)	2009-0014
23	2015/1105 of 8 July 2015	Bifidobacterium animalis ssp. animalis DSM 16284, Lactobacillus salivarius ssp. salivarius DSM 16351 and Enterococcus faecium DSM 21913	2014-0011
24	2015/1114 of 9 July 2015	L-valine produced by Escherichia coli	2012-0023 2014-0015
25	2015/1152 of 14 July 2015	Tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol	2010-0105 2010-0271
26	2015/1408 of 19 August 2015	DL-methionyl-DL-methionine	2012-0034
27	2015/1415 of 20 August 2015	Astaxanthin	2009-0054
28	2015/1416 of 20 August 2015	Sodium bisulphate	2009-0049
29	2015/1417 of 20 August 2015	Diclazuril	2013-0042
30	2015/1426 of 25 August 2015	Benzoic acid, thymol, eugenol and piperine	2013-0052
31	2015/1486 of 2 September 2015	Canthaxanthin	2008-0048
32	2015/1489 of 3 September 2015	Lactobacillus plantarum NCIMB 30238 and Pediococcus pentosaceus NCIMB 30237	2010-0048 2010-0127
33	2015/1490 of 3 September 2015	Carvacrol, cinnamaldehyde and capsicum oleoresin	2013-0010
34	2015/2304 of 10 December 2015	Endo-1,4-beta-xylanase and endo-1,3(4)-beta- glucanase produced by Talaromyces versatilis sp. nov. IMI CC 378536 and Talaromyces versatilis sp. nov DSM 26702	2013-0030
35	2015/2305 of 10 December 2015	Endo-1,4-beta-glucanase (EC 3.2.1.4) produced by Trichoderma citrinoviride Bisset (IM SD142)	2010-0062
36	2015/2306 of 10 December 2015	L-cysteine hydrochloride monohydrate	2010-0152
37	2015/2307 of 10 December 2015	Menadione sodium bisulphite and menadione nicotinamide bisulphite	2010-0099
38	2015/2382 of 17 December 2015	Alpha-galactosidase (EC 3.2.1.22) produced by Saccharomyces cerevisiae (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by Aspergillus niger (CBS 120604)	2009-0014

Commission Implementing Regulations on: http://ec.europa.eu/food/safety/docs/animal-feed-eu-reg-comm_register_feed_additives_1831-03.pdf

EURL reports on: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

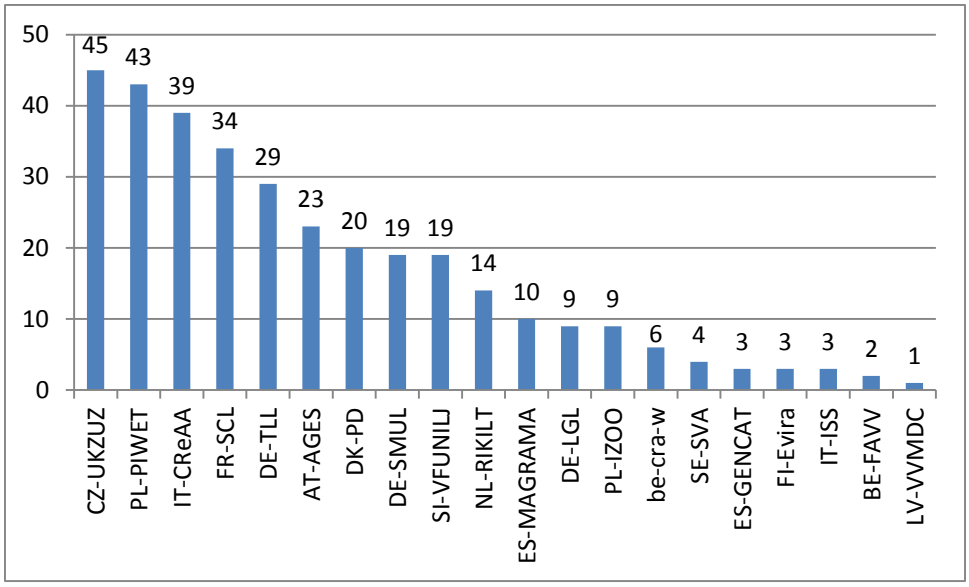
Table 4. Categories / functional groups of feed additives evaluated in 2015

Category		Functional Group		2015
1	technological	a	preservatives	
		b	antioxidants	1
		c	emulsifiers	2
		d	stabilisers	1
		e	thickeners	1
		f	gelling agents	1
		g	binders	2
		h	substances for control of radionuclide contamination	
		i	anticaking agents	8
		j	acidity regulators	2
		k	silage additives	3
		l	denaturants	
		m	mycotoxin binders	1
2	sensory	a	colourants	1
		b	flavouring compounds	2
3	nutritional	a	vitamins, pro-vitamins	5
		b	compounds of trace elements	5
		c	amino acids	
		d	urea and its derivatives	
4	zootechnical	a	digestability enhancers	7
		b	gut flora stabilisers: micro-organisms	7
		c	substances which favourably affect the environment	1
		d	other zootechnical additives	1
5	coccidiostats & histomonostats			3
			Total	**54**

Table 4 presents a detailed overview of the "categories" / "functional groups" evaluated by the EURL in 2015, resulting in 22 technological, 16 zootechnical, 10 nutritional, 3 sensory and 3 coccidiostats & histomonostats dossiers.

As foreseen by Commission Regulation (EC) No 378/2005, every draft "initial" report was reviewed by experts of the various NRL. Their critical and constructive remarks contributed to the quality reports sent by the EURL to the European Food Safety Authority (EFSA) and Directorate General of the European Commission (DG SANTE). These comments are highly appreciated by the EURL and the NRL contributions are systematically acknowledged in the final reports. Figure 1 shows the review activity of the NRLs in 2015, where four NRLs commented to 30 or more initial reports: CZ-UKZUZ, PL-PIWET, IT-CReAA and FR-SCL.

Figure 1 Number of draft reports commented by NRLs during the 2015 review process



CZ-UKZUZ – Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (Czech Republic)

PL-PIWET – Państwowy Instytut Weterynaryjny, Pulawy (Poland)

IT-CReAA – Centro di referenza nazionale per la sorveglienza ed il controllo degli alimenti per gli animali (CReAA), Torino (Italy)

FR-SCL – Laboratoire de Rennes (SCL L35), Service Commun des Laboratoires DGCCRF et DGDDI, Rennes (France)

DE-TLL – Thüringer Landesanstalt für Landwirtschaft (TLL). Abteilung Untersuchungswesen. Jena (Germany)

AT-AGES – Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (Austria)

DK-PD – Fødevarestyrelsens Laboratorie Aarhus (kemisk) (Denmark)

DE-SMUL – Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 — Labore Landwirtschaft, Nossen (Germany)

SI-VFUNIV – Univerza v Ljubljani. Veterinarska fakulteta. Nacionalni veterinarski inštitut. Enota za patologijo prehrane in higieno okolja, Ljubljana (Slovenia)

NL-RIKILT – RIKILT Wageningen UR, Wageningen (The Netherlands)

ES-MAGRAMA – Laboratorio Arbitral Agroalimentario. Ministerio de Agricultura, Alimentación y Medio Ambiente, Madrid (Spain)

DE-LGL – Sachgebiet Futtermittel des Bayrischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim (Germany)

PL-IZOO – Instytut Zootechniki — Państwowy Instytut Badawczy, Krajowe Laboratorium Pasz, Lublin (Poland)

BE-CRAW - Centre wallon de Recherches agronomiques (CRA-W), Gembloux (Belgium)

SE-SVA Avdelningen för kemi, miljö och fodersäkerhet, Statens Veterinärmedicinska Anstalt (SVA), Uppsala (Sweden)

ES-GENCAT – Laboratori Agroalimentari, Departament d'Agricultura, Ramaderia, PESCA, Alimentació i Medi Natural. Generalitat de Catalunya, Cabrils (Spain)

Fi-EVIRA – Elintarviketurvallisuusvirasto/Livsmedelssäkerhetsverket (Evira), Helsinki/Helsingfors (Finland)

IT-ISS – Istituto Superiore di Sanità. Dipartimento di Sanità Pubblica Veterinaria e Sicurezza Alimentare, Roma (Italy)

BE-FAVV – Federaal Laboratorium voor de Voedselveiligheid Tervuren (FLVVT –FAVV); (Belgium)

LV-VVMDC – Pārtikas drošības, dzīvnieku veselības un vides zinātniskais institūts BIOR, Rīga (Latvia)

Executive summary of the Workshop 2015 of the EURL-FA Authorisation

The 15th workshop (WS) of the EURL Feed Additives (EURL-FA) Authorisation was organised and held at IRMM on November 16 - 17, 2015. A total of fourty participants representing 19 National Reference Laboratories (NRLs), DG SANTE, EFSA and EURL-FA. In addition the EU Association of Specialty Feed Ingredients and their Mixtures (FEFANA) attended the public part of the event.

C. von Holst (operating manager of EURL-FA) welcomed the participants and presented the programme of the workshop. The workshop started with presentation on EURL-FA Authorisation activities of 2015, deliverables and work programme of 2016 given by the EURL colleagues. Beside evaluation of the dossiers from Applicants, the additional activities of the EURL included the work on: i) Diclazuril and Optiphos projects; ii) text of Commission implementing Regulation (EU) 2015/1761 amending the current legislation (EC) 378/2005; and iii) compilation of the recommended methods for their further containment in EURL-FA web site.

C. von Holst continued with the presentation on the role of the EURL in the case of the applications related to new use of feed additives (art. 4 (1)) and for the applications where the terms of authorisation for existing feed additives were changed (art. 13(3)), focusing on more detailed explanation on the role of the EURL for the future applications related to renewal of authorisations according article 14.

A. Rodriguez (DG SANTE) gave detailed overview on the re-evaluation status of chemically and botanically defined flavourings. In addition, new functional groups such as hygiene condition enhancers, identifiers and other technological feed additives were presented.

FEFANA continued with the analytical aspects related to the analysis of flavouring compounds, pointing out that the methods for determination of individual substances in the flavouring formulations are feasible, while the determination of individual components in feed is challenging due too low maximum legal limits established.

Then, the EURL colleagues presented the pitfalls related to application of Community method (EC 152/2009) for determination of Diclazuril in feed and the results of collaborative trial using the corrected Community method. Based on the results of the exercise it was concluded by the EURL&NRLs authorisation and control networks that the corrected method will replace the current Community method in the revised Commission Regulation.

The other presentations involved the following topics: i) uncertainty from sample preparation in the case of feed additives (W. Korol, Polish NRL); ii) analysis of TiO_2 for the presence of nanoparticles (J. Omar, EURL); iii) EFSA status report on 2015 - update on the re-evaluation process (M. Innocenti, EFSA); iv) update on Optiphos project aiming at determination of conversion factor that would enable the labelling control of Optiphos feed products when applying the ISO 30024 (M. J. Gonzalez de la Huebra).

Three NRLs: AGES (AT), EVIRA (FI) and PIWET (PL) presented the posters on the structure of their organisations and work activities. In addition, the Polish NRL (IZOO) presented the posters on the organisation of PTs and HPLC method for determination of Vitamin C in feeds, and Spanish NRL (GENCAT) presented the paper copy of desorption electrospray ionization-high resolution mass spectrometry for the screening of veterinary drugs in cross-contaminated feedstuffs. The overall feedback from participants was very positive, the balance between formal presentations and discussions was well perceived.

Update of the administrative documents: EURL-FA Guidance for Applicants and Declaration Form

In 2015, the EURL updated the "Guidance for Applicants of feed additives authorisation", related to the EURL core activities. The current document (ver 3.01) introduces new approaches concerning the management of reference samples and dossier evaluation. https://ec.europa.eu/jrc/sites/default/files/EURL-FA_Guidance_for_Applicants-ver3.01.pdf

At present, **reference samples** are not required when an application is submitted according to:

1. Article 4(1) of Regulation (EC) No 1831/2003 for a new use of an already authorised feed additive; or
2. Article 13 (3) for changing the terms of an existing authorisation; or
3. Article 14 for renewal of an existing authorisation.

These provisions apply only if the proposed modification of the terms of the authorisation does not alter the composition and the characteristics of the product.

During the authorisation process, the Applicant must provide replacement samples to replace the expired samples. As soon as the feed additive is authorised, no replacement samples are required during the entire authorisation period.

Replacement samples are to be provided for applications submitted according to Article 4 (1) of Regulation (EC) No 1831/2003 (new use of a feed additive) if the original reference samples are expired.

Note: The EURL is entitled to request the Applicant to provide additional reference samples, whenever deemed necessary. In addition,

As for the **evaluation of dossiers**, the EURL report is not required when the application is submitted according to: Article 4 (1); or Article 13 (3); or Article 14 of Regulation (EC) No 1831/2003.

These provisions apply only when:

- the methods of analysis for the determination of the concerned feed additive submitted according to Regulation (EC) No 429/2008 (including the relevant validation and verification studies) were already evaluated by the EURL; or
- The proposed conditions for the new use or the proposed modification of the conditions fall within the scope of the methods already evaluated by the EURL.

The Declaration Form (ver. 2) was updated accordingly to reflect these new changes. https://ec.europa.eu/jrc/sites/default/files/new_2015-declaration-form_v2.doc

EURL support to the Commission

In 2015, the EURL contributed to *Commission Implementing Regulation (EU) 2015/1761 of 1 October 2015 amending Commission Regulation (EC) No 378/2005 as regards the Community Reference Laboratory reports, fees and the laboratories listed in Annex II thereto*.

This document specifies new rules related to the EURL evaluation and the fees for applications for renewal of feed additives authorisation according **Article 14.** In such cases, no EURL evaluation/report is required when properly validated and verified methods were submitted and already evaluated by the EURL. Furthermore, no reference samples are to be delivered by the Applicant to the EURL. Consequently, no payment will be invoiced by the EURL to the Applicant.

This document also provides an exhaustive up-to-date list of the National Reference Laboratories, including correct institute names and addresses. This resulted in the addition of one NRL from Greece.

The Diclazuril Collaborative Trial

In 2013, several NRLs acknowledged the fact that the standard operating procedure described in Commission Regulation (EC) No 152/2009 for the determination of a Diclazuril in feed was not fit-for-purpose if applied as such. The EURL identified several experimental conditions that need to be modified or improved. The modified/improved method was then single-laboratory validated by the EURL and satisfactory results for the method performance characteristics were obtained.

Based on these results, the EURL decided together with the network of NRLs to organise in 2015 a collaborative trial to assess the method performance characteristics of this modified method based on high performance liquid chromatography coupled to spectrophotometric detection (LC-UV or LC-DAD) for the determination of Diclazuril in feed. This project was than conducted by the EURL-FA control, which operates under Regulation (EC) No 882/2004. A total of 5 samples (4 blind duplicates + 1 blank feed) were analysed by 14 laboratories. The following performance characteristics were derived from the reported results: - a relative standard deviation for repeatability (RSD_r) ranging from 4.5 % to 11 %; and - a relative standard deviation for reproducibility (RSD_R) ranging from 14 % to 18 %, thus resulting to satisfactory Horrat ratios below 1.5. Based on these satisfactory results, the NRLs agreed that the EURL should recommend DG SANTE to revise the current Community method. The draft of the text describing the "improved" experimental protocol to be included in the revised Regulation replacing (EC) No 152/2009 was drafted by the EURL and reviewed by the concerned NRLs.

The Optiphos conversion factor

The EURL started in 2015 the preparation for an inter-laboratory comparison aiming at the establishment of the conversion factor *(f)* enabling the labelling control of Optiphos feed products when applying the ISO 30024 analytical method.

Several challenges were already identified in 2014: - the lack of a suitable phytate substrate; and - the lack of a clear standard operational procedure for quantification of 6-Phytase in the feed additives.

Nevertheless, some progress was made in the 2015:

- the feasibility study for testing equivalence of commercially available phytate substrates was performed by two NRLs (France and Denmark);
- a preliminary ring trial was organised by the VDLUFA Enzyme group to extend the scope of the ISO method to feed additives. An Optiphos formulation (feed additive) was included and satisfactory results were obtained;
- consequently, a ring trial was organised by VDLUFA to extend the scope of the ISO 30024 standard method to the determination of 6-phytase in feed additives. Satisfactory results were reported. The extended method thus became an official VDLUFA method for the determination of phytase activity in feed additives;
- A dedicated meeting was organised by the EURL with the Chair of the VDLUFA Enzyme Group (AGES) to fine-tune practical details regarding the Optiphos assay (e.g. samples to be analysed and time planning).

The EURL a peer reviewed publication on its activity

Food Additives & Contaminants: Part A

Volume 33, Issue 1, 2016, pages 66-77

Review Article

The work of the European Union Reference Laboratory for Feed Additives (EURL) and its support for the authorisation process of feed additives in the European Union: a review

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ABSTRACT

This paper describes the operation of the European Union Reference Laboratory for Feed Additives (EURL) and its role in the authorisation procedure of feed additives in the European Union. Feed additives are authorised according to Regulation (EC) No. 1831/2003, which introduced a completely revised authorisation procedure and also established the EURL. The regulations authorising feed additives contain conditions of use such as legal limits of the feed additives, which require the availability of a suitable method of analysis for official control purposes under real world conditions. It is the task of the EURL to evaluate the suitability of analytical methods as proposed by the industry for this purpose. Moreover, the paper shows that one of the major challenges is the huge variety of the methodology applied in feed additive analysis, thus requiring expertise in quite different analytical areas. In order to cope with this challenge, the EURL is supported by a network of national reference laboratories (NRLs) and only the merged knowledge of all NRLs allows for a scientifically sound assessment of the analytical methods.

Acknowledgements

The EURL would like to thank our colleagues within DG JRC IRMM for their strong support and interest in EURL-FA activities, related to secretarial support, review of reports and development of tailor-made informatics systems. The efforts and excellent collaboration with the Mail services and the Resources Management Geel are also acknowledged.

We are grateful to all the NRL experts for their valuable contribution in the evaluation of the dossiers and the constructive discussions during the workshop. All this allowed successful evaluations and guaranteed proper dissemination of knowledge and good practices. The list of NRLs is provided in Annex I.

Finally we would like to wish all the best to our colleagues who left the EURL team: Johanna Keltti, Edit Kovacs and Rebeca Fernandez-Orozco. Their contribution was essential to the successful activity of the EURL.

Annex I: List of the NRLs of the EURL-FA network

(updated on 15/03/2016)

Country	National Reference Laboratory
	- Federaal Laboratorium voor de Voedselveiligheid Tervuren (FLVVT –FAVV). BE - Vlaamse Instelling voor Technologisch Onderzoek (VITO), Mol. BE - Centre wallon de Recherches agronomiques (CRA-W), Gembloux. BE
	- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha. CZ
	- Fødevarestyrelsens Laboratorie Aarhus (kemisk). DK - Fødevarestyrelsens Laboratorie Ringsted (kemisk og mikrobiologisk). DK
	- Sachgebiet Futtermittel des Bayrischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim. DE - Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUFA), Speyer. DE - Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 - Labore Landwirtschaft, Nossen. DE - Thüringer Landesanstalt für Landwirtschaft (TLL). Abteilung Untersuchungswesen. Jena. DE
	- Põllumajandusuuringute Keskus (PMK). Jääkide ja saasteainete labor, Saku, Harjumaa. EE - Põllumajandusuuringute Keskus (PMK), Taimse materjali labor, Saku, Harjumaa. EE
	- Laboratorio Arbitral Agroalimentario. Ministerio de Agricultura, Alimentación y Medio Ambiente, Madrid. ES - Laboratori Agroalimentari, Departament d'Agricultura, Ramaderia, PESCA, Alimentació i Medi Natural. Generalitat de Catalunya, Cabrils. ES
	- Laboratoire de Rennes (SCL L35), Service Commun des Laboratoires DGCCRF et DGDDI, Rennes. FR
	- The State Laboratory, Kildare. IE
	- Εργαστήριο Ελέγχου Κυκλοφορίας Ζωοτροφών Θεσσαλονίκης. GR
	- Istituto Superiore di Sanità. Dipartimento di Sanità Pubblica Veterinaria e Sicurezza Alimentare, Roma. IT - Centro di referenza nazionale per la sorveglienza ed il controllo degli alimenti per gli animali (CReAA), Torino. IT
	- Feedingstuffs Analytical Laboratory, Department of Agriculture, Nicosia. CY
	- Pārtikas drošības, dzīvnieku veselības un vides zinātniskais institūts BIOR, Rīga. LV

Country	National Reference Laboratory
	- Nacionalinis maisto ir veterinarijos rizikos vertinimo institutas, Vilnius. LT
	- Laboratoire de Contrôle et d'essais — ASTA, Ettelbruck. LU
	- Nemzeti Élelmiszerlánc-biztonsági Hivatal, Élelmiszer- és Takarmánybiztonsági Igazgatóság, Takarmányvizsgáló Nemzeti Referencia Laboratórium, Budapest. HU
	- RIKILT Wageningen UR, Wageningen. NL
	- The National Institute of Nutrition and Seafood Research (NIFES), Bergen. NO
	- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien. AT
	- Instytut Zootechniki — Państwowy Instytut Badawczy, Krajowe Laboratorium Pasz, Lublin. PL - Państwowy Instytut Weterynaryjny, Pulawy. PL
	- Instituto Nacional de Investigação Agrária e Veterinária, I.P. (INIAV,IP), Lisboa. PT
	- Univerza v Ljubljani. Veterinarska fakulteta. Nacionalni veterinarski inštitut. Enota za patologijo prehrane in higieno okolja, Ljubljana. SI - Kmetijski inštitut Slovenije, Ljubljana. SI
	- Skúšobné laboratórium analýzy krmív, Ústredný kontrolný a skúšobný ústav poľnohospodársky, Bratislava. SK
	- Elintarviketurvallisuusvirasto/Livsmedelssäkerhetsverket (Evira), Helsinki/Helsingfors. FI
	- Avdelningen för kemi, miljö och fodersäkerhet, Statens Veterinärmedicinska Anstalt (SVA), Uppsala. SE
	- LGC Ltd, Teddington. UK
EURL European Union Reference Laboratory Feed Additives	- European Commission, Joint Research Centre, Institute for Reference Materials and Measurements (IRMM). EU

Annex II: List of EURL FAD reports issued in 2015

(listed in anti-chronological order)

FAD No	Product Name	Active Substance(s)	Published on	NRL
2010-0213	Feedlyve® AXC	Endo 1,4-β-xylanase	11/12/2015	
2010-0367	Enzymes as silage additives	Alpha-amylase EC 3.2.1.1 Endo-1,4-beta-glucanase EC 3.2.1.4 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	08/12/2015	AT-AGES
2010-0309	Precipitated and dried silicic acid		27/11/2015	
2013-0055	SmokeEz C-10	Primary Smoke Condensate – Smoke flavouring	23/11/2015	
2014-0036 2014-0045	Maxiban®G160	Narasin; Nicarbazin	13/11/2015	
2015-0014	Lactobacillus brevis TAK 124-1 NCIMB 42149	Lactobacillus brevis TAK 124-1 NCIMB 42149	30/10/2015	IT-CReAA
2015-0013	Lactobacillus plantarum TAK 59 NCIMB 42150	Lactobacillus plantarum TAK 59 NCIMB 42150	23/10/2015	BE-CRA-W
2015-0016	B-Act®	Bacillus licheniformis BL 11 (DSM 28710)	23/10/2015	BE-CRA-W
2013-0020	Iron Dextran	Iron	19/10/2015	
2010-0341	Synthetic Calcium Silicate	Calcium Silicate	30/09/2015	
2014-0029	Bergazym P100	Endo 1,4-β-xylanase	24/09/2015	
2015-0002	Zinc Chelate of Methionine	Zinc Chelate of Methionine	15/09/2015	
2010-0238	Natrolite-phonolite E566	Natrolite-phonolite	04/09/2015	
2014-0037	Bacillus subtilis DSM 27273	Bacillus subtilis DSM 27273	25/08/2015	IT-CReAA
2014-0031	Betaine anhydrous	Betaine	21/08/2015	
2014-0047	Preparation of algae interspaced bentonite		18/08/2015	
2010-0226	Precipitated and dried silicic acid Colloidal silica		18/08/2015	
2011-0023	Ethyl Cellulose		12/08/2015	
2014-0001	Hemicell®	Endo-1,4-β-mannanase (E.C. 3.2.1.78)	12/08/2015	PL-IZOO
2015-0008	Enviva® PRO 202 GT	Bacillus amyloliquefaciens BS 15A-P4, Bacillus amyloliquefaciens LSSAO1, Bacillus amyloliquefaciens BS 2084	07/08/2015	BE-CRA-W
2015-0006	Bacillus subtilis DSM 28343	Bacillus subtilis DSM 28343	30/07/2015	BE-CRA-W
2010-0293	Stenorol®	Halofuginone hydrobromide	29/07/2015	
2014-0006	Fecinor	Enterococcus faecium CECT 4515	30/06/2015	IT-CReAA
2014-0016	Salinomax® 120G	Salinomycin Sodium	12/06/2015	

FAD No	Product Name	Active Substance(s)	Published on	NRL
2014-0044	Natuphos®E	6-phytase	10/06/2015	
2012-0021	Tertiary-Butylhydroquinone (TBHQ)	Tertiary-Butylhydroquinone	08/06/2015	
2013-0047	Ronozyme® WX	Endo 1,4-β-xylanase	04/06/2015	
2010-0096	Natural mixture of talc and chlorite	Natural mixture of talc and chlorite	29/05/2015	
2010-0248	Omega-6-fatty acid as octadecadienoic acid	Conjugated linoleic acid-methylester (trans-10, cis-12-isomer)	29/05/2015	
2011-0018c	Vitamin K3 (Menadione)	Menadione Dimethyl Pyrimidinol Bisulphite	26/05/2015	
2010-0128	Vermiculite	Vermiculite	26/05/2015	
2010-0061	Natrolite-phonolite E566	Natrolite-phonolite	25/03/2015	
2010-0100	Biotin	D-(+)-Biotin	25/03/2015	addendum
2014-0034	Dicopper oxide	Dicopper oxide	24/03/2015	
2013-0048	Lavipan®	Lactococcus lactis IBB500; Carnobacterium divergens S1; Lactobacillus casei LOCK 0915; Lactobacillus plantarum LOCK 0862; Saccharomyces cerevisiae LOCK 0141;	11/03/2015	BE-CRA-W
2010-0398	Lipidol Lecithins E322	Lecithins	09/03/2015	
2014-0022	Proccanius	Lactobacillus fermentum NCIMB 41636; Lactobacillus plantarum NCIMB 41638; Lactobacillus rhamnosus NCIMB 41640	26/02/2015	BE-CRA-W
2013-0035	Alpha-lipoic acid	Alpha-lipoic acid	24/02/2015	
2010-0149	Sodium Selenate	Sodium Selenate	24/02/2015	
2010-0012	Perlite	Sodium potassium aluminum silicate	24/02/2015	
2013-0017	Cibenza® EP150	Protease EC 3.4.21.19; Bacillus licheniformis ATCC 53757	20/02/2015	
2010-0104 2010-0362 2010-0369	Sodium selenite	Sodium selenite	20/02/2015	
2010-0364	Lecithins E322	Lecithins	11/02/2015	
2010-0147	Benzoic acid E210	Benzoic acid	14/01/2015	
2010-0306	Lutein	Lutein	13/01/2015	
2010-0120	Levucell SC	Saccharomyces cerevisiae CNCM I-1077	09/01/2015	IT-CReAA
2010-0121	Levucell SB	Saccharomyces cerevisiae CNCM I-1079	09/01/2015	PL-PIWET

Reports available from the EURL website: *https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports*

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