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Activity Report 2010-2011

European Reference Laboratory for Feed Additives - Authorisation

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FOREWORD

The team of the European Union Reference Laboratory for Feed Additives (EURL-FA) is very proud to present a combined annual report presenting the activities done in 2010 and 2011.

2010 was a very special year for the EURL-FA. This was triggered by the European legislation requiring the industry to send applications for the authorisation of feed additives to the Commission by November 8th 2010. This requirement applied only to additives authorised under the old legislation and was not applicable to new products. As expected, even though this was known since long, the vast majority of applications were submitted in the very last months before the actual deadline.

Prior to submitting an application, the industry had to send to the EURL-FA a dedicated declaration form, to provide reference samples and to pay a registration fee.

A total of 374 declarations and about 1700 reference samples were collected by the EURL team. All samples were individually checked, registered and stored in the EURL sample-bank. In about 25 % of the cases, applicants were contacted for additional information or clarification. This was a major challenge for the team and for the colleagues of the IRMM financial department. The timely processing of declarations was crucial for the applicants, since a positive confirmation from the EURL allowed them to send a valid application to the Commission before the legal deadline. Nevertheless, I am very glad to say that we managed to get through all the declarations!

In addition to the administrative tasks mentioned above, the EURL evaluates the technical dossiers submitted by the applicants to recommend reliable analytical methods for official control, allowing the determination of relevant active substances in various matrices. Requests for dossier evaluation increased significantly since 2009. In 2011 the EURL delivered a total of 87 reports, a record that will be difficult to beat.

Christoph von Holst
Operating manager
EURL – FA

Reminder

Consequences of the Treaty of Lisbon

The Treaty of Lisbon (OJ C 306, 17/12/2007)[1], amending the Treaty on European Union and the Treaty establishing the European Community signed by the twenty seven Member States under the general provisions that '*The Union shall be founded on the present Treaty and on the Treaty on the Functioning of the European Union (hereinafter referred to as "the Treaties"). Those two Treaties shall have the same legal value.*

The Union shall replace and succeed the European Community'.

As of January 2010, the Community Reference Laboratory for Feed Additives therefore became the European Union Laboratory for Feed Additives.

EURL
European Union Reference Laboratory
Feed Additives

As explained in "Your Guide to the Lisbon Treaty" (cf. "Some technical terms")[2]

> *The Lisbon Treaty amends the Treaty on European Union and the Treaty establishing the European Community. It is the latest in a series of treaties updating and consolidating the EU's legal base.*
> *The EU will be given a single legal personality under the Lisbon Treaty.*
> *Currently, the European Community and the European Union have different statutes and do not operate the same decision-making rules. The Lisbon Treaty will end this dual system and the European Union will have its own legal personality.*
> *This change will improve the EU's ability to act, especially in external affairs. The Lisbon Treaty will allow the EU to act more effectively, coherently and credibly in its relations with the rest of the world.*

[1] http://europa.eu/lisbon_treaty/full_text/index_en.htm
[2] http://ec.europa.eu/publications/booklets/others/84/en.pdf

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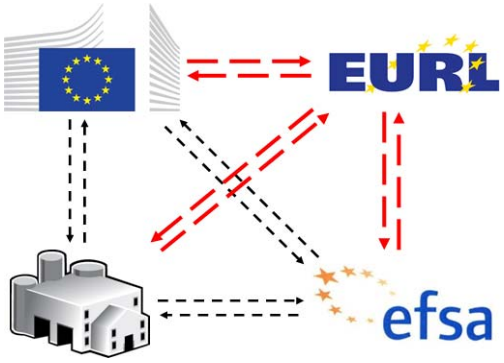
Introduction *(by P. Robouch)*

The procedure for the authorisation of feed additives is described in Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. The main interactions between the four stakeholders (European Commission (COM), European Food Safety Authority (EFSA), EURL and Applicants) are briefly recalled hereafter.



- Applicant sends to EURL a declaration form and a set of reference samples
- Applicant sends to COM the application form, together with the proof of payment and sample delivery
- Applicant sends the full dossier to EFSA
- COM forwards the application to EFSA
- EFSA checks the completeness of the submitted dossier
- EFSA notifies EURL of the start of the evaluation
- Initial report is drafted by the EURL or a NRL
- NRLs review and comment the draft report
- EURL sends the Final Report to COM and EFSA
- EFSA verifies the EURL reports and includes the Executive Summary in the EFSA opinion
- EFSA sends it's opinion to COM
- COM drafts the Authorisation Regulation
- Member States vote at the Standing Committee
- Authorisation is published in the Official Journal

[NRL(s): National Reference Laboratory(ies)]

Regulation (EC) 1831/2003 specifies under Art. 10(2) that within 7 years after it's implementation a request for renewal of authorisation of feed additives is required. Seven years and twenty days after the publication of the regulation (OJ L268, dated 18 Octobre 2003) – corresponding to **November 8th 2010** - was the deadline set by the Commission for the submission of re-authorisation requests. Compared to previous years, a significant increase of applications was expected concerning more than 2500 feed additives.

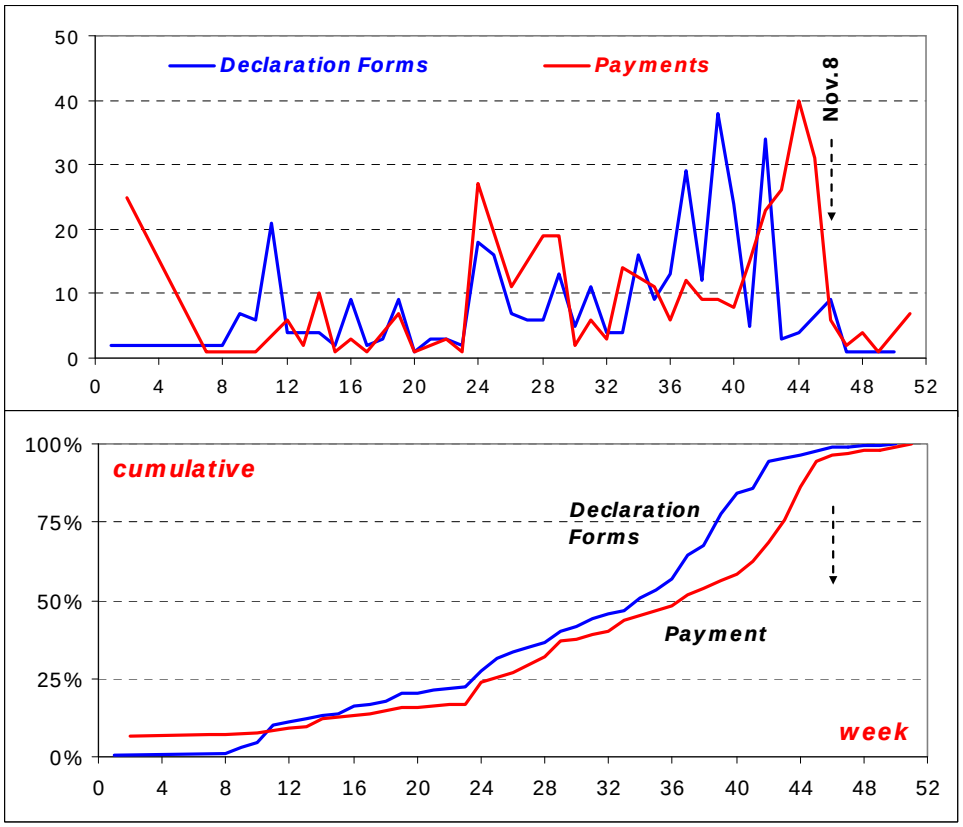
This report presents a review of the administrative tasks and dossiers evaluations performed by the EURL in 2010 and 2011.

Declaration Forms & Payments of Fees *(by A. Görcsi)*

Applicants wishing to apply for (re-)authorisation of a feed additive were requested to submit a declaration form (DF) to the EURL. Each DF was provided an unique identification number (CRL number). Applicant details were registered in the data base and a filing system was established for the additives of concern, to include all the relevant documents received from (and sent to) the Applicant, DG SANCO and/or EFSA. When a fee was to be charged, the IRMM financial department was requested to send a Debit Note (DN) with the appropriate fee to the Applicant. When no fee was to be charged, a No Fee Acknowledgment was sent to the Applicant.

A total of 374 dossiers were registered in 2010 – ten times more than the previous years. The cumulative graph presented in Figure 1 shows that 25%, 50% and 75% of the DF were processed by June 18th, August 27th and October 1st 2010, respectively. In the month of October 2010 the EURL team handled successfully the last 25% of the DF and 40% of all payments. The very last DF was approved on 7th of November 2010 !

Figure 1: Number of Declaration forms and invoices processed by the EURL in 2010. The cumulative graph indicates that 25% of all DF (and DN) were processed in October.



Sample Registration *(by H. Nys)*

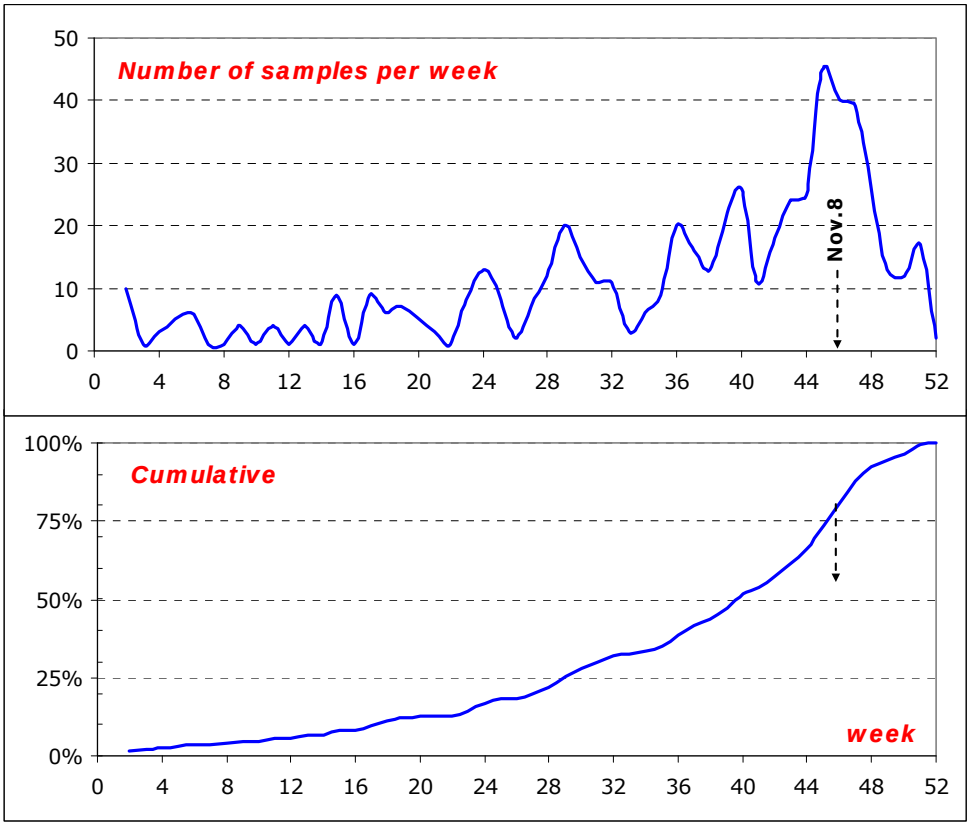
In order to fulfil the requirements set by the Regulation (EC) No. 1831/2003 Applicants are requested to send a set of three reference samples of each product/formulation. A large number of samples was expected to arrive at the EURL premises before the final deadline.

At first, samples arriving by mail or by express couriers were collected on a daily basis and placed temporarily at the storage temperature specified by the Applicant. Then the EURL staff checked whether samples were properly sealed, packed and if they contained a sufficient amount of the various formulations. All the delivered documents were systematically scrutinised and reviewed. Once all requirements were met, samples were registered in the EURL database, properly labeled and stored in the EURL sample bank. As a consequence, Applicants received the Valid Sample Acknowledgement Receipt (VSAR) recalling the critical information, such as expiry date of the sample and the EURL sample number. Last but not least, all the documentation was filed in the corresponding dossiers in the archive room.

On the whole, a total of 1700 reference samples were received in 2010. The cumulative graph (Figure 2) indicates that 25%, 50%, 75% and 100% of the total samples were delivered by July 23rd, October 8th, November 12th and December 16th, respectively. Half of the samples were delivered in October! (372 samples were delivered in weeks 45-47). This created a temporary overflow of handling, registration and storing of samples. Nonetheless, thanks to the joint and enthousiastic effort of the EURL team all samples were properly registered and stored in time.

From the registration room to the EURL sample-bank

Figure 2: Number of samples collected by the EURL in 2010. The cumulative graph indicates that half of the samples were deliverd in October -November.



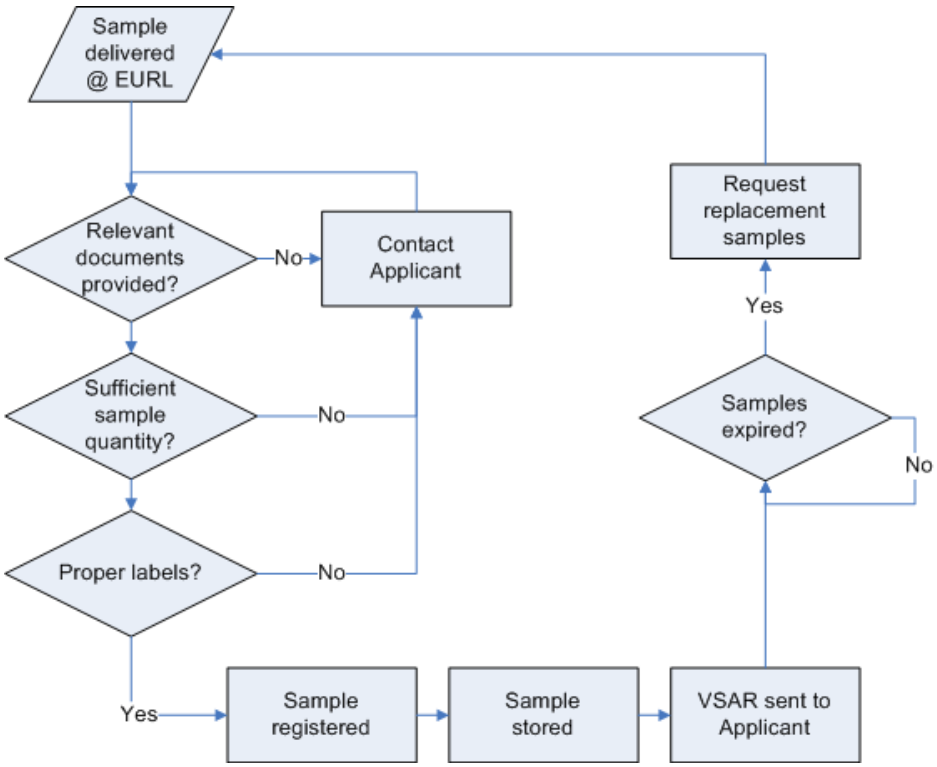
New sample registration procedure *(A. Görcsi, P. Robouch)*

As discussed earlier, Figure 2 shows that only 25% of the 2010 samples were delivered to the EURL in the first half of the year, and a second wave of samples arrived in August 2010. Two major non-compliances were identified during the sample registration process: (i) all relevant documents were not provided systematically; and (ii) sample labels were often inappropriate. Instead of applying the formal procedure requesting Applicants to comply with the set of requirements, the EURL prepared a set of simple forms that were used from September 2010 onwards. This improvement action proved to be very effective. Applicants found these documents user-friendly and the rate of non-compliances decreased significantly. The EURL handled successfully all the 372 samples that arrived in October. Only few phone calls were necessary to clarify some difficult cases. This approach has been formalised in 2011 as the "Sample Registration-Work Instruction". The "Sample Validity Checklist" and two label templates - available from the EURL website for download – are included in Annex II.

http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/guidance_for_applicants/

Two additional letter templates were developed (Annex II). The "Valid Sample Acknowledgment of Receipt (VSAR)" was simplified to focus on the information relevant to the Applicant. Similarly, the letter for "Request for Replacement Samples" was restructured, asking Applicants to consider extending the stated shelf-life and reducing the amount for voluminous samples.

Simplified flowchart of the EURL sample Registration process



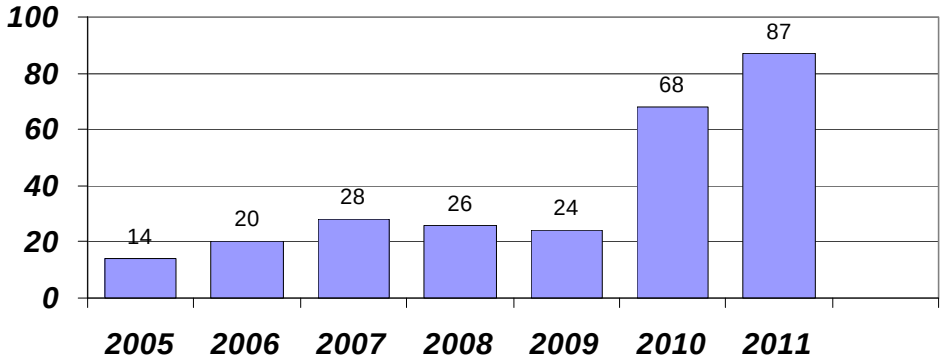
Evaluation of Dossiers *(by P. Robouch)*

While the administrative staff of the EURL was managing Declaration Forms, Debit notes and was taking good care of the reference samples delivered, the team of rapporteurs was reviewing the submitted dossiers in order to recommend the analytical methods to be used in the frame of official control. Table 1 presents the number of FAD dossiers assessed and the corresponding reports issued in the past three years. While till 2009 each dossier was evaluated individually (1 FAD = 1 report), many joint applications (previously referred to as grouped applications) started to be evaluated from 2010 onwards. Figure 3 presents the number of reports issued by the EURL since 2005. A significant increase is noticeable in 2010, to reach a maximum record of 87 reports in 2011. Sixteen of these reports were outsourced to and drafted by NRL rapporteurs from AT-AGES, IT-CReAA, ES-GENCAT, PT-LNIV, PO-NRIAP, DK-PL, SE-SVA, SK-UKSUP and SI-VFUNILJ (details in Annex I).

Table 1: Number of FAD dossiers assessed and Number of FAD reports produced

	2009	2010	2011	*Total*
FAD	24	70	124	194
Reports	24	68	87	156

Figure 3: Number of final reports issued by the EURL since 2005



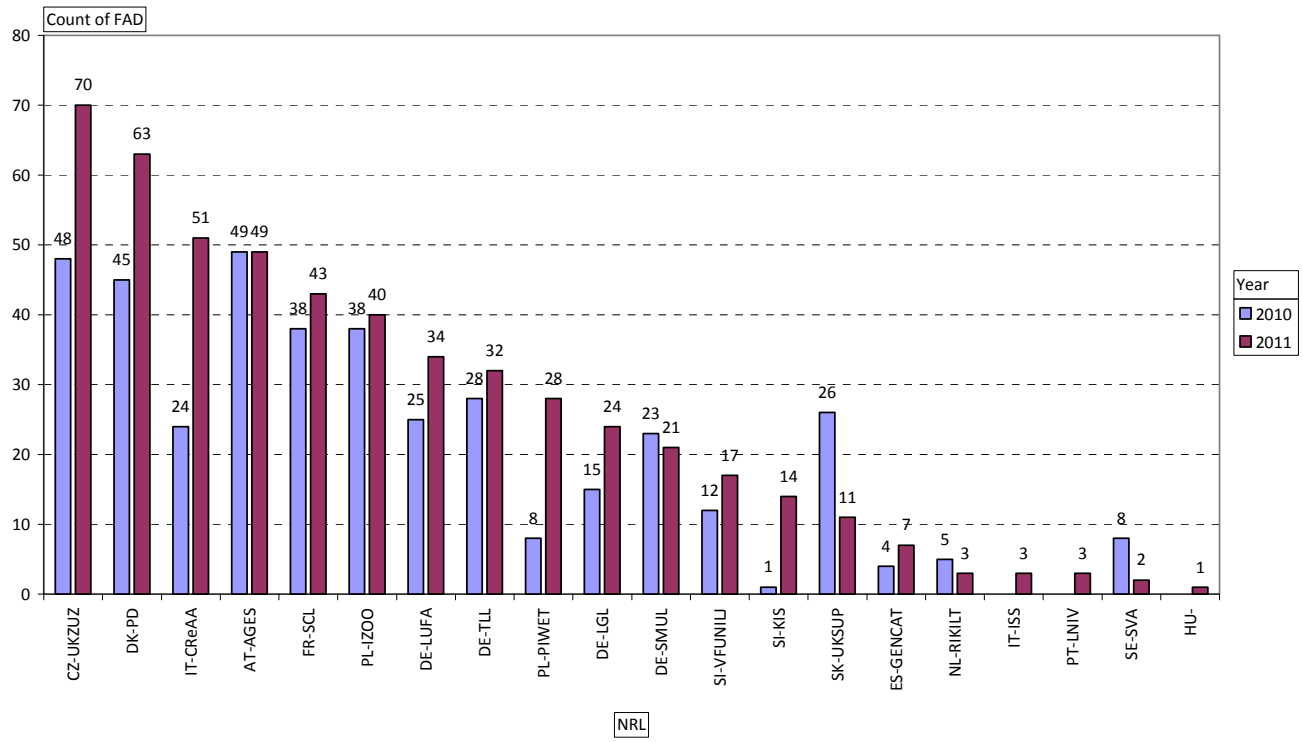
The complete list of issued reports is provided in Annex I. Unlike in previous annual reports the compilation of the 153 executive summaries is not included in the present manuscript. All reports are available from the EURL website:
http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports

A detailed overview is presented in Table 2 showing the various categories and functional groups reviewed. This includes 49 Sensory (including 13 chemically defined group dossiers), 42 Zootechnical, 38 Technological, 31 Nutritional and 6 coccidiostats dossiers.

Table 2: Categories / functional groups evaluated in 2010-2011

	Category		Functional Group	2010	2011
1	technological	a	preservatives	2	8
		b	antioxidants	3	1
		e	thickeners	1	
		f	gelling agents	1	
		g	binders		2
		h	substances for control of radionuclide contamination		1
		i	anticaking agents		1
		j	acidity regulators		2
		k	silage additives	3	11
		m	mycotoxin binders	1	1
2	sensory	a	colourants	1	10
		b	flavouring compounds	18	20
3	nutritional	a	vitamins, pro-vitamins	6	11
		b	compounds of trace elements	2	5
		c	amino acids		6
		d	urea and derivatives		1
4	zootechnical	a	digestibility enhancers	12	4
		b	gut flora stabilisers: micro-organisms	12	3
		c	substances which favourably affect the environment	2	
		d	other zootechnical additives	2	7
5	coccidiostats		coccidiostats	6	
			Total	72	94

Figure 4: Number of comments submitted by the NRLs during the review process in 2010 and 2011.



Each draft report undergoes a review cycle where each NRL is invited to comment. Several NRLs contribute systematically to this review process (Figure 4), among which we find representatives from Austria, Czech Republic, Denmark, France, Germany, Italy, Poland and Slovakia (*sorted by alphabetical order*). Their contribution is a valuable support that is systematically acknowledged in the Final Report sent by the EURL to EFSA and to DG SANCO.

Table 3 summarises the comprehensive list of EURL contributions/support to the EFSA opinions published in the EFSA Journal (Table 4) and to the Commission Regulations (Table 5) published in the Official Journal. These numbers will certainly increase in 2012, seen the many FAD reports already finalised by the EURL are still to be voted by the Member State representatives and to be authorised by the Commission.

Table 3: EURL support to EFSA and COM

	EFSA Journal	DG SANCO (OJ)
2010	22	20
2011	54	46

Table 4: EURL executive summaries included in EFSA opinions

	EFSA Journal reference	Active substances	FAD Num
	in 2011		
1	2011;9(12):2451 [19 pp.]	Biogalactosidase BL (alpha-galactosidase and beta-glucanase)	2009-0014
2	2011;9(12):2447 [13 pp.]	Erythrosine (E127)	2010-0382
3	2011;9(12):2446 [22 pp.]	Propionic acid, sodium propionate, calcium propionate and ammonium propionate	2010-0356
4	2011;9(12):2444 [13 pp.]	Neohesperidine dihydrochalcone	2010-0158
5	2011;9(12):2443 [7 pp.]	Protural (sodium benzoate)	2009-0005
6	2011;9(12):2442 [15 pp.]	Coxidin® (monensin sodium)	2009-0035
7	2011;9(12):2441 [13 pp.]	Anthranilate derivatives (chemical group 27)	2010-0047
8	2011;9(12):2440 [14 pp.]	Allylhydroxybenzenes (chemical group 18)	2010-0021
9	2011;9(11):2449 [8 pp.]	Lactobacillus pentosaceus (DSM 14025)	2010-0171
10	2011;9(11):2439 [8 pp.]	Biosprint® (Saccharomyces cerevisiae)	2008-0058
11	2011;9(11):2416 [12 pp.]	Naringin	2010-0129
12	2011;9(11):2415 [16 pp.]	Sodium bisulphate (SBS)	2009-0049
13	2011;9(11):2413 [17 pp.]	Vitamin B1 (thiamine mononitrate and thiamine hydrochloride) (DSM)	2010-0052
14	2011;9(11):2411 [17 pp.]	Vitamin B1 (thiamine mononitrate and thiamine hydrochloride (Lohman)	2010-0040
15	2011;9(11):2410 [17 pp.]	Pantothenic acid (calcium D-pantothenate and D-panthenol)	2010-0073
16	2011;9(11):2408 [11 pp.]	Lactobacillus plantarum (DSM 8862 and DSM 8866) (BIO-SIL®)	2011-0001
17	2011;9(9):2375 [14 pp.]	Animavit® (Bacillus subtilis CBS 117162)	2008-0060
18	2011;9(9):2370 [11 pp.]	Lactobacillus paracasei (DSM 16773)	2010-0172
19	2011;9(9):2369 [11 pp.]	Pediococcus pentosaceus (DSM 12834)	2010-0171
20	2011;9(9):2368 [11 pp.]	Lactobacillus brevis (DSM 12835)	2010-0170
21	2011;9(9):2367 [11 pp.]	Lactobacillus plantarum (DSM 12836)	2010-0169
22	2011;9(9):2366 [11 pp.]	Lactococcus lactis (NCIMB 30160)	2010-0110
23	2011;9(9):2365 [11 pp.]	Lactobacillus rhamnosus (NCIMB 30121)	2010-0103
24	2011;9(9):2364 [11 pp.]	Pediococcus acidilactici (DSM 16243)	2010-0102
25	2011;9(9):2363 [11 pp.]	Lactobacillus paracasei (DSM 16245)	2010-0087
26	2011;9(9):2362 [10 pp.]	Lactobacillus plantarum (DSM 12837)	2010-0086
27	2011;9(9):2361 [11 pp.]	Lactobacillus buchneri (DSM 12856)	2010-0085
28	2011;9(9):2359 [11 pp.]	Lactobacillus buchneri (DSM 16774)	2010-0084
29	2011;9(9):2358 [9 pp.]	VevoVitall® (Benzoic acid)	2010-0029
30	2011;9(9):2357 [17 pp.]	Sodium benzoate, propionic acid and sodium propionate (E700)	2010-0376
31	2011;9(9):2356 [10 pp.]	BioPlus 2B (Bacillus licheniformis DSM 5749 and Bacillus subtilis DSM 5750)	2009-2023
32	2011;9(9):2355 [18 pp.]	Copper chloride tri hydroxide (tribasic copper chloride, TBCC)	2010-0046
33	2011;9(9):2354 [10 pp.]	Thaumatin	2010-0138
34	2011;9(9):2353 [15 pp.]	Choline chloride	2010-0024
35	2011;9(6):2278 [11 pp.]	AveMix® XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase)	2010-0189
36	2011;9(6):2277 [14 pp.]	Econase XT P/L (endo-1,4-beta-xylanase)	2010-0006
37	2011;9(5):2173 [10 pp.]	InteSwine® (Saccharomyces cerevisiae)	2010-0051
38	2011;9(5):2172 [10 pp.]	Natugrain® TS (endo-1,4-beta-xylanase and endo-1,4-beta-glucanase)	2010-0034
39	2011;9(5):2171 [16 pp.]	Vitamin B6 (pyridoxine hydrochloride)	2010-0139
40	2011;9(4):2139 [16 pp.]	FRESTA® F essential oils from caraway and lemon, dried spices and dried herbs	2009-0055
41	2011;9(4):2138 [11 pp.]	Lactobacillus buchneri (DSM 22963)	2010-0168
42	2011;9(4):2116 [18 pp.]	Avatec®150G (lasalocid A sodium)	2008-0050
43	2011;9(4):2115 [2 pp.]	Clinacox® 0.5% (diclazuril)	2010-0010
44	2011;9(4):2110 [52 pp.]	Sel-Plex® (organic form of selenium produced by Saccharomyces cerevisiae CNCM I-3060)	2009-0029
45	2011;9(3):2113 [11 pp.]	Lactobacillus plantarum (DSM 21762)	2010-0109
46	2011;9(3):2102 [32 pp.]	Cycostat® 66G (robenidine hydrochloride)	2008-0052
47	2011;9(2):2009 [12 pp.]	Coxidin® (monensin sodium)	2009-0035
48	2011;9(2):2008 [13 pp.]	Danisco Xylanase G/L (endo-1,4-beta-xylanase)	2009-0038
49	2011;9(2):2007 [24 pp.]	bentonite (dioctahedral montmorillonite)	2010-0018
50	2011;9(2):2005 [15 pp.].	Protural (sodium benzoate)	2009-0005
51	2011;9(1):1954 [12 pp.]	Cygro® 1% (maduramicin ammonium α)	2008-0051
52	2011;9(1):1951 [15 pp.]	Miya-Gold® (Clostridium butyricum)	2010-0005
53	2011;9(1):1950 [14 pp.]	Taminizer D (dimethylglycine sodium salt)	2009-0036
54	2011;9(1):1949 [12 pp.]	Avizyme 1505 (endo-1,4-beta-xylanase, subtilisin and alpha-amylase)	2009-0006
	in 2010		
55	2010;8(12):1919 [10 pp.]	AveMix® XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase)	2009-0062 2010-0011
56	2010;8(12):1917 [14 pp.]	Vitamin B6 (pyridoxine hydrochloride)	2010-0139
57	2010;8(12):1916 [22 pp.]	Danisco® Glycosidase TPT/L (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase)	2010-0007
58	2010;8(12):1915 [12 pp.]	Ronozyme P (6-phytase)	2009-0012
59	2010;8(10):1867 [13 pp.]	Calsporin (Bacillus subtilis)	2009-0013
60	2010;8(10):1866 [13 pp.]	Clinacox 0.5% (diclazuril)	2008-0053 2009-0058
61	2010;8(10):1864 [9 pp.]	Biosprint (saccharomyces cerevisiae)	2009-0028
62	2010;8(10):1862 [27 pp.]	Ronozyme P (6-phytase)	2009-0012
63	2010;8(7):1695 [8 pp.]	Sodium carbonate (soda ash)	2008-0045
64	2010;8(7):1662 [8 pp.]	Biosprint (saccharomyces cerevisiae)	2009-0028
65	2010;8(7):1661 [13 pp.]	Cylactin (enterococcus faecium)	2008-0021
66	2010;8(7):1659 [10 pp.]	Biosprint (saccharomyces cerevisiae)	2009-0028
67	2010;8(6):1635. [28 pp.]	Vitamin E	2009-0024
68	2010;8(6):1634 [10 pp.]	Ronozyme NP (6-phytase)	2008-0008
69	2010;8(6):1633 [15 pp.]	AviPlus (citric acid, sorbic acid and thymol)	2008-0049
70	2010;8(4):1574 [45 pp.]	Maxiban G160 (narasin & nicarbazin)	2008-0037
71	2010;8(3):1550 [8 pp.]	Quantum (6-phytase)	2005-0028
72	2010;8(3):1549 [10 pp.]	Monteban G100 (narasin)	2009-0011
73	2010;8(2):1502 [10 pp.]	Pediococcus pentosaceus DSM 16244	2009-0024
74	2010;8(1):1427 [9 pp.]	Natuphos (3-phytase)	2008-0043
75	2010;8(1):1426 [11 pp.]	Calsporin® (Bacillus subtilis)	2009-0013
76	2010;8(1):1425 [19 pp.]	L-isoleucine	2009-0001

Table 5: EURL recommendations supporting Commission regulations

	Commission Regulation (EU) No	active substance	FAD Num
	in 2011		
1	1263/2011 of 5 December 2011	Pediococcus pentosaceus (DSM 12834)	2010-0171
2	1263/2011 of 5 December 2011	Pediococcus acidilactici (DSM 16243)	2010-0102
3	1263/2011 of 5 December 2011	Lactococcus lactis (NCIMB 30160)	2010-0110
4	1263/2011 of 5 December 2011	Lactococcus lactis (DSM 11037)	2010-0032
5	1263/2011 of 5 December 2011	Lactobacillus rhamnosus (NCIMB 30121)	2010-0103
6	1263/2011 of 5 December 2011	Lactobacillus brevis (DSM 12835)	2010-0170
7	1263/2011 of 5 December 2011	Lactobacillus plantarum (DSM 12837)	2010-0086
8	1263/2011 of 5 December 2011	Lactobacillus plantarum (DSM 12836)	2010-0169
9	1263/2011 of 5 December 2011	Lactobacillus paracasei (DSM 16773)	2010-0172
10	1263/2011 of 5 December 2011	Lactobacillus paracasei (DSM 16245)	2010-0087
11	1263/2011 of 5 December 2011	Lactobacillus buchneri (DSM 12856)	2010-0085
12	1263/2011 of 5 December 2011	Lactobacillus buchneri (DSM 16774)	2010-0084
13	1110/2011 of 3 November 2011	endo-1,4-beta-xylanase produced by Trichoderma reesei (CBS 114044)	2010-0006
14	1111/2011 of 3 November 2011	Lactobacillus plantarum (NCIMB 30236)	2011-0004
15	1074/2011 of 24 October 2011	Saccharomyces cerevisiae NCYC R-625	2010-0051
16	1068/2011 of 21 October 2011	endo-1,4-beta-xylanase produced by Aspergillus niger (CBS 109.713); endo-1,4-beta-glucanase produced by Aspergillus niger (DSM 18404)	2010-0034
17	900/2011 of 7 September 2011	Avatec 150G (Lasalocid A sodium)	2008-0050
18	888/2011 of 5 September 2011	Clinacox 0,5 % (Diclazuril)	2010-0010
19	885/2011 of 5 September 2011	Bacillus subtilis ATCC PTA-6737	2008-0039
20	886/2011 of 5 September 2011	6-phytase produced by Trichoderma reesei (CBS 122001)	2008-0040
21	887/2011 of 5 September 2011	Enterococcus faecium CECT 4515	2009-0057
22	881/2011of 2 September 2011	Bacillus subtilis DSM 17299	2005-0021
23	868/2011 of 31 August 2011	Lactobacillus buchneri (DSM 22963)	2010-0168
24	868/2011 of 31 August 2011	Lactobacillus plantarum (DSM 21762)	2010-0109
25	532/2011 of 31 May 2011	Cycostat 66G (Robenidine hydrochloride)	2008-0052
26	527/2011 of 30 May 2011	endo-1,4-β-xylanase produced by Trichoderma reesei (MUCL 49755), endo-1,3(4)-β-glucanase produced by Trichoderma reesei (MUCL 49754) polygalacturonase produced by Aspergillus aculeatus (CBS 589.94)	2008-0022
27	528/2011 of 30 May 2011	endo-1,4-β-xylanase produced by Trichoderma reesei (ATCC PTA 5588)	2009-0038
28	515/2011 of 25 May 2011	Vitamin B6 (pyridoxine hydrochloride)	2010-0139
29	495/2011 of 20 May 2011	Coxidin (Monensin sodium)	2009-0035
30	496/2011 of 20 May 2011	Sodium benzoate	2009-0005
31	388/2011 of 19 April 2011	Cygro 10 G (Maduramicin ammonium alpha)	2008-0051
32	389/2011 of 19 April 2011	endo-1,4-beta-xylanase produced by Trichoderma reesei (ATCC PTA 5588), alpha-amylase produced by Bacillus amyloliquefaciens (ATCC 3978) and subtilisin produced by Bacillus subtilis (ATCC 2107)	2009-0006
33	371/2011 of 15 April 2011	Dimethylglycine sodium salt	2009-0036
34	373/2011 of 15 April 2011	Clostridium butyricum FERM BP-2789	2010-0005
35	361/2011 of 13 April 2011	Enterococcus faecium NCIMB 10415	2009-0060
36	336/2011 of 7 April 2011	Bacillus amyloliquefaciens CECT 5940	2009-0041
37	335/2011 of 7 April 2011	endo-1,4-beta-xylanase produced by Trichoderma reesei (MUCL 49755); endo- 1,3(4)-beta-glucanase produced by Trichoderma reesei (MUCL 49754)	2008-0022
38	337/2011 of 7 April 2011	endo-1,4-beta-xylanase produced by Trichoderma reesei (ATCC PTA 5588); endo-1,3(4)-beta-glucanase produced by Trichoderma reesei (ATCC SD 2106)	2007-0036
39	221/2011 of 4 March 2011	6-Phytase produced by Aspergillus oryzae (DSM 14223)	2009-0012
40	212/2011 of 3 March 2011	Pediococcus acidilactici CNCM MA 18/5M	2008-0051
41	184/2011 of 25 February 2011	Bacillus subtilis C-3102 (DSM 15544)	2011-0184
42	170/2011 of 23 February 2011	Saccharomyces cerevisiae MUCL 39885	2008-0058
43	169/2011 of 23 February 2011	Clinacox 0,5 % (Diclazuril)	2010-0010
44	171/2011 of 23 February 2011	6-Phytase produced by Aspergillus oryzae (DSM 14223)	2009-0012
45	68/2011of 23 February 2011	Bacillus subtilis ATCC PTA-6737	2008-0039
46	26/2011 of 14 January 2011	Vitamin E	2008-0047
	in 2010		
47	1119/2010 of 2 December 2010	Saccharomyces cerevisiae MUCL 39885	2008-0006
48	1120/2010 of 2 December 2010	Pediococcus acidilactici CNCM MA 18/5M	2008-0015
49	1118/2010 of 2 December 2010	Clinacox 0,5 % Premix (diclazuril)	2008-0053 2009-0058
50	1117/2010 of 2 December 2010	citric acid, sorbic acid, thymol and vanillin	2008-0049
51	998/2010 of 5 November 2010	Lactosan (enterococcus faecium DSM 7134)	2008-0007
52	999/2010 of 5 November 2010	6-Phytase produced by Aspergillus oryzae (DSM 17594)	2009-0012
53	891/2010 of 8 October 2010	6-phytase	2008-0040
54	883/2010 of 7 October 2010	saccharomyces cerevisiae NCYC Sc 47	2007-0049
55	885/2010 of 7 October 2010	Maxiban G160	2008-0037
56	514/2010 of 15 June 2010	pediococcus pentosaceus DSM 16244	2009-0024
57	350/2010 of 23 April 2010	manganese chelate of hydroxyl analogue of methionine	2007-0011
58	348/2010 of 23 April 2010	L-isoleucine	2009-0001
59	349/2010 of 23 April 2010	copper chelate of hydroxyl analogue of methionine	2007-0012
60	335/2010 of 22 April 2010	zinc chelate of hydroxyl analogue of methionine	2007-0010
61	333/2010 of 22 April 2010	bacillus subtilis C-3102	2006-0033
62	327/2010 of 21 April 2010	Natuphos (3-phytase)	2008-0043
63	277/2010 of 31 March 2010	6-phytase	2008-0040
64	107/2010 of 8 February 2010	bacillus subtilis ATCC PTA-6737	2008-0039
65	104/2010 of 5 February 2010	potassium diformate	2004-0004
66	8/2010 of 23 December 2009	serine protease	2008-0026

"Pre-filled" reports *(by P. Robouch)*

While EURL colleagues were effectively handling incoming declaration forms and taking good care of the reference samples received, the team of rapporteurs faced a significant increase of dossiers to be evaluated: from an average of 24 dossiers per year to 68 and 87 reports issued in 2010 and 2011, respectively. Such an increase was expected due to the many Article 10 applications and this may even increase in the next years.

Knowing that the team would not increase proportionally, the EURL implemented a more effective drafting style that proved to be applicable even for grouped/joint dossiers. A reporting template has been consolidated to include: - an executive summary; - an introductory "background" section; - the terms of reference; - the method evaluation section (Chapter 3) reviewing and recommending analytical methods for the determination of the active substances in the relevant matrices (such as feed additive, premixtures, feedingstuffs, water or silage or tissues); - the conclusions and recommendations to be included in the authorisation; - a statement referring to documentation and samples provided; - proper bibliography/references; - the references of the raporteur laboratory having drafted the report; and – the acknowledgement section listing the NRLs having reviewed and commented this draft version. While several sections are systematically compiled (pre-filled) by the EURL dossier responsible, the critical evaluation of the analytical methods submitted by the Applicants is performed by an expert rapporteur from the EURL team or from an NRL to which the drafting was outsourced. The finalisation of conclusions and executive summary is fairly straightforward.

This systematic approach has been thoroughly tested at first within the EURL team of rapporteurs. All reports are systematically reviewed before review by the NRL network. The fact that only few major comments were submitted may indicate the high quality of the drafted reports.

This drafting philosophy was then presented to NRL experts during the training session organised on 21-23 January 2010. Nine potential rapporteurs from AT-AGES, BE-FLVVT-FAVV, DE-LUFA, ES-GENCAT, ES-MARM, LT-NMVRV, LU-ASTA and PT-LNIV attended the training seminar. Finally the approach of pre-filled reports was also presented during the 2011 Workshop.

As from 2011, NRL experts drafting the outsourced reports need to evaluate analytical methods and draft Chapter 3 and draw appropriate conclusions; the rest of the report is to be compiled by the EURL dossier responsible.

EURL-FA website revamped *(by C. M. Pinto)*

http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/

A change of denomination from CRL to EURL took place in 2010, creating the opportunity to renew some parts of its web page. The main objective of this revamping exercise was to simplify the queries of Applicants, and to create a place providing a web page where all required documents for applications could easily be found; and to provide a clear view of the activities related to the evaluation of applications.

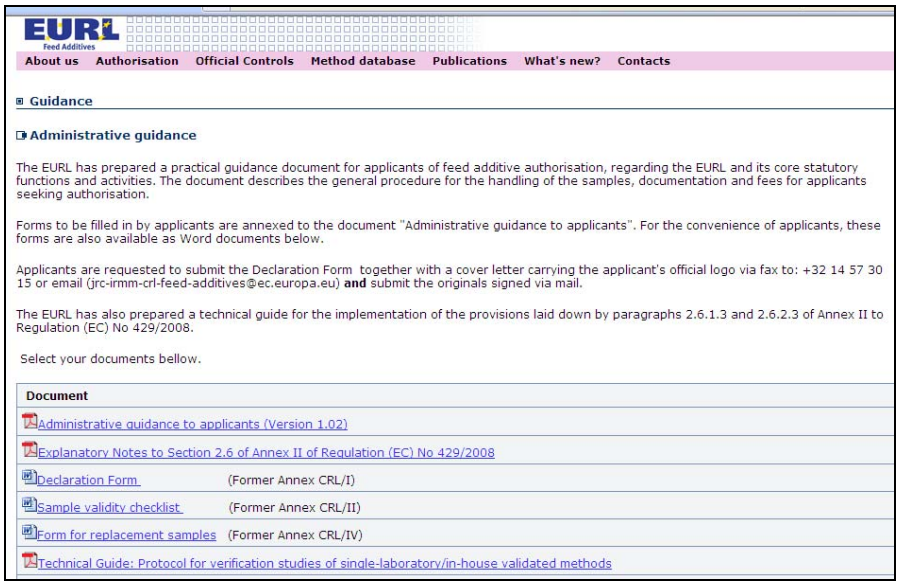
One main area of this change occurred in the part dedicated to Administrative Guidance, where the documents and legislation for Applicants were consolidated into an user-friendly area, where all documents are available for download.

The other area where modifications were also implemented was the Evaluation reports page. The screen now contains all the reports produced by the EURL in a retro-chronological order, sorted by decreasing date of publication - the most recent report first. Reports are available for download simply clicking on the respective FAD number.

Finally, the list of publications and the list of network laboratories have been updated on a regular basis.

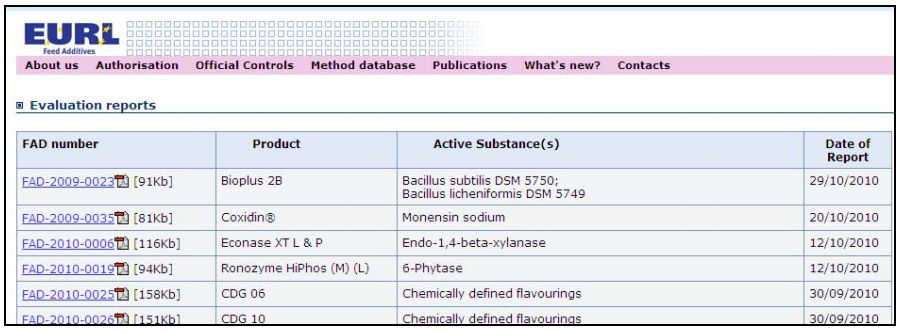
Administrative guidance page

http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/guidance_for_applicants/



Evaluation Reports page

http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports



FAD number	Product	Active Substance(s)	Date of Report
FAD-2009-0023 [91Kb]	Bioplus 2B	Bacillus subtilis DSM 5750; Bacillus licheniformis DSM 5749	29/10/2010
FAD-2009-0035 [81Kb]	Coxidin®	Monensin sodium	20/10/2010
FAD-2010-0006 [116Kb]	Econase XT L & P	Endo-1,4-beta-xylanase	12/10/2010
FAD-2010-0019 [94Kb]	Ronozyme HiPhos (M) (L)	6-Phytase	12/10/2010
FAD-2010-0025 [158Kb]	CDG 06	Chemically defined flavourings	30/09/2010
FAD-2010-0026 [151Kb]	CDG 10	Chemically defined flavourings	30/09/2010

EURL-FA Workshop 2010 - Executive Summary *(by D. Mitić)*

The 10th Workshop of the EURL Feed Additives was organised and held at IRMM on 02-03 December 2010. A total of twenty-seven participants, representing nineteen National Reference Laboratories (NRLs), DG SANCO and the EURL team, attended the event.

The EURL 2010 activities were reviewed and the issues concerning dossier evaluations were discussed. Participants were updated about (i) the name change from CRL-FA to EURL-FA, in accordance with the Lisbon Treaty; (ii) the state of the ongoing re-evaluation exercise of feed additives; (iii) new legislation related to the distinction between feed and feed materials and labelling; and (iv) the EURL experience with verification studies, based on two "real-life" examples. Furthermore, participants were updated on two CEN projects, which resulted in standard methods for coccidiostats – for Semduramicin and Decoquinate. Additionally, the issue of phytase analysis was discussed and the possibility to co-ordinate a new ring trial with low levels of phytase activity in various matrices (incluiding premixtures) was raised. Finally, the the future priorities of EURL-FA were outlined.

Due to the re-evaluation exercise there was a sharp increase in the number of evaluations in 2010. In this context, the support from the NRLs is fundamental, both in the reviewing process and in the drafting the evaluation reports. In order to be prepared to evaluate the many dossiers to come, the EURL organised a training seminar for Rapporteurs in January 2010.

The workshop also hosted a discussion on the frequent comments from NRLs regarding the unavailability of methods for certain matrices (feedingstuffs, water) and when no limits are specified (i.e. vitamins). NRLs were encouraged to inform the EURL about which analytical methods are needed for official control "in the field". A final topic concerned probiotics and the suggestion of German colleagues to use the VDLUFA method instead of CEN methods. It was advised that NRLs should contact the relevant CEN committee.

The workshop was concluded by awarding three certified Rapporteurs, having successfully attended the training and having prepared FAD reports according to the EURL requirements. The awardees were Gabrijela Tavčar–Kalcher (VF-UNI-LJ, SLO), Erik Nordkvist (SVA, SE) and Korol Waldemar (CLPP-PL).

EURL-FA Workshop 2011 - Executive Summary *(by D. Mitić)*

The 11th Workshop of the EURL was organised by the IRMM in Brussels on 10 September 2011. A total of thirty-two participants, representing 24 National Reference Laboratories (NRLs), DG SANCO and the EURL were present.

The EURL-FA 2011 activities were reviewed focusing on the increase in evaluated dossiers (72 final reports delivered to EFSA). Participants were updated about

(i) on-going and future DG SANCO activities in the area of feed and the preparation of the new feed catalogue;

(ii) the state of the ongoing re-evaluation exercise with special emphasis on non-holder specific applications;

(iii) the proposal of Leipzig NRL (DE) to improve CEN methods or consider VDLUFA methods for official control for probiotics in feed; and

(iv) on-going plans to improve and standardize outsourcing of drafting reports by NRLs.

Due to the sharp increase in the number of evaluations in 2011 and the expected similar trend in 2012, the EURL will outsource more dossiers. Therefore, there will be a need for a larger number of Rapporteurs. Participants were invited to voice their opinion on the subject of "pre-filled reports" and to suggest efficient ways on how to identify rapporteurs when reports are to be outsourced.

Two additional issues were discussed related to (a) the use of bacteriophages as possible feed additives and (b) the organisation of a ring-trial for the Optiphos phytase in order to compare the results obtained by the single laboratory validated method submitted by the Applicant to those obtained using the EN ISO 30024 method.

The last presentation outlined the EURL priorities for 2012. It was agreed that the 2012 workshop would be organised and hosted by the Slovenian National Reference Laboratory of the Veterinary Faculty of the University of Ljubljana, in collaboration with the EURL.

The workshop was concluded by awarding four certificates to the NRLs that contributed most to the review process (in alphabetical order): AT-AGES, DK-PD, IT-CReAA and CZ-UKZUZ.

Acknowledgment

We sincerely thank our colleagues of the JRC IRMM for their strong support and interest in the EURL-FA activities, both with regards to secretarial support, review of reports and development of tailor made systems. We would like to acknowledge the efforts and excellent collaboration with the Mail services and the Resource Management Geel (former Management Support Unit).

We are also very grateful to all experts from the NRLs for contributing to the evaluation of the dossiers and to the discussions in the workshops which was indispensable for the successful operation of the evaluation procedure. The list of NRLs is provided hereafter.

Finally we would like to wish all the best to the colleagues that left the EURL team: Giuseppe Simone; Hilde Nys; Gerhard Buttinger and Roberto Molteni. Their valuable contribution was essential to the successful activity of the EURL.

The EURL-FA Network Map

(updated 30 Oct. 2012)

The list of NRLs of the network

Country	National Reference Laboratory
	- Federaal Laboratorium voor de Voedselveiligheid Tervuren (FLVVT – FAVV), Tervuren. 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
	- Fødevarestyrelsen, Ringsted. DK
	- Schwerpunktlabor Futtermittel des Bayerischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim. DE - Landwirtschaftliches Untersuchungs- und Forschungsanstalt (LUFA) Speyer, Speyer. DE - Sächsische Landesanstalt für Landwirtschaft. Fachbereich 8 – Landwirtschaftliches Untersuchungswesen, Leipzig. 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 i Pesca, Generalitat de Catalunya, Cabrils. ES
	- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes. FR
	- The State Laboratory, Kildare. IE
	- Istituto Superiore di Sanità. Dipartimento di Sanità alimentare ed animale, Roma. IT - Centro di referenza nazionale per la sorveglienza ed il controllo degli alimenti per gli animali (CReAA), Torino. IT

Country	National Reference Laboratory
	- Feedingstuffs Analytical Laboratory, Department of Agriculture, Nicosia. CY
	- Valsts veterinārmedicīnas diagnostikas centrs (VVMDC), Riga. LV
	- Nacionalinis maisto ir veterinarijos rizikos vertinimo institutas, Vilnius. LT
	- Laboratoire de Contrôle et d'essais – ASTA, Ettelbruck. LU
	- Mezőgazdasági Szakigazgatási Hivatal Központ, Élelmiszer- és Takarmány-biztonsági Igazgatóság, Takarmányvizsgáló Nemzeti Referencia Laboratórium, Budapest. HU
	- RIKILT- Instituut voor Voedselveiligheid, Wageningen. NL
	- LabNett AS, Agricultural Chemistry Laboratory, Stjørdal. NO
	- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien. AT
	- Instytut Zootechniki w Krakowie. Krajowe Laboratorium Pasz, Lublin. PL - Państwowy Instytut Weterynaryjny, Pulawy. PL
	- Instituto Nacional dos Recursos Biológicos, I.P./Laboratório Nacional de Investigação Veterinária (INRB,IP/LNIV), Lisboa. PT
	- Univerza v Ljubljani. Veterinarska fakulteta. Nacionalni veterinarski inštitut. Enota za patologijo prehrane in higieno okolja, Ljubljana - Kmetijski inštitut Slovenije, Ljubljana. SL
	- Skúšobné laboratórium - Oddelenie analýzy krmív, Ústredný kontrolný a skúšobný ústav poľnohospodársky, Bratislava. SK
	- Elintarviketurvallisuusvirasto/Livsmedelssäkerhetsverket (Evira), Helsinki/Helsingfors. FI
	- Foderavdelningen, Statens Veterinärmedicinska Anstalt (SVA), Uppsala. SE
	- The Laboratory of the Government Chemist, Teddington. UK
EURL European Union Reference Laboratory Feed Additives	* European Commission, Joint Research Centre, Institute for Reference Materials and Measurements. EU

Annex I

List of EURL FAD reports

issued in 2010 – 2011

(listed in anti-chronological order)

Full reports available on the EURL-FA website
http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/

FAD Nr	Product Name	Active Substance(s)	Published on	NRL
in 2011				
2010-0078	Propyl Gallate	Propyl Gallate	09/12/2011	
2011-0029	Fecibiol & Fecibiol Plus	Enterococcus faecium CECT 4515; Bacillus amyloliquefaciens CECT 5940	06/12/2011	UKSUP
2011-0002	Toxfin Dry	Bentonite-Montmorillonite; Sepiolite	25/11/2011	
2010-0304	Vitamin B2	Riboflavin; Riboflavin 5'-phosphate ester monosodium salt	25/11/2011	AGES
2010-0144 2010-0225	L-Carnitine Group	L-Carnitine; L-Carnitine L-tartrate	25/11/2011	
2010-0188 2010-0303 2010-0312	SANCO Group Formic salts	Ammonium formate; Sodium formate; Potassium diformate; Calcium formate	25/11/2011	
2010-0405	Probiomix	Lactobacillus plantarum KKP 593/p; Lactobacillus rhamnosus KKP 825	10/11/2011	
2010-0127 2010-0252 2010-0259 2010-0280	10 microorganisms for silage (part 2)	7 Pediococci; 3 Lactobacilli	08/11/2011	
2010-0123	Tannic acid	Tannic acid	07/11/2011	
2010-0174 2010-0216 2010-0253	SANCO Group Betaine	Betaine; Betaine anhydrous	28/10/2011	
2008-0048	Canthaxanthine	Canthaxanthine	28/10/2011	
2010-0358	E141 Copper complex chlorophills	E141 Copper complex chlorophills	28/10/2011	
2010-0254	Methionine Zinc	Methionine Zinc	28/10/2011	
2010-0059 2010-0063 2010-0072 2010-0142 2010-0228	SANCO Group Zinc	Zinc Acetate dihydrate; Zinc Chloride anhydrous; Zinc Oxide; Zinc Sulphates mono and hepta-hydrate; Zinc chelates of amino acids hydrate; Zinc chelates of glycine hydrate	28/10/2011	
2010-0202 2010-0203 2010-0204	Iron Oxides	Iron Oxide (Black, Red, Yellow)	25/10/2011	
2010-0112 2010-0198 2010-0263 2010-0265 2010-0307	SANCO Group Niacine	Niacine; Niacinamide; Nicotineamide; Vitamine B3	28/09/2011	
2010-0154 2010- 0187 2010-0357	SANCO Group Citrate	Citric acid; tripotassium citrate; trisodium citrate dihydrate	19/09/2011	
2010-0348	Carmoisine	Carmoisine	19/09/2011	
2010-0347	Allura Red	Allura Red	19/09/2011	
2010-0268 2011-0011	Orthophosphoric acid	Orthophosphoric acid	16/09/2011	
2010-0143	Malic acid	Malic acid	14/09/2011	
2010-0197	Folic acid	Folic acid	16/09/2011	
2010-0222 2010-0399	Formaldehyde	Formaldehyde	05/09/2011	
2010-0033 2010-0048 2010-0084 2010-0085 2010-0086 2010-0087 2010-0102 2010-0103 2010-0106 2010-0108	FAD-2010-0110 FAD-2010-0169 FAD-2010-0170 FAD-2010-0171 FAD-2010-0172 FAD-2010-0176 FAD-2010-0192 FAD-2010-0240 FAD-2010-0278 FAD-2011-0001	(45 microorganisms for silage) 39 lactococci; 2 lactobacilli; 2 pediococci; 1 bacillus; 1 saccharomyces	02/09/2011	

FAD Nr	Product Name	Active Substance(s)	Published on	NRL
2010-0352	Brown HT	Brown HT	08/08/2011	
2010-0233	Bentonite - Montmorillonite	Bentonite - Montmorillonite	08/08/2011	
2010-0382	Erythrosine	Erythrosine	08/08/2011	
2010-0346	Indigo Carmine	Indigo Carmine	08/08/2011	
2010-0224	Apoester	Ethyl ester of beta-apo-8'-carotenoic acid	26/07/2011	
2010-0267	Bixin	Norbixin potassium	12/07/2011	
2010-0200	Vitamin A	All- E -Retinol (Acetate, Palmetate, Propionate)	12/07/2011	
2010-0037 2010-0242	Ammonium chloride	Ammonium Chloride	04/07/2011	
2010-0376 2010-0356	Propionic acid & salts + E700	propionic acid; sodium-propionate; calcium-propionate; ammonium-propionate; sodium benzoate	04/07/2011	
2010-0079	Suilectin	Kidney bean lectin (Phaseolus vulgaris)	04/07/2011	
2010-0029	VevoVitall®	Benzoic acid	04/07/2011	
2010-0189	Rovabio (R) Excel AP & LC	Endo-1,3(4)-β-glucanase ; Endo-1,4-β-xylanase	01/07/2011	PL
2010-0407	Carophyll Red 10 %		30/06/2011	
2011-0007	Tetra-basic zinc chloride	Zinc chloride hydroxide hydrate (TBZC)	16/06/2011	
2010-0292	Origanum heracleoticum L.	oregano essential oil	14/06/2011	
2010-0008	Optiphos	6-phytase	18/05/2011	
2010-0261	L-Cystine	L-Cystine	06/05/2011	
2010-0260	L-Tyrosine	L-Tyrosine	06/05/2011	
2011-0004	Lactobacillus plantarum	Lactobacillus plantarum E-98 NCIMB 30236	06/05/2011	
2010-0251	Melissa Officinalis dry extract	Melissa Officinalis dry extract	06/05/2011	
2010-0056	L-Tryptophan	L-Tryptophan	03/05/2011	
2010-0046	Tribasic copper chloride	Di copper chloride tri hydroxide (TBCC)	02/05/2011	
2010-0161	SANCO Group acetates	acetic acid; calcium acetate; sodium diacetate	28/04/2011	
2010-0034	Natugrain TS	Endo-1,4-β-xylanase; Endo-1,4-β-glucanase	27/04/2011	
2010-0209	Lignosulphonate	Lignosulphonate	19/04/2011	
2010-0145 2010-0193	SANCO group sorbates	Sorbic Acid; Potassium sorbate	18/04/2011	
2010-0217	Disodium inosine guanosine	Disodium inosine guanosine	15/04/2011	
2010-0058 2010-0081	L-Threonine	L-Threonine	15/04/2011	
2010-0129	Naringin	Naringin	15/04/2011	
2010-0158	Neohesperidine dihydrochalcone	Neohesperidine dihydrochalcone	15/04/2011	
2010-0138	Thaumatin	Thaumatin	15/04/2011	
2010-0157	Sodium saccharin	Sodium saccharin	11/04/2011	
2010-0139	Vitamin B6	Pyridoxine Hydrochloride	31/03/2011	
2010-0100	Biotin	D-(+)-Biotin	29/03/2011	
2010-0168	Lactobacillus buchneri	Lactobacillus buchneri DSM 22963	22/03/2011	
2010-0117	CDG 28	Chemically defined flavourings	18/03/2011	
2010-0116	CDG 29	Chemically defined flavourings	18/03/2011	
2010-0107	CDG 34	Chemically defined flavourings	18/03/2011	
2010-0067	Lysine	Lysine (conc., HCl, sulphate)	18/03/2011	
2010-0113	Urea, technically pure	Urea	18/03/2011	
2009-0029 2010-0044	Sel-Plex®2000 and Selenomethionine	Selenomethionine	08/03/2011	
2010-0109	Lactobacillus plantarum	Lactobacillus plantarum DSM 21762	28/02/2011	
2010-0125	CDG 08	Chemically defined flavourings	22/02/2011	
2010-0119	CDG 13	Chemically defined flavourings	22/02/2011	
2010-0118	CDG 14	Chemically defined flavourings	22/02/2011	
2010-0093	Crina Poultry plus	Benzoic Acid; Thymol; Eugenol; Piperine	16/02/2011	
2010-0115	Glycyrrhizic acid, ammoniated	Glycyrrhizic acid, ammoniated	11/02/2011	
2010-0036	Optimun	Nucleotides (adenine, cytosine, guanine, thymine, uracil and purified RNA)	07/02/2011	

FAD Nr	Product Name	Active Substance(s)	Published on	NRL
2010-0099	Vitamin K3	Menadione Sodium Bisulphite ; Menadione Nicotinamide Bisulphite	07/02/2011	
2010-0062	Hostazym C	Endo-1,4-beta-glucanase	03/02/2011	
2010-0032	Biomax	Lactococcus Lactis DSM 11037	27/01/2011	
2010-0040	Vitamin B1	Thiamine mononitrate & Thiamine hydrochloride	24/01/2011	
2010-0074	CDG 05	Chemically defined flavourings	21/01/2011	
2010-0089	CDG 11	Chemically defined flavourings	21/01/2011	
2010-0075	CDG 21	Chemically defined flavourings	21/01/2011	
2010-0076	CDG 22	Chemically defined flavourings	21/01/2011	
2010-0082	CDG 33	Chemically defined flavourings	21/01/2011	
2010-0051	InteSwine	Saccharomyces cerevisiae NCYC R-625	21/01/2011	
2010-0030 2010-0073	Pantothenic acid	Calcium-D-Pantothenate; D-Panthenol	21/01/2011	
in 2010				
2010-0038	Actisaf Sc 47	Saccharomyces cerevisiae (NCYC Sc47)	17/12/2010	
2010-0064	CDG 12	Chemically defined flavourings	10/12/2010	
2010-0065	CDG 17	Chemically defined flavourings	10/12/2010	
2010-0053	CDG 24	Chemically defined flavourings	10/12/2010	
2010-0054	CDG 26	Chemically defined flavourings	10/12/2010	
2010-0010	Clinacox (R) 0.5%	Diclazuril	08/12/2010	
2010-0066	Biomin MTV	Trichosporon mycotoxinivorans DSM 14153	06/12/2010	
2010-0049	Vitamin B2	Riboflavin	23/11/2010	LNIV
2010-0041	CDG 04	Chemically defined flavourings	12/11/2010	
2010-0042	CDG 16	Chemically defined flavourings	12/11/2010	
2010-0043	CDG 20	Chemically defined flavourings	12/11/2010	
2010-0047	CDG 27	Chemically defined flavourings	12/11/2010	
2009-0022	Lactiferm	Enterococcus faecium M&$ NCIMB 11181	10/11/2010	UKSUP
2010-0052	Vitamin B1	Thiamine (mononitrate) - (VITAC)	09/11/2010	GENCAT
2009-0023	Bioplus 2B	Bacillus subtilis DSM 5750; Bacillus licheniformis DSM 5749	29/10/2010	
2009-0035	Coxidin®	Monensin sodium	20/10/2010	
2010-0006	Econase XT L & P	Endo-1,4-beta-xylanase	12/10/2010	
2010-0019	Ronozyme HiPhos M & L	6-Phytase	12/10/2010	
2010-0025	CDG 06	Chemically defined flavourings	30/09/2010	
2010-0026	CDG 10	Chemically defined flavourings	30/09/2010	
2010-0027	CDG 15	Chemically defined flavourings	30/09/2010	
2010-0028	CDG 23	Chemically defined flavourings	30/09/2010	
2010-0024	Choline Chloride	Choline Chloride	21/09/2010	
2009-0062 2010-0011	AveMix XG10	Endo-1,4-beta-xylanase; Endo-1,3(4)-beta-glucanase	16/09/2010	
2010-0018	Mycofix(R)Secure	Bentonite (Dioctahedral Montmorillonite)	15/09/2010	
2010-0021	CDG 18	Chemically defined flavourings	09/09/2010	
2010-0022	CDG 31	Chemically defined flavourings	09/09/2010	
2010-0001	Hostazym X	Endo-1,4-beta-xylanase	02/09/2010	AGES
2010-0009	Ronozyme RumiStar (CT) (L)	alfa-amylase	02/09/2010	
2009-0015	Endofeed	Endo-1,3(4)-beta-glucanase , Endo-1,4-beta-xylanase	25/08/2010	
2009-0041	Ecobiol	Bacillus amyloliquefaciens CECT 5940	17/08/2010	
2009-0060	Cylactin LBC / Cernivet LBC	Enterococcus faecium NCIMB 10415	16/08/2010	PL
2009-0057	Fecinor / Fecinor plus	Enterococcus faecium CECT 4515	16/08/2010	
2010-0015	CDG 01	Chemically defined flavourings	11/08/2010	
2010-0013	CDG 02	Chemically defined flavourings	11/08/2010	
2009-0014	Biogalactosidase BL AlphaGal BL	Endo-1,4-beta-glucanase; alpha-galactosidase	09/08/2010	NRIAP
2009-0054	Astaxanthin	Astaxanthin	02/08/2010	
2009-0006	Avizyme 1505	Endo-1,4-beta-xylanase; alpha-amylase; Subtilisin	30/07/2010	
2009-0017	Clinoptilolite (E 568)	Clinoptilolite of sedimentary origin	14/07/2010	
2009-0059	GalliProTect GalliPro Tect WS	Bacillus licheniformis DSM 17236	14/07/2010	

FAD Nr	Product Name	Active Substance(s)	Published on	NRL
2010-0007	Danisco Glycosidase TPT and Danisco Glycosidase L	Endo-1,4-beta-xylanase; Endo-1,3(4)-beta-glucanase	29/06/2010	
2009-0036	Taminizer D	Dimethylglycine sodium salt	24/06/2010	
2010-0005	Miya-Gold R EU	Clostridium butyricum MIYAIRI 588	22/06/2010	
2008-0053 2009-0058	Clinacox (R) 0.5%	Diclazuril	14/06/2010	
2009-0038	Danisco Xylanase L & G	Endo-1,4-beta-xylanase	09/06/2010	
2009-0037	Prostora Max	Bifidobacterium animalis AHC7	07/06/2010	
2009-0046	Beta Carotene	Beta Carotene	31/05/2010	LNIV
2009-0050	CDG 25	Chemically defined flavourings	25/05/2010	
2009-0027	Formic Acid	Formic acid	21/05/2010	CISTA
2009-0045	Vitamin B6	Pyridoxine Hydrochloride	10/05/2010	GENCAT
2009-0049	Sodium Bisulphate	Sodium bisulphate (SBS)	04/05/2010	CReAA
2009-0034	Biomin C3	Bifidobacterium animalis spp. animalis DSM 16284; Enterococcus faecium DSM 21913; Lactobacilus salivarius spp. salivaarius DSM 16351	26/04/2010	
2008-0020	Biomin® IMB 52	Enterococcus faecium DSM 3530	23/04/2010	
2009-0007	PepSoyGen-C	Bacillus subtilis GR-101; Aspergillus oryzae GB-107	23/04/2010	
2009-0056	Cassia gum	Polygalactomannan	21/04/2010	
2009-0044	Kemtrace Zn	Zinc propionate	20/04/2010	
2009-0010	SelenoSource AF2000	Selemized yeast produced by Saccharomyces cerevisiae NCYC R645	06/04/2010	
2009-0055	Fresta®F	Carvone	30/03/2010	SVA
2009-0025	Bactocell PA 10 Fermaid PA 10	Pediococcus acidilactici CNCM MA 18/5M	16/03/2010	
2008-0051	Cygro 10G	Maduramicin ammonium	11/03/2010	
2009-0011	Monteban	Narasin	08/03/2010	
2009-0012	Ronozyme P20000 L	6-Phytase	03/03/2010	
2009-0003	Ronozyme NP (CT, L, M)	6-Phytase	17/02/2010	
2008-0058	Biosprint	Saccharomyces Cerevisiae MUCL39885	04/02/2010	
2008-0050	Avatec® 150G	Lasalocid sodium	03/02/2010	
2009-0028	Biosprint	Saccharomyces Cerevisiae MUCL39885	03/02/2010	
2008-0047	Vitamin E	all-rac-alfa-tocopheryl acetate; RRR-alpha-tocopheryl acetate; RRR-alpha-tocopherol	01/02/2010	VFUNILJ
2009-0024	Pediococcus pentosaceus	Pediococcus pentosaceus DSM 16244	22/01/2010	CReAA

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Annex II

Forms related to the sample registration

- Sample Validity Check (F-0347) *
- Labels for reference SAMPLES (F-0348) *
- Labels for reference STANDARDS (F-0349) *
- Valid Sample Acknowledgment of Receipt, VSAR (F-0071)
- Letter - Request for replacement samples (F-0336)

(*) Forms available on the EURL-FA website - finalised on 27/07/2011
http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/guidance_for_applicants/

Samples Validity Checklist

Contact information

Applicant
Contact person
Street
ZIP – City, Country
Telephone
Fax
e-mail

Product information

Additive name
Trade name (if appropriate)
EURL sample number (for replacement samples only)
Sufficient quantity ☐ Tamper-proof closure ☐
Shipping conditions (temperature)
Specify Storage temperature

Documents provided

Tick relevant box

- Certificate of analysis ☐
- Material Safety Data Sheet (MSDS) ☐
- Proper labels ☐
- Letter of access to culture collection (for μ-organisms) ☐
- Copy of the Application Form sent to DG SANCO (signed and/or submission number on it) – for new samples only ☐
- Public summary of the technical dossier - for new samples only ☐
- Scientific summary of the technical dossier - for new samples only ☐

I hereby certify that the above information is correct as of the date of signing

....

date *signature*

Labels for Reference SAMPLES

Please provide the relevant information

Name of the additive	
Name of the applicant	
Address of the applicant	
Specific name of active components	
Physical state	
Net weight-volume/container	
Directions/Conditions for use	
Safety recommendations, if any	
Storage conditions	
Identification number, if any	
Batch reference number	
Manufacturing date	
Expiry date	
Concentration or activity (enzyme) or c.f.u. (μ-org)	
Units	
I.U.B. identification number (enzyme)	
Specific name of the enzyme	
Strain identification number (μ-org)	
Incorporation in premixtures (flavour)	

Labels for Reference STANDARD

Please provide the relevant information

Name of the active agent	
Name of the producer	
Address of the producer	
Net weight-volume/container	
Safety recommendations, if any	
Storage conditions	
Batch reference number	
Manufacturing date	
Expiry date	
Concentration or activity (enzyme) or c.f.u. (μ-org)	
Units	

EUROPEAN COMMISSION

JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements
European Union Reference Laboratory for Feed Additives

European Union Reference Laboratory
Feed Additives

JRC.D.5/CvH/ag/Ares (2012)
Geel, xxxxxx

Contact person
«Applicant»
«Street»
«Zipcode_City»
«Country»

Subject: **Valid Samples Acknowledgment of Receipt (VSAR)**
Reference: **CRL/xxxx**

Dear «Contact_person»,

The EURL-FA hereby acknowledges receipt of your samples of <<Sample_name>>. The samples are considered **VALID** and have been registered with the following EURL Sample Number **<<Sample_Number>>.**

You are requested to:

1. keep this document for future reference;
2. retain the EURL Sample Number (required for future applications related to the same feed additive) and
3. monitor the Expiry Date in order to supply replacement samples on time, in accordance with Article 3 (3) of Regulation (EC) No. 378/2005. as last amended by Regulation (EC) No 885/2009.

Please provide the missing documentation (selected below) at your earliest convenience:

- ☐ Copy of the Application form sent to DG SANCO
- ☐ Letter of access to culture collection (for micro-organisms)
- ☐ Public summary of the technical dossier
- ☐ Scientific summary of the technical dossier

Thank you for your collaboration.
Yours Sincerely,

Sample labels

Christoph von Holst
EURL-FA Operating Manager

Cc.: DG SANCO, EFSA

EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Reference Materials and Measurements
European Union Reference Laboratory for Feed Additives

European Union Reference Laboratory
Feed Additives

JRC.D.5/CvH/ag/Ares (2012)
Geel, xx/xx/xxxx

«Contact_person»
«Applicant»
«Street»
«Zipcode_City»
«Country»

Subject: **Request for Replacement Samples**
Reference: **«Sample_name»**

Dear «Contact_person»,

I would like to inform you that your samples of **«Sample_name»**, (CRL Sample Number **«Sample_number»)** deposited at the EURL-FA in accordance with Article 7.3 (F) of Regulation (EC) No 1831/2003 have expired.

As provided for in Article 3(3) of Regulation (EC) No 378/2005, as last amended by Regulation (EC) No 885/2009 "*The applicant shall maintain the reference samples valid for the entire period of the authorisation of the feed additive by supplying new reference samples to the CRL to replace those expired*".

You are kindly requested to send replacement samples to the EURL-FA.

The following documents are required:

- Sample Validity Checklist (F-0347)[1]
- Certificate of Analysis
- Proper labels (F-0348)[1]
- Up-to-date MSDS

Before sending the samples, please consider:

a) whether you could extend the expiry date of the samples currently stored at the EURL-FA instead of sending replacement samples – your mail reply specifying the new expiry date will be sufficient;

b) contacting the EURL when each sample container will be larger than 1L or will contain more than 300 g of product;

c) specifying a storage temperature different from (or lower then) the one used for transport, in order to extend the expiry date (i.e. sent at room temperature & to be stored at +4 or -30 ^{o}C). Please provide the relevant information (storage temperature and expiry date) in your cover (accompanying) letter.

Please note that non compliant samples and/or documentation will be discarded and you will be requested to send new samples and/or documentation.

Should you have any questions, do not hesitate to contact us.

Thank you for your collaboration

Yours Sincerely,

Christoph von Holst
EURL-FA Operating Manager

[1] http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/guidance_for_applicants/

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Office:2440 Geel - Belgium Retieseweg, 111. email: JRC-IRMM-CRL-FEED-ADDITIVES@ADDITIVES@ec.europa.eu

European Commission
JRC76376 – Joint Research Centre – Institute for Reference Materials and Measurements

Title: **Activity report 2010-2011 of the European Reference Laboratory for Feed Additives - Authorisation**

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Abstract

The activities of the EURL Feed Additive – Authorisation are presented for 2010 and 2011. The implementation of simplified processes allowed the successful approval of 374 declaration forms, the accurate registration of 1700 reference samples and the publication of 156 reports. In addition one workshop of the EURL network was organised every year.

As the Commission's in-house science service, the Joint Research Centre's mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle.

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