National Reference Laboratory for Feed Additives

End of Year Report 2021 - 2022

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1. Introduction

Retained EU Regulation No. 1831/2003 on *additives for use in animal nutrition* describes 'feed additives' as substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions:

(a) favourably affect the characteristics of feed,
(b) favourably affect the characteristics of animal products,
(c) favourably affect the colour of ornamental fish and birds,
(d) satisfy the nutritional needs of animals,
(e) favourably affect the environmental consequences of animal production,
(f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or
(g) have a coccidiostatic or histomonostatic effect.

Feed additives should not:

(a) have an adverse effect on animal health, human health or the environment,
(b) be presented in a manner which may mislead the user,
(c) harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products.

Antibiotics, other than coccidiostats or histomonostats, are not authorised as feed additives.

Depending on their functions and properties feed additives are allocated to one or more of the categories listed in Article 6 of Regulation (EC) No 1831/2003. The categories are:

(a) technological additives: any substance added to feed for a technological purpose;
(b) sensory additives: any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals;

(c) nutritional additives;
(d) zootechnical additives: any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment;
(e) coccidiostats and histomonostats.

Technological additives, sensory additives, nutritional additives and zootechnical additives have sub-divisions of functional groups to which the feed additives are allocated, as applicable.

- In the category ‘technological additives’, the following functional groups are included:
  (a) preservatives: substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites;
  (b) antioxidants: substances prolonging the storage life of feedingstuffs and feed materials by protecting them against deterioration caused by oxidation;
  (c) emulsifiers: substances that make it possible to form or maintain a homogeneous mixture of two or more immiscible phases in feedingstuffs;
  (d) stabilisers: substances which make it possible to maintain the physico-chemical state of feedingstuffs;
  (e) thickeners: substances which increase the viscosity of feedingstuffs;
  (f) gelling agents: substances which give a feedingstuff texture through the formation of a gel;
  (g) binders: substances which increase the tendency of particles of feedingstuffs to adhere;
  (h) substances for control of radionuclide contamination: substances that suppress absorption of radionuclides or promote their excretion;
  (i) anticaking agents: substances that reduce the tendency of individual particles of a feedingstuff to adhere;
  (j) acidity regulators: substances which adjust the pH of feedingstuffs;
  (k) silage additives: substances, including enzymes or micro-organisms, intended to be incorporated into feed to improve the production of silage;

(l) denaturants: substances which, when used for the manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed materials;

(m) substances for reduction of the contamination of feed by mycotoxins: substances that can suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action;

(n) hygiene condition enhancers: substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination;

(o) other technological additives: substances or, when applicable, microorganisms added to feed for a technological purpose and which favourably affect the characteristics of the feed.

- In the category 'sensory additives', the following functional groups are included:

  (a) colourants:

  (i) substances that add or restore colour in feedingstuffs;

  (ii) substances which, when fed to animals, add colours to food of animal origin;

  (iii) substances which favourably affect the colour of ornamental fish or birds;

  (b) flavouring compounds: substances the inclusion of which in feedingstuffs increases feed smell or palatability.

- In the category 'nutritional additives', the following functional groups are included:

  (a) vitamins, pro-vitamins and chemically well-defined substances having similar effect;

  (b) compounds of trace elements;

  (c) amino acids, their salts and analogues;

  (d) urea and its derivatives.

- In the category ‘zootechnical additives’, the following functional groups are included:
  (a) digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials;
  (b) gut flora stabilisers: micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora;
  (c) substances which favourably affect the environment;
  (d) other zootechnical additives;
  (e) physiological condition stabilisers: substances or, when applicable microorganisms, which, when fed to animals in good health, favourably affect their physiological condition, including their resilience to stress factors.

Feed additives play an important role in animal nutrition, addressing various aspects such as feed safety, reduction of environmental emissions and sustainability in livestock farming. As feed additives are regulated products, following Great Britain’s exit from the EU all new feed additives are required to be authorised by the FSA/FSS before they can be used in GB. Feed additives that are currently approved for use in the EU can continue to be used in GB but will need to go through the GB risk analysis process when their current authorisation expires. Guidance on the authorisation process for feed additives can be found on the FSA website at: https://www.food.gov.uk/business-guidance/regulated-products/feed-additives-guidance. The register of feed additives which lists the feed additives permitted for use in GB can also be found on the FSA’s website at https://data.food.gov.uk/regulated-products.

LGC currently holds the role of National Reference Laboratory (NRL) for feed additives for Great Britain. The tasks and objectives for the feed additive NRL are as follows:

Part 1: NRL Core function

Objective 1. Secretariat services

(a) disseminating relevant information/advice to the CA, when required, Official Laboratories (OLs) and other relevant laboratories in a timely and effective manner;
(b) co-ordinating the activities of OLs and other relevant laboratories in food in relation to the core functions described below;
(c) creating and maintaining an efficient two-way channel of communication with OLs and relevant laboratories and international organisations, including information on analytical methods and relevant legislation;
(d) providing regular updates to the CA on NRL activities, and up-to-date information on UK OLs and other relevant laboratories to the CA as requested;
(e) creation and maintenance of a dedicated website for communication of the work of the NRL including provision of advice and support to OLs, information on methods of analyses, Standard Operating Procedures (SOPs), latest developments and other background information.

Objective 2. Advice and representation within the UK and internationally
(a) providing impartial expert advice as requested to the CA, OLs and other relevant laboratories on analytical methodology in the context of official controls and risk assessment;
(b) representing the UK at relevant international meetings, and working groups, consulting the CA on objectives and requirements before each meeting and providing the CA with an internal report of the meeting within 10 working days of each meeting;
(c) participating in activities organised by international organisations and contributing to the scientific input at international meetings and in manner which supports UK policy based on best available scientific knowledge;
(d) advising the CA, OLs and other relevant laboratories on best scientific practice in testing for official controls purposes and undertaking activities in consultation with the CA that facilitate and promote their application in the UK within the policy aims of the CA;
(e) keeping abreast of and advising the CA, OLs and other relevant laboratories of developments for the sampling, testing and detection of feed additives;

(f) identifying and informing the CA, OLs and other relevant laboratories of emerging analytical issues or developments at a national or international level and recommending action to address them;
(g) where appropriate, partake and/or keep abreast of standardisation activities (e.g. CEN, ISO, etc.) relevant to the work area.

Objective 3. Production of standard operating procedures, codes of practice and guidance documents
(a) contributing to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OLs and other relevant laboratories, as requested by the CA.

Objective 4. Compliance assessment via audits and ring trials
(a) ensuring consistency and quality of testing approaches applied by UK OLs and other relevant laboratories, including advising on corrective action following adverse reports on OLs from UKAS;
(b) planning and coordinating proficiency tests for UK OLs and other relevant laboratories as appropriate (taking into account the number of relevant laboratories), analysing and evaluating the outcome, informing the CA and OLs of the results and advising on further action;
(c) co-ordinating the participation of UK OLs and other relevant laboratories in international method validation studies and other initiatives, informing the CA and OLs of the results and advising on further action;
(d) where relevant, participating in proficiency tests and method validation studies organised by international organisations, informing the CA of the results and implementing any corrective measures required;
(e) co-ordinating training exercises to promote best laboratory practice in respect of analysis.

Objective 5. Co-ordination within the UK of international initiatives
(a) where appropriate, co-ordinating the recommendations of international organisations related to the standardisation of testing methods.

Objective 6. Communication of results and data use

(a) ensuring that the CA receives regular updates of any developments related to the core functions of the NRL;

(b) notifying the CA immediately by email of any deviations or significant unexpected situations which may affect the cost, specifications and timing of the annual work programme;

(c) notifying the CA immediately by email of any unusual occurrences resulting from any of the core functions of the NRL;

(d) providing annual reports of work summarising all activities completed as part of their annual work programme, to the CA by 31st March each year. Annual reports will be approved by the CA prior to publication by NRLs on NRL dedicated websites. If requested by the CA, the Contractor may also need to provide interim reports during the annual work programme;

(e) any results or reports arising from the work of the NRL will not be communicated to any external parties without the written permission of the CA;

(f) the use of the data for presentations and/or papers will not be permitted unless written permission has been sought and given by the CA;

(g) maintaining records. Retention periods will be agreed and defined in the contract and if necessary the contractor will assist with transfer of archived reference material;

(h) in other work related to the core functions of the NRL, the specified deadlines agreed between the CA and the Contractor should be met;

(i) if necessary, at the end of the Contract all information and data gained from, and required for, NRL function over the course of the Contract will be handed over to the CA. This will include assisting with transfer of archived reference materials;

(j) providing an internal report of meetings with other organisations within 10 working days of the meeting.

(k) engaging in quarterly dialogues with the CA to review contract management requirements and update on progress against work programme. Informal monthly check-ins with the CA may also be organised to ensure any potential or evolving issues are flagged and work is kept on track;

(l) organising regular network meetings, as appropriate and on at least an annual basis to update their official controls networks and CA on method updates,

enforcement, training and other relevant information issues and to discuss PT programmes and results;

(m) reviewing NRL finances regularly and communicate spending, including a break-down of costs, with the CA on a monthly basis.

Part 2: Feed Additive Regulated Product Authorisation

Objective 1. Infrastructure development

This objective underpins the provision of a support structure to build a resilient base for all feed additive method validation authorisations.

Objective 2. Maintenance of infrastructure

This objective ensures maintenance of competency of core activities in support of the UK authorisation process.

Objective 3. Core authorisation activities

Evaluation of applications as per FSA specification. The evaluation report should be submitted to the FSA within 3 months of receipt of method application and shall include an evaluation indicating if the methods of analysis in the data submitted in the application are suitable to be used for official controls.

This report provides an update for the National Reference Laboratory role for Feed Additives for the year April 2021 to March 2022.

2. Quality and staff competence

The Office of the Government Chemist at LGC, which hosts the feed additives NRL role, has continued to maintain its quality systems to the requirements of ISO17025. Annual assessments carried out by UKAS, together with internal audits, help ensure that quality and accreditation is maintained.

To maintain the ongoing competency of staff, proficiency tests (PTs) are regularly participated in. It is generally accepted that the number of PTs directly relevant to the analysis of feed and feed additives is limited. FAPAS rounds available in 2022 were reviewed and relevant rounds shortlisted. Where possible, rounds involving feed were chosen for participation in 2022 (Table 1) but, in order to cover the

necessary range of analytes / techniques, a significant number of food rounds have also been chosen.

Matrix	Analytes
Animal feed (Cereal based)	Arsenic (total), Cadmium, Lead, Mercury (total), Nickel - all at natural / low levels
Pig ration	Moisture, ash, total oil, protein, vitamin E and zinc
Poultry feed	Coccidiostats and chloramphenicol

Table 1: FAPAS feed PT rounds proposed for participation in 2022

Feed additives cover a very wide range of chemicals / materials / substances, and therefore experience and competency is needed in a wide range of techniques. Table 2 gives examples of the types of analytes included in 2022's PT schedule and the techniques that will be used for each.

Techniques	Example analyses
HPLC-UV	Vitamins
HPLC-FL	Aflatoxins
ICP-OES	Trace elements / nutritional elements
GC-FID	Congeners and fatty acids
GC-MS	PAH
LC-MS	Coccidiostats / chloramphenicol
ELISA	Meat species / allergens
Gravimetric	Moisture, fat
General wet chemistry	Sulphur dioxide, formaldehyde

Table 2: Examples of analytes for inclusion in PT schedule and the relevant techniques

While these rounds will act as a basis for ongoing competency, additional rounds and suppliers will be reviewed throughout the year so that we are aware if any more suitable rounds become available. Alternate suppliers such as LGC AXIO Proficiency Testing, BIPEA Proficiency Testing, France, AAFCO Proficiency Testing, USA and Test Veritas S.r.l, Italy, have been reviewed but no current proficiency tests applicable to feed / feed additives were found that were more suitable than those organised by FAPAS.

It should be noted that while the cost of the directly relevant feed rounds will be attributed to the NRL role, the remaining majority will be funded either directly by LGC or the Government Chemist programme. This enables the widest range of analytes / matrices to be covered in the most cost-effective way to each programme.

Between April 2021 and March 2022 results were reported for 15 FAPAS rounds. 61 of 63 results were classed as satisfactory, i.e. a z-score of less than 2 was obtained or the result was reported as being either ‘satisfactory’ or ‘agrees’.

For the feed samples analysed in 2021, a Z-score of less than 2 was obtained for moisture, ash, oil, protein and zinc in a sample of pig ration. The z-score for vitamin E was slightly above 2 (2.1) however the z-score was calculated by FAPAS based on an assigned value of the median of the results submitted. Of the seven results submitted by participants one was significantly lower than the others (15.3 compared to a mean of 55.43) which skewed the assigned value downwards leading to higher than expected z-scores for the remaining participants.

FAPAS sample 02446 poultry feed was analysed for coccidiostats, however, in line with our quality procedures, the results were not submitted as the quality controls did not meet the acceptance criteria. The analysis will be investigated and repeated.

3. Horizon scanning

The Rapid Alert System for Food and Feed (RASFF) is reviewed monthly to try and detect trends and help identify possible future issues. The product categories reviewed are: feed additives, feed materials, feed premixtures, compound feed and pet food. In the eleven months April 2021 to February 2022 there were 217 RASFF notifications for the above categories. 39 % (84) of the notifications related to Salmonella in products such as frozen pet food, fish meal, soybean meal, rapeseed meal and feeder mice. The next highest category was for the presence of ragweed (*Ambrosia spp*.) with 7 % (16) notifications, predominantly in sorghum and sunflower seeds. Table 3 gives the reasons for all 217 notifications.

Reason for recall	Number of recalls											
	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct - 21	Nov-21	Dec-21	Jan-22	Feb-22	Total
Salmonella	10	10	7	7	7	13	9	5	4	6	6	84
Ragweed (Ambrosia spp.)	1		1			2	4	1	5		2	16
Unauthorised additives		2	2	3	1	1	2	1		3		15
Mould / Bacteria / Clostridium		3		1	2			4	1		1	12
Pesticides		1	3	2		1	1			1	1	10
Arsenic / Cadmium / Lead / Mercury / Selenium				1	2	3	1	1			1	9
Foreign bodies / Splinters			2	1				2	3	1		9
Aflatoxin		2		1	1			1		2	1	8
Enterobacteriaceae				1	1		1	2		1	2	8
Ruminant DNA			1			1			3	1		6
Cyanide		1	1	1	1					1		5
Ethylene oxide				1		1	1			1		4
Veterinary drugs - Sulfadimidine / Tetracycline / Phenoxymethylpenicillin	1								2		1	4
Canthaxanthin	2	1										3
Dioxins					3							3
GMO				1	2							3
Zinc, copper, manganese			2	1								3
Coccidiostats - Narasin / Salinomycin						1		1				2
Metal particles / Metal										1	1	2
Matrine, Amitraz and Pyrrolizidine Alkaloids / Quinolizidine alkaloids									1	1		2
Antibiotic resistant genes				1								1
Outbreak of feline pancytopenia			1									1
PCBs		1										1
Polycyclic aromatic hydrocarbons									1			1
Processed animal protein	1											1
Rye ergot											1	1
Toxins					1							1
Zinc and monensin						1						1
Incorrect quality										1		1
Total	15	21	20	22	21	24	19	18	20	20	17	217

Table 3: RASFF notifications involving feed additives, feed materials, feed premixtures, compound feed and pet food in the 11 months from April 2021 to February 2022

During the 11 months reviewed there were 15 RASFF notifications relating to the presence of unauthorised feed additives. These notifications are summarised in Table 4.

	Number of recalls											
Unauthorised additives	**Apr-21**	**May-21**	**Jun-21**	**Jul-21**	**Aug-21**	**Sep-21**	**Oct-21**	**Nov-21**	**Dec-21**	**Jan-22**	**Feb-22**	**Total**
Not stated		1					1			1		3
Colours			1	1	1							3
CBD		1										1
Cobalt			1									1
Sulphur, inositol				1								1
Picea mariana oil				1								1
Ethoxyquin						1						1
Wood and lufa material							1					1
Co-enzyme Q10								1				1
Cobalt carbonate, cobalt carbonate hydroxide monohydrate										1		1
Astaxanthin										1		1
Total	0	2	2	3	1	1	2	1	0	3	0	15

Table 4: Unauthorised feed additive RASFF notifications from April 2021 to February 2022

In the period April 2021 to February 2022 there was one RASFF notification relating to CBD in various products from the USA designed for pets. The notification was recorded as an unauthorised feed additive on the RASFF system however it should be noted that in Great Britain the Veterinary Medicines Directorate (VMD) consider that 'veterinary products containing cannabidiol (CBD) are veterinary medicines and should be regulated as such'.

No significant trends were identified from the RASFF notifications.

4. Standardisation activities

Kirstin Gray was nominated as a UK expert on CEN/TC 327/WG3 "Feed additives and drugs", a group on which the UK was unrepresented. Members of the UK mirror group to CEN/TC 327, AW/10, were surveyed and had no objections to this appointment.

A meeting of CEN/TC 327/WG3 "Feed additives and drugs" was held on 18th January 2022. The online meeting was to discuss comments received on prEN 17697 'Animal feeding stuffs: Methods of analysis - PFGE typing of *Lactobacilli, Pediococci, Enterococci* and *Bacilli* in animal feeds'. The comments received on the

pre-EN standard state that pulsed field gel electrophoresis (PFGE) is not suitable for the claimed scope and is no longer considered a routine procedure in microbiology laboratories. Following a ballot, it was agreed to change the type of deliverable from an European Standard (EN) to a Technical Specification (TS) as this would enable the method for PFGE typing to be used by laboratories that wish to, but it would not fall under the cascade of methods which would obligate laboratories to use PFGE for control purposes.

The following 5 standards were reviewed by CEN/TC 327/WG3 and published:

- EN 15784: 2021 “Animal feeding stuffs: Methods of sampling and analysis — Detection and enumeration of *Bacillus spp*. used as feed additive"
- EN 15786: 2021 “Animal feeding stuffs: Methods of sampling and analysis — Detection and enumeration of *Pediococcus spp*. used as feed additive”
- EN 15787: 2021 “Animal feeding stuffs: Methods of sampling and analysis — Detection and enumeration of *Lactobacillus spp*. used as feed additive”
- EN 15788: 2021 “Animal feeding stuffs: Methods of sampling and analysis — Detection and enumeration of *Enterococcus (E. faecium) spp*. used as feed additive”
- EN 15789: 2021 “Animal feeding stuffs: Methods of sampling and analysis — Detection and enumeration of *Saccharomyces cerevisiae* used as feed additive”

The following 2 standards developed within CEN/TC 327/WG 3 were also published:

- EN 17547:2021 “Animal feeding stuffs: Methods of sampling and analysis - Determination of vitamin A, E and D content - Method using solid phase extraction (SPE) clean-up and high performance liquid chromatography (HPLC)”
- EN 17550:2021 “Animal feeding stuffs: Methods of sampling and analysis - Determination of carotenoids in animal compound feed and premixtures by high performance liquid chromatography - UV detection (HPLC-UV)”

5. OL Advice and training

Following an e-mail sent asking the OLs if they had any issues with particular methods, felt there was a need for specific PT or had any training needs relating to

feed additives, responses were received from 2 laboratories about issues with repeatability for the determination of vitamin A. The OLs were contacted for more detailed information on the issues, which are currently being looked into.

6. Meetings

Paul Hancock attended the stakeholder meeting on animal feed hosted by the FSA NI, held on the 16th December. Whilst the meeting was dominated by the current avian flu outbreak, further updates were given on protein sources for use in feeds in NI, transmission of African swine fever in feed, salmonella in rats and mice used as reptile feed, updates on additives and GMO in feed and an update from the Veterinary Medicines Directorate.

Kirstin Gray, and other colleagues from within LGC, attended the UKAS and FSA/FSS joint webinar on LAB 33 on 16th December. The aim of this webinar was to clarify UKAS' role in auditing Official Control Laboratories and National Reference Laboratories. The additional auditing will be carried out as part of the labs' annual UKAS assessment visit and information relevant to either their OL or NRL roles will be provided to the FSA/FSS.

The EU Reference Laboratory (EURL) annual workshops for feed additives control and authorisation were scheduled to take place virtually in November 2021 and the EURL was contacted to request permission for a representative of the GB NRL to attend. The response from the EURL was that 'the European Commission policy is that the annual EURL workshops are restricted to the NRLs from the EU/EFTA. We therefore unfortunately cannot answer your request positively'.

Meetings have been held quarterly with the FSA to discuss activities carried out under the NRL role and any issues that have arisen.

7. NRL network meeting

The annual network meeting was scheduled to take place virtually on 5th April 2022 but due to circumstances beyond LGC's control was postponed, a new date is yet to be confirmed. The meeting will be held in conjunction with the NRL for GMO in food and feed and will be an opportunity for the NRLs to provide relevant updates on methods, enforcement, training and other relevant activities, as well as providing a forum for exchange of information and for participants to raise any further training needs and support requirements. The FSA will also be in attendance to provide a brief update on relevant scientific and policy areas. The draft agenda for the meeting scheduled for 5th April is as follows, a similar agenda will be used for the rescheduled meeting:

Agenda

Meeting:	Joint NRL (Feed Additives and GMOs) Network Meeting
Time & Date:	9:30 -13:30 Tuesday 5th April 2022
Venue:	MS Teams Meeting
9.30	**Welcome and introductions** • Apologies for absences • Scope of the meeting
9.40	**FSA update**
10.00	**Feed Additives National Reference Laboratory** • Updates • Training activities • Future work programme • Q&A
11.30	**Break**
11.45	**GMO National Reference Laboratory** • Updates • Training activities • Future work programme • Q&A
13.15	**Feedback / general discussion**
13:25	**AOB**
13.30	**Close**

8. Feed2021 conference

Feed2021 was hosted by Ages, the Austrian Agency for Health and Food Safety, and took place virtually on 23rd – 24th June 2021 with over 170 participants; Kirstin Gray attended from LGC. The conference was the seventh in a series of conferences initiated by the European Union's leading reference laboratories and research institutions in animal feed and comprised of the following five sessions:

- Feed Safety
- Feed Fraud and Feed Authenticity
- Natural Toxins and Impact of Climate Change
- Impact of Feed on Animal Health and Welfare
- Sustainability and Circular Economy in the Area of Feed.

The conference programme is provided in Annex 1.

Points of interest included:

EFSA currently carry out risk assessments for regulated products including feed additives. The OpenEFSA portal is described as 'The single public interface for all information related to EFSA's scientific work'. The website can be found at https://open.efsa.europa.eu/ and can be used to 'follow the risk assessment process from receipt of the dossier to adoption of the opinion: status of assessments, dossiers and studies (non-confidential versions), meeting agenda and minutes, info on experts, etc…'.

The review of Regulation (EC) Number 152/2009 laying down the methods of sampling and analysis for the official control of feed, is ongoing and the Regulation was expected to be updated by the end of 2021. In addition to amendments to bring methods up to date, the main amendments will be:

- Provisions on sampling e-commerce
- Extension of the provisions for measurement uncertainty and recovery correction to the analysis of feed additives to check compliance with minimum and maximum contents.
- Specific reference to EN standards. EN standards to be the same level as EU methods in the methods cascade.
- Annex VIII Methods of analysis to control illegal presence of no longer authorised additives in feed, to be deleted.

The EURL for feed additives (JRC) is currently working on a DG SANTE mandate on the determination of p-phenetidine, an impurity in ethoxyquin, in compound feed and fishmeal. The method involves extraction of the sample followed by SPE clean-up and LC-MS/MS. Good in-house validation data has been obtained at 125 ng/kg in fish feed, the target value for p-phenetidine if ethoxyquin is re-authorised with a maximum content of 50 mg/kg feed. JRC envisage an interlaboratory comparison of the method in 2022 after which it is hoped that limits for p-phenetidine will be set.

9. NRL Forward Workplan

In 2022/23 the NRL core activities, e.g. horizon scanning, PT participation and dissemination of relevant information and advice as required, will continue. Input will also be made into the revision / review of any relevant Regulations, for example Retained EU Regulation 378/2005 and Retained EU Regulation 152/2009.

The systems and processes drafted for the evaluation of feed additive authorisation applicants and receipt and storage of reference samples will be maintained and dossiers will be evaluated as required.

10. NRL website

Information about LGC's NRL roles are found on our website at: https://www.lgcgroup.com/what-we-do/national-laboratory-and-government-roles/national-laboratory-roles/national-reference-laboratories/. Additional webpages are to be added and will provide information on the authorisation process, guidance for submission of reference samples and standards relating to authorisation applications and a database of additives newly authorised for use in GB together with information on methods of analysis for control.

11. Feed Additive Authorisation

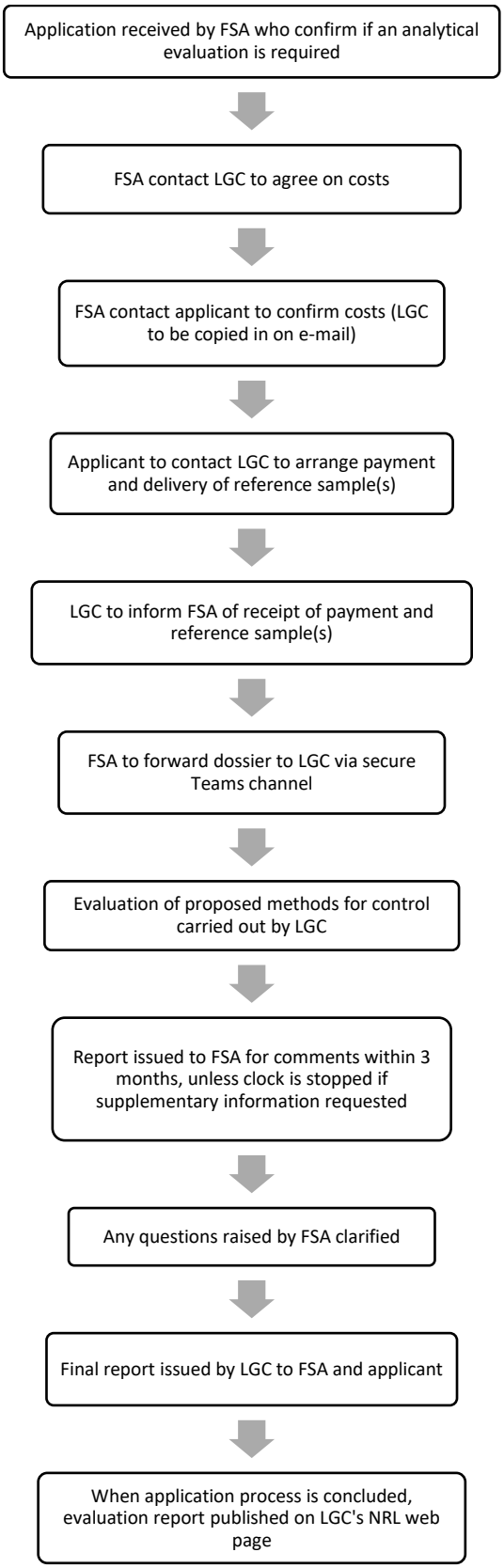
Feed additives play an important role in animal nutrition, addressing various aspects such as feed safety, reduction of environmental emissions and sustainability in livestock farming. Feed additives are regulated products and as such require authorisation before use. Following Great Britain's exit from the EU, all new feed

additives need to be authorised by the Competent Authority (FSA/FSS) before use in GB. Feed additives that are currently approved for use in the EU can continue to be used in GB but an application is required to be submitted at least one-year prior to expiry to be progressed through the GB risk analysis process.

Under part 2 of the NRL contract, feed additive regulated product authorisation, the NRL is responsible for:

- the reception, preparation, storage and maintenance of reference samples and reference standards where applicable;
- evaluating the data provided by the applicant for authorisation to place the feed additive on the market, for the purpose of testing and evaluation or validation of the method for detection;
- submitting a full evaluation report to the FSA Risk team for each application within 3 months from the date of receipt of a valid application and payment of fee. This period can be extended for complex applications or where supplementary information is requested.

The proposed analytical method evaluation process can be summarised as follows:


Application received by FSA who confirm if an analytical evaluation is required
FSA contact LGC to agree on costs
FSA contact applicant to confirm costs (LGC to be copied in on e-mail)
Applicant to contact LGC to arrange payment and delivery of reference sample(s)
LGC to inform FSA of receipt of payment and reference sample(s)
FSA to forward dossier to LGC via secure Teams channel
Evaluation of proposed methods for control carried out by LGC
Report issued to FSA for comments within 3 months, unless clock is stopped if supplementary information requested
Any questions raised by FSA clarified
Final report issued by LGC to FSA and applicant
When application process is concluded, evaluation report published on LGC's NRL web page

A meeting with held with the FSA on 22nd October to review the authorisation process with regards to the analytical methods evaluation. The process document produced by Mark Bond (FSA) was discussed and clarified as much as was possible at the current time. Additional follow-up meetings have been held to continue the discussions.

Three entire dossiers were provided by the FSA. These were used to help familiarise LGC with the type and scope of data provided by applicants. A draft report for *Saccharomyces cerevisiae* MUCL 39885 was prepared considering the information provided in the dossier and the EURL report for the initial application. The format of the report was based on the 'light-touch' reports previously prepared by LGC with the inclusion of additional information requested by the FSA. The review of the dossier for *Saccharomyces cerevisiae* MUCL 39885 (FSA #24) highlighted the importance of reviewing both the original EURL report and any new information provided by the applicant as since the EURL report was issued in 2010 technology has moved on and the recommended technique for the characterisation and identification of the yeast strain has changed from PCR typing to whole genome sequencing.

To assist the applicants with the submission of reference samples and standards, guidance documents have been prepared to be placed on the NRL webpages. The documents drafted to date are as follows, and copies can be found in Annexes 2 to 6:

- Fee structure*
- Submission of reference samples and standards
- Sample submission form
- Standard submission form
- Sample submission cover letter.

* Prior to being placed on the NRL webpage, when agreed / confirmed with the FSA, the exact fees will be added to the Fee Structure guidance document.

A new shared mailbox has been set-up to facilitate communications between the NRL, the FSA and feed additive authorisation applicants. The e-mail address is feed.additives@LGCgroup.com

A SharePoint online Microsoft 365 site has been set-up specifically for the feed additives NRL where all data and information will be stored securely according to the requirements of the contract and GDPR.

Annex 1: Feed2021 Conference programme

Wednesday 23 June 2021

09:00 Words of Welcome, Thomas Kickinger, Managing Director, AGES

09:15 Welcome speech, Ministry of Agriculture, Regions and Tourism, Austria

09:35 Keynote Speech: Past and present challenges on the safety and efficacy assessment of feed additives, Frank Verdonck, EFSA

Session 1: Feed Safety

10:05 Introduction

10:10 Keynote Speech: Update and outlook on regulatory developments and enforcement of feed safety at EU levels, with focus on undesirable substances in feed, Frans Verstraete, DG SANTE, European Commission

10:40 Carryover in feed production and transfer from feed to food of undesirable compounds in the animal food production chain - FAO expert meeting, Marc Berntsen, Institute of Marine Research, Norway

11:00 Break

11:30 Determination of cross-contamination levels for antimicrobial active substances regarding new EU-legislation, Robin S. Wegh, Wagening Food Safety Research, The Netherlands

11:50 Determination of p-Phenetidine in feed: Analytical challenge for the safe use of ethoxyquin in animal nutrition, Ursula Vincent, European Commission Joint Research Centre, Belgium

12:10 Metals and nitrogenous compounds in feed – compounds of analytical and regulatory interest, Heidi Amlund, National Food Institute Denmark, Denmark

12:30 Lunch break

13:15 Lab Tour Biomin

13:45 Introduction

13:50 Advances in feed safety - whole genome sequencing of microbial contaminants, Werner Ruppitsch, AGES, Austria

14:10 Limitations of microbiological testing for Salmonella spp. and Enterobacteriaceae in field samples to assess feed safety, Erwin Witters, Kemin, The Netherlands

14:30 Rapid detection of residues from packaging remnants in former foodstuff products by multivariate analysis of RGB images, Matteo Ottoboni, University of Modena and Reggio Emilia, Italy

14:50 Detection of microplastic in feed ingredients, L. Raamsdonk, Wageningen Food Safety Research, The Netherlands

15:10 European standardization and how to be involved, Charlotte Mosies, NEN, The Netherlands

15:20 IAG Feed Microscopy Association and its work in establishing a standardized method of detection and quantification of packaging material in feed, Geneviève Frick, Agroscope, Switzerland

15:30 Break

Session 2: Feed fraud and feed authenticity

16:00 Introduction

16:05 Keynote Speech: Enforcement of EU feed legislation with specific focus on truthfulness of feed labelling and feed fraud, Wolfgang Trunk, DG SANTE, European Commission

16:35 Vibrational spectroscopy and imaging coupled with chemometrics for the authenticity of protein feed: the example of antibiotic mycelia residues, Zengling Yang, China Agricultural University, China

16:55 DART mass spectrometry: A rapid tool for the identification of feed additives, Christoph von Holst, European Commission Joint Research Centre, Belgium

17:15 Evaluation of the cross-reactivity between plasma peptides and mastitis milk for the development of multiple reaction monitoring mass spectrometry for bovine plasma powder detection, Marie-Caroline Lecrenier, Walloon Agricultural Research Centre, Belgium

17:35 End of day 1

Thursday 24 June 2021

Session 3: Natural Toxins and Climate

9:00 Introduction

9:05 Keynote Speech: How to tackle natural toxins in view of globalisation and climate change, Rudolf Krska, University of Natural Resources and Life Sciences, Vienna and FFoQSI Competence Centre for Feed & Food, Austria

9:35 Mycotoxin risks in stored Swedish grain, Erik Nordkvist, National Veterinary Institute Uppsala, Sweden

9:55 Classification of the maize assortment regarding the susceptibility to ear fusariosis – 10 year experience in AT, Elisabeth Viktoria Reiter, AGES, Austria

10:15 Mitigation of mycotoxin exposure with feed enzymes, Dieter Moll, Biomin, Austria

10:35 Application of the HRMS-QExactive for the development of a comprehensive mass spectral database for pyrrolizidine alkaloids, Ewelina Kowalczyk, National Veterinary Institute Pulawy, Poland

10:55 Break

Session 4: Impact of Feed on Animal Health and Welfare

11:30 Introduction

11:35 Keynote Speech: Feed - Impact on physiology, health and welfare of farm animals, Jürgen Zentek, Freie Universiät Berlin, Germany

12:05 Speciality Feed Ingredients' contribution to sustainable animal farming/pivotal role in the fight against antimicrobial resistance, Jörg Seifert, FEFANA

12:25 Studies on the mechanisms of action of phytogenic feed additives including Next-Generation Sequencing (NGS), Klaus Teichmann, Biomin, Austria

12:45 Undesirable substances in interspersed substrates - impact on animal and consumer health, Felicitas Koch, BfR, Germany

13:05 Lunch break

13:45 Lab Tour: The world of FFoQSI - Visit to the Austrian Competence Centre for Feed & Food, Quality, Safety and Innovation Institute for Bioanalytics and Agro-Metabolomics, FFoQSI

14:15 European Feed Microbiology Organization - Promoter of microbiological feed quality, Manuela Zadravec, EFMO

14:25 Official Controls and Accredited Third Party Certification - Working together to secure the feed supply chain, Emmanouil Geneiatakis, FAMI-QS, Belgium

Session 5: Sustainability and Circular

14:35 Introduction

14:40 Keynote Speech: FEFAC Charter 2030: A comprehensive view on sustainable feed production, Asbjørn Børsting, FEFAC

15:10 Effects of confectionary or bakery former food products as cereal substitute on growth performance in post-weaning piglets, Luciano Pinotti, University of Milan, Italy

15:30 Multi-omics analysis of Atlantic salmon liver tissue after exposure to pirimiphos-methyl, Josef D. Rasinger, Havforsknings instituttet, Norway

16:00 Extraction of functional nutritive derivates from unicellular organisms by novel technologies for sustainable production of animal feed, Miladinovic, Dejan, Norwegian University of Life Science, Norway

16:20 Connecting agri-food supply chains through insect farming: upcycling underused materials into animal feed ingredients, Christophe Derrien, IPIFF

16:50 Closing session

17:00 End of conference

Annex 2: Fee structure

Fees for the scientific evaluation of methods of analysis proposed for official control

LGC provides scientific method validation services to the Competent Authority (FSA/FSS) as part of the authorisation process for placing on the market of feed additives for use in Great Britain (GB). The primary objective of the evaluation of the analytical methods is to establish whether the methods are suitable for enforcement of the conditions of use of the feed additives, for example whether the methods are capable of accurately determining the feed additive content at the set minimum and maximum concentrations.

Once the FSA has confirmed that a GB application for feed additive authorisation requires analytical evaluation of the methods of analysis they will contact LGC and the price for the evaluation will be confirmed based on the authorisation type. Once the fee has been confirmed, the applicant will be directed to contact LGC to arrangement payment of the fee. The following e-mail address is to be used for any correspondence related to the scientific evaluation: feed.additives@lgcgroup.com.

The fees support the costs of LGC for the scientific evaluation and preparation of the evaluation report and the costs related to the handling of the reference samples, and are as follows:

Type of authorisation	**Fee**
New feed additive	[To be added following review by the FSA]
New use of an existing feed additive Changing terms of authorisation - Article 13(3) of Retained EU Regulation No 1831/2003:	[To be added following review by the FSA]
Renewal of authorisation: Existing feed additive (Art.10(2) of Retained EU Regulation No 1831/2003) re-authorisation	[To be added following review by the FSA]

The above fees are per additive, however additives requiring similar analysis, for example vitamin A and vitamin E or groups of trace elements, may be assessed together and the fees determined accordingly.

These fees are valid until 31st March 2023 and will be reviewed annually on 31st March thereafter.

Fees shall be payable by the applicant to LGC within 30 days of the date of receipt of the invoice. Any method evaluation services provided as part of the feed additive function at LGC will not commence until such fees have been received.

Annex 3: Submission of reference samples and standards

Submission of reference samples and standards

Article 3 of Retained EU Regulation No 378/2005 on detailed rules for the implementation of Retained EU Regulation No 1831/2003 Retained EU Regulation No 1831/2003 concerning applications for authorisations of feed additives states that any person submitting an application for an authorisation for a feed additive or for a new use of a feed additive shall supply three reference samples in a form in which the feed additive is intended to be placed on the market by the applicant.

In addition, the applicant shall also provide reference standards of the pure active agents in the case of feed additives:

— belonging to the category zootechnical additives referred to in Article 6(1)(d) of Retained EU Regulation No 1831/2003, except feed additives consisting of or containing micro-organisms;

— belonging to the category coccidiostats and histomonostats referred to in Article 6(1)(e) of Retained EU Regulation No 1831/2003;

— falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs);

— for which Maximum Residue Limits have been established in Annex I or III of Retained EU Regulation No 2377/90 or following Retained EU Regulation No 1831/2003.

An expiry date shall be provided for all reference samples and reference standards. Prior to the expiry date being reached it is expected that replacement samples and standards, where applicable, will be sent to LGC. These replacement samples shall be clearly marked, as detailed below, including with the original FSA reference number.

Quantity

Three reference samples of the feed additive, each weighing between 10 and 100 g shall be supplied. The weight provided should take into consideration

(a) the concentration of the active ingredient in the product and (b) the maximum proposed dose.

The quantity of the reference standard supplied should be sufficient to allow for 100 analyses and should not be less than 1 g.

For coccidiostats, 100 mg of reference standard is sufficient.

If there are any questions or doubts about the reference samples and standards that should be supplied, please contact LGC using the e-mail address: feed.additives@lgcgroup.com.

Packaging

The containers the reference samples and standards are packaged in should not affect the physical or chemical properties of the feed additive. The containers shall be sealed with a tamper-evident closure.

The following containers are suitable:

- High density polyethylene (HDPE) bottles. For photosensitive substances, amber / brown HDPE bottles should be used.
- Glass containers should be avoided unless the feed additive is incompatible with plastic. For photosensitive substances, amber / brown glass bottles should be used. Glass bottles with external plastic coating should be used for any hazardous substances.
- Closures: polypropylene (pp), Teflon or Polytetrafluoroethylene (PTFE)-coated screw closures with tamper-evident seals should be used.

Labelling

Each reference sample and standard container shall be labelled clearly with the following:

- Name of feed additive
- FSA Authorisation application reference number
- Expiry date / shelf life
- Storage temperature

Transportation

The applicant is responsible for ensuring the reference samples and standards are received at LGC in an acceptable condition and that appropriate transport conditions, for example with respect to temperature, are used. All containers shall be packed appropriately so no damage / leakage occurs during transport and should comply with all relevant transport regulations.

The samples and standards are to be sent to the following address:

Feed Additives National Reference Laboratory
LGC Ltd
Queens Road
Teddington
TW11 0LY
United Kingdom

When the samples / standards have been dispatched, LGC should be notified (feed.additives@lgcgroup.com) of the transportation method, for example the name of the courier used, expected delivery date and tracking number, if available.

If samples / standards require cold storage, delivery to LGC should not be made outside 08:00 – 16:30 Monday to Friday.

Documentation

The following documents need to be completed for each set of samples / standards sent to LGC:

- Sample submission form - One to be completed for each different reference sample or standard sent
- Sample submission cover letter - To be signed, dated and printed on company headed paper
- Material safety data sheet (MSDS) for all relevant materials.
- Where the application concerns a feed additive consisting of or containing micro-organisms, an authorisation for LGC to access the microbial strain

deposited at the internationally recognised culture collection mentioned in point 2.2.1.2. of Annex II of Retained EU Regulation No 429/2008, is also required.

Hardcopies of all of these documents, apart from the MSDS, are to be included with samples / standards.

Copies of all of the documents are to be e-mailed to feed.additives@lgcgroup.com prior to the samples / standards being dispatched.

The FSA reference number is to be included in all e-mail correspondence.

Annex 4: Sample submission form

Feed Additive Reference Samples – Sample submission form

Please provide the following information, where applicable:

FSA reference:	
Name of the additive:	
Name and address of the applicant:	
Applicant authorisation number:	
E-mail address of the applicant:	
Specific name of active component(s):	
Physical state:	
Net weight/volume:	
Safety recommendations, if any:	
Specific requirements/Storage conditions:	
Identification number, if any:	
Batch reference number:	
Manufacturing date:	
Expiry date:	
Concentration or activity (enzyme) or CFU (micro-organism):	
Units	
I.U.B. identification number (enzyme):	
Specific name of the enzyme:	
Strain identification number (micro-organism):	

Annex 5: Standard submission form

Feed Additive Reference Standards – Standard submission form

Please provide the following information, where applicable:

FSA reference:	
Specific name of active component(s):	
Name and address of the applicant:	
Applicant authorisation number:	
E-mail address of the applicant:	
Physical state:	
Net weight/volume:	
Safety recommendations, if any:	
Purity:	
Specific requirements/Storage conditions:	
Identification number, if any:	
Batch reference number:	
Manufacturing date:	
Expiry date:	
Concentration or activity (enzyme):	
Units	
I.U.B. identification number (enzyme):	

Annex 6: Sample submission cover letter

Contact information

Name and address of applicant:

Contact name:

Telephone number:

E-mail address:

Product information

Additive name:

FSA reference:

Storage temperature:

Documents provided

- Sample submission form ☐
- Standard submission form ☐
- Material Safety Data Sheet(s) (MSDS) ☐
- Letter of access to culture collection (for micro-organisms) ☐

Hard copies of the above documents, apart from the MSDS, together with a signed copy of this document, printed on headed company paper, are to be enclosed with the reference samples / standards. Copies of all documents are to e-mailed to feed.additives@lgcgroup.com together with details of the transportation method used to send the samples / standards, for example the name of the courier used, expected delivery date and tracking number, if available.

I hereby confirm the following:

- All samples and standards, where applicable, have been labelled appropriately (Name of feed additive, FSA reference, expiry date and storage temperature),
- All samples and standards, where applicable, have been packaged appropriately, including with a tamper-evident closure,
- Replacement samples and standards, where applicable, will be provided when the expiry date of the enclosed samples / standards is reached,
- That the above information is correct as of the date of signing.

....

Name Position

....

Signature Date