

Earned Recognition Feed Hygiene and Medicated Feed

March 2016

Memorandum of Understanding between:

**The Food Standards Agency;
The Veterinary Medicines Directorate;
Food Standards Scotland; and
The Agricultural Industries Confederation**



This Memorandum of Understanding (MOU) is an agreement between the following organisations:

- a) The Food Standards Agency (FSA) of Aviation House, 125 Kingsway, London, WC2B 6NH
- b) The Veterinary Medicines Directorate, (VMD) of Woodham Lane, New Haw, Surrey, KT15 3LS
- c) Food Standards Scotland (FSS), Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL
- d) The Agricultural Industries Confederation (AIC) of, Confederation House, East of England Showground, Peterborough, PE2 6XE.

1. Purpose

This MOU seeks to set out the general principles of collaboration, cooperation, roles and responsibilities that support the approach to earned recognition between the Food Standards Agency, the Veterinary Medicines Directorate, Food Standards Scotland and the Agricultural Industries Confederation.

This MOU provides a specific framework for the delivery of earned recognition in relation to the manufacture, storage and transportation of feed materials including additives, specified feed additives (coccidiostats), premixtures, and compound feeding stuffs, including medicated feeding stuffs, by compliant feed business operators that are members of the AIC schemes detailed in Annex A.

2. Background to Earned Recognition

Feed business operators (FeBOs) involved in the manufacture of those products referred to in section 1 above are responsible for ensuring their products satisfy the requirements of the law detailed in Annex B. The FSA, VMD and FSS recognise that the application of official controls relating to such manufacture should recognise those businesses that comply with legislative requirements whilst offering necessary safeguards to minimise any risks to consumer and animal health and the environment. They aim to do that through risk-based inspections and, where necessary, appropriate enforcement actions to remedy deliberate, persistent or serious non-compliance.

Earned recognition will be available to those FeBOs who are compliant members of an assurance scheme recognised by the FSA, VMD and FSS (see Annex A).

A scheme can obtain Approved status by demonstrating it complies with the 'Criteria for Earned Recognition' as set out in Annex C. This process examines the governance of the scheme, checks that the scheme standards reflect legislative requirements for the sector under consideration, and the certification process is robust and impartial. Where a scheme is approved, compliant members of the

scheme will benefit from a reduced frequency of inspection on the basis that the business and scheme are taking positive action to reduce risks and comply with legislative requirements, verified through a third party certification process.

The application of earned recognition by the FSA, VMD and FSS is recognition that compliant members of an approved scheme have a lower risk, allowing the enforcement authority to focus on less compliant businesses.

3. Overview of the Parties Concerned

Food Standards Agency

The FSA is a non-Ministerial government department responsible for food and feed safety and hygiene in England, Wales and Northern Ireland. The FSA is the Central Competent Authority (CCA) responsible for ensuring the delivery of official feed and food law controls in England, Wales and Northern Ireland. The FSA works through its headquarters in London and offices in York, Belfast and Cardiff.

Official controls are delivered by a range of enforcement authorities in the UK. In GB these include the FSA, FSS, local authority environmental health and trading standards departments, whereas in Northern Ireland, local authority environmental health departments or the Department of Agriculture and Rural Development (DARD), on behalf of the FSA, are responsible for delivery of official food controls.

Official feed controls are delivered by local authorities in GB and by DARD in Northern Ireland.

Veterinary Medicines Directorate

The VMD is an executive agency of the Department for Environment, Food and Rural Affairs (Defra), and is the Competent Authority for the regulation of veterinary medicines in the UK.

The vision of the VMD is the responsible, safe and effective use of veterinary medicinal products. It aims to protect public health, animal health and the environment, and promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines.

The VMD authorises veterinary medicines in the UK and inspects premises on which veterinary medicines are manufactured, stored and supplied. In Great Britain, the VMD is the enforcing authority for approving and inspecting FeBOs, including commercial feed mills and farms, manufacturing products regulated under Schedule 5 of the Veterinary Medicines Regulations 2013, that is:

- specified feed additives (SFAs - being coccidiostats and histomonostats), and premixtures, complementary feedingstuffs and final feedingstuffs containing SFAs; and
- premixtures and final feedingstuffs containing veterinary medicinal products.

These are collectively referred to as Schedule 5 products.

Food Standards Scotland

FSS is a non-Ministerial body of the Scottish Administration, part of Scottish Government, responsible for food and feed safety and standards and nutrition in Scotland. As Central Competent Authority, FSS is responsible for ensuring delivery of official feed and food controls in Scotland.

Agricultural Industries Confederation

The AIC is an independent, not for profit organisation that works on behalf of its members in the agricultural supply sector. While AIC represents several sectors within the feed industry and manage a number of assurance schemes, this MOU relates to the following schemes:

- Universal Feed Assurance Scheme (UFAS)
- Feed Materials Assurance Scheme (FEMAS)
- Trade Assurance Scheme for Combinable Crops (TASCC)

UFAS was launched in 1998 and accounts for well in excess of 95% of the commercially produced compound feed in the UK and Ireland. The scheme has been amended to include a Merchants' Standard. In total UFAS have in excess of 700 members in the UK.

FEMAS covers all feed ingredients intended for direct feeding to animals or for inclusion in compound feeds and blends. FEMAS members are an extremely diverse group of businesses ranging from specialist additive manufacturers to food processors and brewers.

TASCC covers the trading of combinable crops, storage and transportation of feed materials and ingredients.

Schemes are based on HACCP principles, which form the bedrock of EU Food and Feed legislation. The schemes are audited and certified by an independent certification body, in accordance with the internationally recognised standard ISO17065. This means that the certification body is itself independently assessed every year to ensure that the standard is implemented and administered consistently and fairly.

AIC require businesses to be audited before membership is approved and members are subject to an annual audit.

AIC has worked with the FSA, VMD and FSS to ensure standards within the schemes reflect legislative requirements for both feed and medicated feed hygiene.

4. Food Standard Agency, Veterinary Medicines Directorate and Food Standards Scotland - Roles and Responsibilities

The FSA, VMD and FSS are jointly responsible for assessing and approving those scheme(s) recognised by all organisations (as shown in Annex A) for earned recognition under this MOU, using the Criteria for Earned Recognition, and will jointly work together to verify compliance. For those schemes only recognised by the FSA and FSS, the FSA and FSS will have responsibility. The FSA, VMD and FSS will work with the AIC to verify compliance with the requirements of this MOU.

When the VMD and/or the FSA and FSS are satisfied that an AIC scheme meets the approval Criteria for Earned Recognition, each will ensure those responsible for enforcement are informed of earned recognition arrangements and the inspection frequency for delivering Official controls.

To ensure continuing compliance and confidence in the earned recognition process, the VMD and/or the FSA and FSS will verify a scheme's ongoing compliance with the Criteria for Earned Recognition that led to approved status for the scheme. Positive verification will enable the VMD and/or the FSA and FSS to have continued confidence in the approved schemes.

Should an approved scheme fail to continue to meet approval criteria, the VMD and/or the FSA and FSS will ensure that the AIC understands what areas need to be rectified and the FSA's/VMD's/FSS's response should no action be taken.

The FSA's/VMD's/FSS's key responsibilities include:

- evaluating evidence supplied by the assurance scheme to determine whether the scheme meets criteria and key requirements that allow the FSA/VMD/FSS to approve the scheme for earned recognition;
- administration of the MOU with the parties concerned to formally agree approved status, roles and responsibilities;
- organising meetings and exchange of management data with the assurance scheme in line with Annexes D and E;
- ensuring enforcement authorities are provided with information to identify businesses that qualify for earned recognition through membership of the approved scheme and understand the frequency that inspections will be carried out;

- working with enforcement authorities to ensure they inspect a sample group of businesses that qualify for earned recognition and that any adverse findings are reported to the FSA, VMD and FSS;
- working with the AIC to improve the earned recognition process where necessary;
- ensuring information supplied by the assurance schemes is treated as confidential, is retained as confidential information and any restrictions placed upon it are observed;
- working with other government departments to promote, where possible, a joint approach to earned recognition;
- adhering to all statutory requirements and best practice (including any relevant governmental protocols such as the Ministerial and Civil Service Codes and the Security Policy Framework <http://www.cabinetoffice.gov.uk/resource-library/security-policy-framework>). Compliance with applicable laws and standards including EU procurement rules, data protection and freedom of information legislation;
- notifying the AIC of any changes to legislation or guidance relevant to the assurance schemes covered by this MOU;
- notifying the AIC where enforcement action relating to scheme members results in prosecution by enforcement authorities. In relation to activities enforced by the VMD, AIC will be informed when other enforcement action will be or has been taken against a member of the schemes; and
- working together to promote and support the earned recognition process and, subject to legislative restrictions, share information that supports this process.

The FSA, VMD, AIC and FSS acknowledge there will be occasions when specific information, including personal information about members of the schemes, needs to be shared between each other.

When this is in relation to food safety matters that can affect public health the information exchange will be treated as a disclosure under Section 29 of the DPA (prevention or detection of crime/ capture or prosecution of offenders).

When this is in relation to other matters, for example where information on new members of the scheme is provided, the reason for processing the information that would apply under the Data Protection Act is that the information is necessary for administering justice, or for exercising statutory, governmental, or other public functions;

The reliance on using this exemption and reason to release specific food safety information is to be reviewed annually to ensure it remains applicable in all circumstances. Additionally, the FSA is able to disclose the data it holds under The Food Standards Act 1999 Section 19.

5. Agricultural Industries Confederation / Roles and Responsibilities

The primary function of the AIC in relation to earned recognition is to:

- ensure approved schemes remain compliant with 'Criteria for Earned Recognition';
- notify the FSA/VMD/FSS of any proposed change to the operation and management of the AIC that would impact on governance, standard setting, certification or the ability of the schemes to share management data as detailed in Annex C;
- provide and update the FSA/VMD/FSS with contact details relating to the certification body engaged to carry out scheme audits;
- work with the FSA, VMD and FSS to continually improve the earned recognition process;
- ensure management data are provided to support the earned recognition process, as specified in Annexes D and E;
- support the process of meetings with the FSA, VMD and FSS as detailed in Annex D;
- ensure information supplied by the FSA, VMD or FSS is treated as confidential, is retained as confidential information and any restrictions placed upon it are observed; and
- notify the FSA, VMD, FSS and appropriate competent authorities immediately the certification body becomes aware of a threat to public health or animal health, any situation where animal welfare is compromised, or any unlawful activities. AIC to provide identified officials with the specific details of such non-compliance including name, address and inspection report to facilitate any remedial action and enforcement.

6. General Principles of Collaboration between the FSA/VMD/FSS and the AIC

The FSA, VMD, FSS and AIC agree to adopt the following principles implementing this MOU:

- to share information, experience and skills to learn from each other and develop effective working practices, work collaboratively to identify solutions, eliminate duplication of effort, mitigate risk and reduce cost;
- to act in a timely manner;
- to coordinate communications in relation to earned recognition and ensure the details in Annex F are kept up to date;
- to ensure sufficient and appropriately qualified resources and systems are put in place to fulfil the responsibilities set out in this MOU; and
- to act in good faith and to support the purpose and objectives of the MOU.

7. Governance

The FSA, VMD, FSS and AIC are jointly responsible for the development and support of governance systems as detailed in Annex D.

If there is any dispute arising out of or in connection with this MOU, the concerned parties shall try to settle it amicably in the first instance. In the event resolution is not reached, the dispute shall be referred to the Chief Executives or nominated person responsible for each party.

The MOU is a voluntary arrangement; however, each party should provide six months' notice in writing of their intention to withdraw support from the MOU.

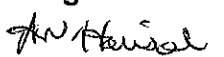
This MOU shall commence on the date it is agreed and subject to earlier termination on the terms of this MOU shall continue in force subject to annual review

8. Application of this MOU


In relation to the enforcement of legislation identified in Annex B, this MOU will extend to England, Wales, Northern Ireland and Scotland.

Memorandum of Understanding between the Food Standards Agency, the Veterinary Medicines Directorate, Food Standards Scotland and the Agricultural Industries Confederation in relation to Earned Recognition for feed

The Food Standards Agency agrees and accepts the roles and responsibilities and principles as detailed in this MOU in relation to the approved assurance schemes listed in Annex A.

Name	Signed	Position
NOUETTE HARRISON		HEAD OF LOCAL DELIVERY
Date	28th APRIL 2016	

The Veterinary Medicines Directorate agrees and accepts the roles and responsibilities and principles as detailed in this MOU in relation to the approved assurance schemes listed in Annex A.

Name	JOHN MILLWARD	Signed		Position	HEAD OF COMPLIANCE VMD
Date	20 APRIL 2016				

Food Standards Scotland agrees and accepts the roles and responsibilities and principles as detailed in this MOU in relation to the approved assurance schemes listed in Annex A.

Name LORNA MURRAY **Signed** *Lorna Murray* **Position** HEAD OF ENFORCEMENT
Delivery, FSS.

Date 13/04/16

The Agricultural Industries Confederation agrees and accepts the roles and responsibilities and principles as detailed in this MOU in relation to working with the FSA and the VMD in relation to attaining approved status for its schemes listed in Annex A.

Name JOND KELLY **Signed** *Jond Kelly* **Position** CHIEF OPERATING OFFICER.

Date 13/04/16.

Annex A

Assurances schemes recognised under this MOU as qualifying for earned recognition

This MOU recognises the following Agricultural Industries Confederation schemes for earned recognition as detailed below:

- Universal Feed Assurance Scheme (UFAS)
- Feed Materials Assurance Scheme (FEMAS)
- Trade Assurance Scheme for Combinable Crops (TASCC)

	England	Northern Ireland	Scotland	Wales
UFAS manufacture	FSA/VMD	FSA	VMD/FSS	FSA/VMD
UFAS merchant	FSA	FSA	FSS	FSA
TASCC	FSA	FSA	FSS	FSA
FEMAS	FSA	FSA	FSS	FSA

Annex B

Legislation covered by the MOU

The following legislation (as amended) is covered by the MOU:

- EC Regulation 183/2005 on Feed Hygiene (including Commission Regulation 225/2012 on feed oils and fats);
- EC Regulation 767/2009 on the Marketing and Use of Feed;
- EC Regulation 1831/2003 on Feed Additives;
- EC Regulation 2002/32 on Undesirable Substances in Animal Feed;
- EC Regulation 1829/2003 on Genetically Modified Food and Feed; and
- EC Regulation 178/2002 on the principles of feed and food law.
- EC Directive 90/167 on medicated feedingstuff

Annex C

Criteria for Earned Recognition

1.0 Standard Setting

- 1.1 The industry scheme and standards should cover applicable legislative requirements for the sector it covers, and include the following aspects of governance surrounding the establishment and setting of standards:
- **Governance:** The role and governance of the standard setting body should be clearly defined within the scheme and include representatives of all relevant stakeholders;
 - **Standards:** There should be clearly defined processes for developing standards, with access to expertise and experience in relation to the sector to which the standards relates;
 - **Legislation:** Processes should be in place to ensure standards are reviewed and developed in line with legislative changes; and,
 - **Risk based:** A risk based approach to standard setting should be used drawing upon HACCP or an equivalent risk assessment process that identifies safety hazards and controls.

2.0 Compliance and Certification

- 2.1 The industry schemes should clearly describe compliance as well as processes for assessment and review, in particular:
- **Compliance:** The scheme should provide guidance on interpretation and assessment of compliance and how non-conformities with standards are dealt with;
 - **Review:** Systems should be in place to monitor and adjust scheme requirements to ensure they achieve acceptable standards of compliance; and,
 - **Assessment:** The scheme should have appropriate mechanism for the development and review of inspection criteria, with the ability of relevant stakeholders, including central competent authorities, to contribute to this process.
- 2.2 The industry scheme must have the following processes/criteria in place for its certification bodies:
- UKAS accreditation or equivalent having ISO17065 accreditation;
 - A quality management system, including clearly defined management structure, processes for monitoring audits and the objective collection and recording of evidence as part of the certification process;
 - A certification process that is reviewed at least annually to ensure it is operating effectively and in accordance with the requirements of the assurance scheme;

- A process to ensure non-conformances are tracked, closed off or otherwise addressed subject to the schemes requirements;
- A process to monitor the competence/performance of assessor;
- A process to ensure those responsible for certification are kept up to date with developments in standards and guidance for interpretation of standards; and
- A certification decision making process that is clear, transparent, proportional, consistent and documented.

3.0 Assessment Process

3.1 The industry scheme will need to demonstrate the following:

- The assessment process must be underpinned with guidance that deals with the assessment of standards and how non-conformities are dealt with in relation to the risk posed by non-compliance. Guidance should include procedures for dealing with repeat non-conformities, failure to rectify non-conformities and situations when certification should be withheld or suspended and circumstances in which it might be reinstated. In addition the guidance must include verification of corrective action;
- The assessment must be carried out by assessors who are impartial, competent and maintain relevant sector knowledge;
- Frequency of assessments must be no less than the minimum set by legislation for the sector covered by the assurance scheme, risk based and take into account previous history;
- Assessment must review all the standards set by the scheme applicable to the business and as a minimum must include a visual inspection of the site, observation of operations and examination of records;
- Comprehensive records of assessment findings should be maintained. (Date, name of assessor, scope of assessment, non-conformities, timescales for rectification etc.); and
- Where possible assessments should be unannounced or at short notice.

4.0 Assessor Authorisation/Competence

4.1 The industry scheme should have defined the following and have systems in place to ensure the certification body has:

- Criteria for appointing and authorising assessors including reference to professional qualifications, auditing skills, relevant experience and arrangements for ensuring on-going competency; and
- Induction and continued learning to enable assessors to demonstrate a clear understanding of scheme requirements and procedures, guidance for interpretation of standards and how non-conformities are dealt with.

5.0 Standard Mapping

- 5.1 Scheme standards will need to encompass legislation applicable to the sector the scheme identifies with. The FSA, VMD and FSS will work with the assurance scheme to ensure applicable legislation is identified.
- 5.2 If the FSA, VMD or FSS identifies that the scheme fails to cover any of the relevant legislative measures, the assurance scheme will be notified and invited to amend the scheme.
- 5.3 Legislation against which standards will be assessed is detailed in Annex B.

6.0 Data Sharing and Communications

- 6.1 The industry scheme must be in a position to ensure that:
- Information is made available to the FSA, VMD, FSS and the enforcement authority about membership of the scheme (new members/members that leave or are suspended from the scheme) and such data are kept up to date;
 - Processes are in place to ensure the FSA, VMD, FSS and the enforcement authority are informed quickly or have access to up to date information about members that are suspended from the scheme and,
 - Processes are established to ensure that the FSA, VMD, FSS and the enforcement authority are informed immediately if an immediate threat to public health, animal health, welfare or the environment is identified due to the activities covered by this MOU.
- 6.2 The industry scheme must be in a position to agree the following with the FSA, VMD and FSS
- The review of planned and actual assessments;
 - The review of high level non-conformance/compliance data, rectification timescales;
 - The establishment of effective communications, between the assurance scheme, the FSA, VMD, FSS and enforcement authorities;
 - The FSA and the VMD are notified of changes to the scheme with particular reference to standards that reflect legislative requirements;
 - The review of criteria that lead to earned recognition being approved for the scheme;
 - Key contact details;
 - The frequency of meetings with the FSA, VMD and FSS to discuss the operation of the scheme; and
 - It will enter into a memorandum of understanding to support the earned recognition process with the FSA, VMD and FSS.

**Annex D
FSA, VMD and FSS Governance of Earned Recognition**

Meeting	Activities	Inputs	Outputs	Attendees
Annual	Senior officials to review the evidence to justify continued support for earned recognition	FSA/VMD/FSS report including governance and performance information e.g. evidence of compliance with key requirements, results of monitoring, data management as set out in Annexes C and E Agenda/notes of 1/4 meetings with AIC	Decision concerning the continuing justification for approved scheme status Notes of meetings Letter of confirmation of outcome to AIC	Review lead taken by the FSA, VMD and FSS
Annual	Review of approved scheme against the FSA Criteria for Earned Recognition and principles of the MOU	Management data as set out in Annexes C and E supplied by AIC, VMD, FSA and FSS Review any changes to legislation to ensure that those changes have been incorporated into (or will be incorporated into) the scheme's standards	Evidence collected to support continued justification of earned recognition Notes of meetings Report to senior officials	Review lead taken by the FSA, VMD and FSS Nominated resource from AIC

Meeting	Activities	Inputs	Outputs	Attendees
Quarterly Meetings	Review of specific criteria in relation to the approved scheme, to verify: <ul style="list-style-type: none"> • Confidence in the audit process; • Ability of the scheme to deliver the audit process; • Confidence in compliance with standards; • Confidence in data sharing; and • Non-compliance information 	Management data as set out in Annexes C and E supplied by AIC, VMD, FSA and FSS	Notes of meetings	Review lead taken by the FSA, VMD and FSS Nominated resource from AIC

Annex E

Data management

Management data	FSA/VMD/FSS	Enforcing authority
Membership of schemes		
The identification of members of the scheme indicating when the member was audited	Electronic access to AIC data	Electronic access to AIC data
The identification of members that leave, join or are suspended from the scheme	Electronic access to AIC data	Electronic access to AIC data or data supplied by the FSA or FSS
Total number of unique members	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Management of the audit programme/process		
Completion of the audit schedule - audits completed/overdue	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Training of auditors	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Number of witness audits carried out by the certification body and outcome	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Results of verification arrangements for monitoring auditors	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Confirmation that Certification Bodies are UKAS certified or equivalent	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Performance of scheme members		
Levels of compliance by scheme – number of non-compliances against identified standards, including: <ul style="list-style-type: none"> ▪ Identification of the most frequent non-compliances by sector • Levels of compliance identified against standards categorised as key to public health 	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Number of members suspended and reason	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Number of withdrawals by scheme and the reasons	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Number of businesses with outstanding rectification work over the defined timescale (for minor non-conformances)	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Confirmation that members have been suspended in line with scheme timescales (for major non-conformances)	Quarterly basis reported to the FSA/VMD/FSS by AIC	

Management data	FSA/VMD/FSS	Enforcing authority
Number of unannounced audits carried out by the certification body, results, problems rectification plan	Quarterly basis reported to the FSA/VMD/FSS by AIC	
Results of VMD/local authority inspections of scheme members	Quarterly basis reported to AIC by FSA/VMD/FSS	

Annex F

Agreement Managers and Co-ordinators

- FSA - England: Head of Animal Feed Delivery
 - Wales: Head of Local Authority Support and Audit
 - Northern Ireland: Head of Operational Policy and Delivery
- VMD - Lead on Feed
- FSS - Head of Enforcement Delivery
- AIC - UFAS/FEMAS Technical Manager and TASC Technical Manager

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