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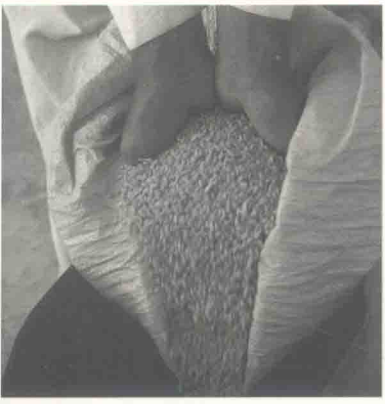

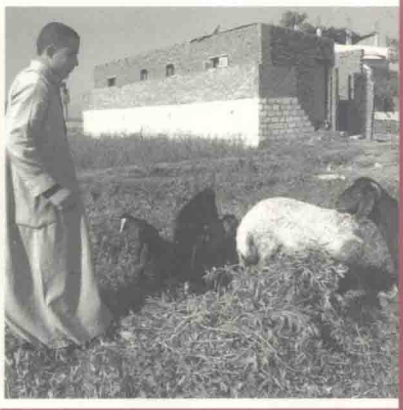

manual

QUALITY ASSURANCE FOR MICROBIOLOGY IN FEED ANALYSIS LABORATORIES

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QUALITY ASSURANCE FOR MICROBIOLOGY IN FEED ANALYSIS LABORATORIES

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Foreword

Animal feeding impacts on many areas of agriculture: productivity, environmental emissions, water pollution, land use, animal health, product safety, product quality and animal welfare.

Every sector of the livestock industry, the associated services and the wellbeing of both animals and humans are influenced by animal feeding. Proper animal feeding is the supply of a diet balanced in all nutrients and free from contaminants and undesirable substances, at a level that meets the production objective (considering the animal's physiological state) and generates animal products that are safe for human consumption.

One of the most significant contaminants of animal feed are microbiological agents. The detection and enumeration of harmful bacteria, yeasts, fungi and parasites is imperative for the health of the animals and of the humans consuming animal products. A robust Quality Management System, within microbiology laboratories engaged in testing animal feed, is vital to guarantee that only reliable data is produced which ensures confidence in the microbiological testing undertaken.

Reports received from international experts visiting animal nutrition laboratories which are engaged in analysing feeds and feed ingredients in developing countries, highlight the need to strengthen quality assurance systems in these laboratories. Without a robust Quality Management System in place, the microbiology laboratory personnel are unable to evaluate the quality of the results being generated. Various ring trials conducted in developed countries have shown an unacceptable variation for some matrices being routinely determined in feed analysis laboratories. Similarly evidence received from the feed industries in developing countries on the reliability of feed analysis data suggests this is inconsistent. Therefore an urgent need to produce a document covering quality assurance systems was realized.

A previous document (Quality Assurance for Animal Feed Analysis Laboratories) was developed and prepared by a panel of nine experts. The emphasis was on the basic analysis used for determining the nutritional value of feeds and feed ingredients. The document gave a comprehensive account of good laboratory practices, quality assurance procedures and examples of standard operating procedures as used in individual specialist laboratories.

At the time of preparation a need was identified for an additional document dealing specifically with microbiological procedures and quality assurance in microbiology laboratories. One of the original panel of experts, with suitable microbiology and quality assurance experience, was approached to write such a document. This document has been peer reviewed by a number of international experts. The adoption of the practices and procedures in the manual will assist microbiology laboratories in acquiring the recognition of competence required for certification or accreditation and will also enhance the quality of the microbiological data generated by feed analysis laboratories. In addition, ensuring good laboratory practices presented in the document will enhance the health and safety of the laboratory workers, protect the environment from laboratory-discharged pollutants and increase the efficiency of laboratories. The document will also provide a strong base for microbiology laboratories on which they can develop a system which will meet the requirements of international standards. It will be useful for Laboratory Practitioners, Laboratory

Analysts, Laboratory Managers, research students and teachers and it is hoped that it will enable workers in animal industry to appreciate the importance of proven reliable data and the associated quality assurance approaches. This document, through increasing skills and knowledge of laboratory personnel and researchers, will also result in quality assurance systems becoming an integral part of the functioning of a microbiology laboratory. It will assist countries to initiate the process of getting their feed analysis laboratories accredited to international standards.

An additional effect of implementing and adopting these quality control/assurance approaches will be strengthening of the research and education capabilities of students graduating from R&D institutions and promotion of a better trading environment between developing and developed economies. This will have long-term benefits and will promote investment in both feed industries and R&D institutions.

This document will also serve as a basis for developing a self-learning e-module and for organising training workshops aimed at Laboratory Managers and Technical Analysts on quality control/assurance approaches in microbiology laboratories.

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We thank all peer reviewers (listed at the end of this manual) and Fallou Gueye and Philippe Ankers for taking time for critically reading this manual and for their comments and suggestions that led to improvement of this manual. The production of this manual was coordinated and managed by Harinder P.S. Makkar. Excellent support provided by Philippe Ankers is highly appreciated. The desktop publishing by Carmen Hopmans and Claudia Ciarlantini is also acknowledged.

Contents

PART 1

The Quality Management System in a microbiology laboratory

Introduction

Availability of animal feed and efficient feeding are the foundations of successful livestock production. The feeding of a balanced ration and proper feed formulation increases animal productivity, animal product quality and animal welfare. Also to decrease livestock associated pollution of the environment feeding of a diet that matches the physiological status of the animal is essential.

For the best health protection of both the animal and human population and to facilitate trade between developing and developed countries, the harmonising of Quality Assurance approaches is imperative.

A wide range of microbiological organisms occur either naturally or as contaminants of cereal grains, forages and vegetable matter. Some of these microbes can have beneficial effects such as the fermentation of forages in the process of producing silage, or the probiotic properties of some bacteria and yeasts which may be added to animal feeds.

Animal feed may become contaminated with bacteria, yeasts or fungi which are harmful, such *as E. coli, Listeria* spp., *Salmonella* spp. or *Aspergillus* spp. as a result of faecal or slurry contamination or, in the case of *Aspergillus* spp., this may occur in the field or as a result of storage in damp conditions. Ingestion of contaminated animal feed can have adverse effects on animal health and production and may introduce infection to the human population.

A robust Quality Management System provides the mechanism to ensure confidence in the laboratory results issued to customers and provides a mechanism to constantly monitor microbiology laboratory results and identify any opportunities for improvement that may be noted.

A Quality Management System provides management, staff and customers with confidence that all technical, administrative and human factors that may influence the quality of the results being generated are constantly monitored with the aim to prevent any non-conformities and identify any opportunities for improvement. A robust quality assurance system ensures credibility of data produced by animal nutrition/feed analysis laboratories and satisfies the customer expectation that results will be reliable and trustworthy.

Mutual recognition and the harmonisation of laboratory standards facilitate international trade in animal products and will ultimately improve the health of both farm animals and the human population throughout the world.

This manual has been prepared to complement the previous publication 'Quality Assurance for Animal Feed Laboratories' (FAO, 2011) and describes additional procedures for detection and isolation of microbiological agents which may be found in animal feeds. Both documents may be used by animal nutrition/feed analysis laboratories and serve as a reference source which specific laboratory facilities can use to implement standard operating procedures (SOPs) appropriate to their specific situations. However the principles laid down are generalized and may not apply to every laboratory situation.

The Quality Management System described in this manual is based on ISO/IEC 17025:2005 principles and EA-04/10 'Accreditation for Microbiological Laboratories' and is intended to help laboratory personnel maintain the standards expected while providing a consistent, reliable, efficient and professional service with the level of quality required and expected by the laboratory's customers. This is achieved by the commitment of management and staff at all grades to apply laboratory practices that ensure the quality of testing services and results produced.

Since the work in individual laboratories varies greatly it is essential to have a flexible yet detailed Quality Management System. The laboratory personnel must have an understanding of the principles underlying quality assurance and must apply them in all areas of their work. Only in this way can they maintain credibility, which is the most important attribute of any laboratory. This manual provides a strong foundation for microbiology laboratories on which they can develop a Quality Management System which will meet requirements imposed by international standards.

This manual has been divided in two main sections. The first section presents general aspects of quality assurance procedures and good laboratory practices that must be put in place in a feed analysis laboratory performing microbiological testing. The second section contains some basic microbiology procedures for preparation and handling of microbiological samples and isolation and detection procedures for some common animal feed microbial contaminants. Most of the methods described have been taken from laboratories which hold ISO/IEC 17025:2005 accreditation, the workers in these laboratories have been using these methods for many years and the methods have proved reliable. However, other methods or variants of the method presented in this manual may also be used.

ISO/IEC 17025:2005 should be read in conjunction with EA-04/10 (European co-operation for Accreditation) Accreditation for Microbiology Laboratories. This document supplements ISO/IEC 17025:2005 and provides specific guidance for laboratories performing microbiological testing. EA-04/10 also provides guidance for microbiology laboratories working toward GLP (Good Laboratory Practice), GMP (Good Manufacturing Practice) and GCP (Good Clinical Practice).

REFERENCES

FAO. 2011. *Quality assurance for animal feed analysis laboratories*. FAO Animal Production and Health Manual No. 14. Rome, Italy.

ISO/IEC 17025:2005. *General requirements for the competence of testing and calibration laboratories*. Geneva, Switzerland.

Glossary of terms

Accreditation: The confirmation by a third party accreditation body (usually governmental) that a laboratory meets the requirements of an accreditation standard e.g. ISO/IEC 17025:2005.

Accuracy: The difference between an observed or measured value and the accepted or 'true value'. Since accuracy is affected by both random and systematic errors, accuracy can also be defined as the sum of systematic plus random error.

Anomaly: An unexpected occurrence which has had (or had the potential to have) a negative effect on the work undertaken by the laboratory.

Biosecurity: A set of preventive measures designed and applied to reduce the risk of introducing a pathogenic agent into an enclosed laboratory.

Blank: A sample containing no added analyte or a sample treated in such a manner that the desired reaction does not take place, e.g., one of the reagents used to produce a reaction is omitted.

Certification: The confirmation by an independent, third party certification body that conformity is demonstrated with the specific requirements of a standard e.g. ISO 9001:2008 or ISO 14001:2004. Certification may also be referred to as 'Registration'.

Collection of Substances Hazardous to Health Regulations 2002 (COSHH): Documentation detailing specific hazards relating to exposure, health and incident planning associated with a substance in the workplace. (Statutory in the UK).

Complaint: An expression of dissatisfaction from a customer regarding the quality of work performed by the laboratory.

Containment Level (CL): The bio-containment precautions that are to be taken when handling potentially harmful biological agents in an enclosed laboratory. These range from CL 1 (minimum level) to CL 4 (the highest).

Corrective and Preventive Action (CAPA): Corrective actions are actions taken when a process deviates outside the specification of the Quality Management System. Corrective Actions removes the 'cause' and Preventive Action prevents recurrence. CAPA may be undertaken as result of an anomaly, non-conformance or customer complaint.

Document: A controlled written policy, procedure, or work instruction that defines what operators do and how to do it. Controlled means that the document states who wrote and/or authorized the policy or procedure, when it was issued and states a version number to avoid the use of a document that is no longer valid. Control of documentation will normally be the responsibility of the Quality Assurance Manager.

Gap Analysis: An audit with the purpose of establishing the current 'gap' between current activities and those which would meet the requirements of a standard or Management System.

High Efficiency Particulate Absorption (HEPA): A type of filter used in laboratories which can remove 99.97% of particles greater than 0.3 µm from the air that passes through it. Such filters are frequently used in biological safety cabinets in microbiology laboratories.

Impact assessment: The procedure of investigating and establishing the effect a non-conformance or anomaly may have had on work undertaken.

Integrated Management System (IMS): A combined management system which fulfils the requirements of the Quality Management System (ISO 17025:2005 or ISO 9001:2008) and an Environmental Management System (ISO 14001:2004) and/or Occupational Health and Safety Management System (BS OHSAS 18001:2007).

ISO The 'International Organization for Standardization': The international standard setting body which is based in Geneva, Switzerland. ISO comprises representatives from various national standards organisations from around the world and promotes and disseminates standards.

Internal Quality Assurance (IQA/ring trial): Samples sourced by the laboratory in order to demonstrate competence and may take the place of proficiency samples.

Internal Quality Control (IQC:) Samples of traceable known value which may be used to confirm that a procedure or process has worked as intended.

Limit of Detection (LOD): The lowest perceivable signal above the background for a particular procedure. The LOD is defined as the mean of the blank plus three standard deviations of the mean of the blank.

Material Safety Data Sheet (MSDS): Information supplied with a substance or chemical which provides workers and emergency personnel with information regarding safe working and handling. Information in MSDS can include physical data, toxicity, first aid, health effects, reactivity, storage, disposal, PPE requirements and information regarding spills.

Measurement Uncertainty (MU): An expression of confidence in the reliability of the results of laboratory tests.

Non-conformance: A finding that is noted during audit which contravenes the Quality Management System, Health and Safety Management System, Environmental Management System, an SOP or standard.

Personal Protective Equipment (PPE): Safety equipment supplied to laboratory workers and visitors to reduce the risk of injury or contamination. This includes laboratory coats, eye protectors, gloves etc.

Proficiency Sample (External Quality Assurance, EQA): Samples provided by an external source in order to compare laboratory results between similar laboratories. These may be used as an internal quality control sample. External Proficiency Providers should hold accreditation to ISO/IEC 17043:2010 – Conformity assessment – general requirements for proficiency testing.

Quality Assurance (QA): Planned and systematic activities implemented within the laboratory that provide confidence in the accuracy and reliability of results generated.

Quality Control (QC): Activities used to monitor a process or to check a result and provide assurance that all activities are performing within predetermined limits set by the laboratory.

Quality Management System (QMS): All documented and implemented processes within an organisation which describe work activity.

Records: Can be electronic or paper. Examples include chain of custody paperwork, sample results, worksheets, QA/QC data, audit results, calibration records, etc.

Standard Operating Procedure (SOP): Document describing specified steps taken in a method. This method can be a specific analytical procedure or a policy controlling a more generic aspect of the work performed (e.g. training records, handling complaints or using balances). SOPs may be paper or electronic but must be controlled and available at the point of use.

Traceability: The property of the result of a measurement whereby it can be related to stated references, usually international standards, through an unbroken chain of comparisons.

Trainee: A person receiving training in the workplace.

Trainer: A person who is trained and competent in a procedure and is training another.

Validation: The robust process of demonstrating and documenting that a procedure is fit for purpose and establishing the limits of testing that may apply.

Quality assurance purpose and guidelines

Laboratory quality programs are a critical part of improving the agriculture laboratories in developing countries. The Laboratory Quality Manual is the essential source for communicating to the laboratory staff the manner in which laboratory testing is to be conducted. Adherence to the Quality Manual by laboratory staff is essential to ensure both the quality and consistency of microbiology results generated. Recognizing that the Laboratory Quality Manual may not cover all situations and variables arising from the laboratory setting, any significant departures must have the concurrence of management and must be appropriately documented.

The management within the laboratory is responsible for the quality and integrity of all data generated in the laboratory. The management, collectively, assures this quality through adherence to the Laboratory Quality Manual, quality assurance plan, and through the development and adherence to standard operating procedures (SOPs).

Third party recognition (accreditation or certification) of a Quality Management System provides assurance to customers that the Quality Management System operated by a laboratory meets the requirements of internationally recognized standards. The international standard for the general requirements for the competence of testing and calibration laboratories is ISO/IEC 17025:2005.

Many organisations will hold certification (or registration) to ISO 9001:2008 (Quality Management System Requirements) which forms a basis for ISO/IEC 17025:2005. Testing and calibration laboratories that comply with ISO/IEC 17025:2005 will also operate in accordance with ISO 9001:2008.

Laboratories may also wish to consider certification to ISO 14001:2004 (Environmental Management System) and/or BS OHSAS 18001:2007 (Occupational Health and Safety Management Systems) which are compatible with ISO 9001:2008 and ISO/IEC 17025:2005.

If a laboratory holds accreditation/certification to more than one international standard it may develop an Integrated Management System (IMS) which has one Quality Manual and one set of SOPs which cover all requirements of the standards for which accreditation/certification is held.