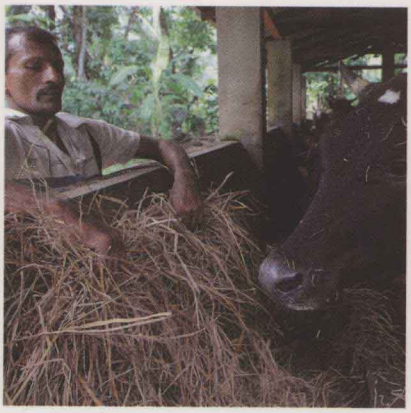
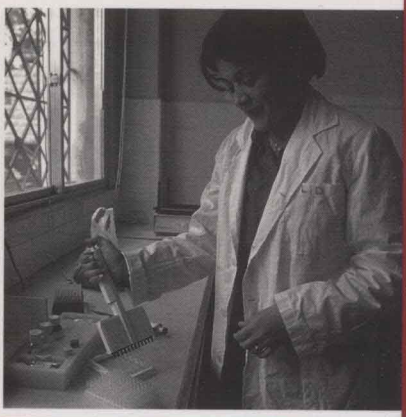
14 ISSN 1810-1119

FAO ANIMAL PRODUCTION AND HEALTH

manual

QUALITY ASSURANCE FOR ANIMAL FEED ANALYSIS LABORATORIES

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Jim Balthrop, Benedikt Brand, Richard A. Cowie, Jürgen Danier, Johan De Boever, Leon de Jonge, Felicity Jackson, Harinder P.S. Makkar and Chris Piotrowski

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2011

Information for users of this Manual

Should you face any problem in using methods described in this manual or have a query regarding a method, you may contact experts listed in the FAO Network of Experts: http://www.fao.org/ag/againfo/home/documents/Network_Quality-control.pdf

Recommended citation

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

ISBN 978-92-5-107050-5

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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 deleterious components, at a level that meets the production objective, considering the animal's physiological state, and generates animal products that are safe for human consumption. The availability of accurate, reliable and reproducible analytical data is imperative for proper feed formulation. Also only reliable data can lead to the generation of sound scientific data.

Reports received from international experts visiting animal nutrition laboratories, engaged in analysing feeds and feed ingredients in developing countries, highlight the need to strengthen quality assurance systems in these laboratories. As suitable quality assurance systems are not in place, the laboratory personnel are unable to evaluate the quality of the data being generated. Various ring tests conducted in developed countries have shown an unacceptable variation for some analytes 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 realised.

The current document has been developed and prepared by a panel of nine experts. The emphasis is on the basic analysis used for determining the nutritional value of feeds and feed ingredients. The document gives a comprehensive account of good laboratory practices, quality assurance procedures and examples of standard operating procedures as used in individual specialist laboratories. The adoption of these practices and procedures will assist laboratories in acquiring the recognition of competence required for certification or accreditation and will also enhance the quality of the data reported by feed analysis laboratories. In addition, ensuring good laboratory practices presented in the document will enhance the 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 laboratories on which they can develop a system which will meet the requirements of international standards. It will be useful for Laboratory Analysts, Laboratory Managers, research students and teachers and it is hoped that it will enable workers in animal industry, including the aquaculture 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 feed analysis 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. Based on the feedback from users, the document will be expanded in future by including important techniques for feed additives, microbiology, drug residues and other undesirables.

Berhe G. Tekola
Director
Animal Production and Health Division
Food and Agriculture Organization
of the United Nation

Authors

Jim Balthrop
Office of the Texas State Chemist
Quality Assurance Manager
P.O. Box 3160
College Station, Texas 77841, USA

Benedikt Brand
Staatliches Veterinäruntersuchungsamt
Arnsberg
Dez. 43: Verbraucherschutz, Futtermittel
Zur Taubeneiche 10-12
59821 Arnsberg
Germany

Richard A Cowie
Senior Quality Assurance Manager
SAC
Ferguson Building
Craibstone Estate
Aberdeen
AB21 9YA
Scotland

Jürgen Danier
c/o Bioanalytic Weihenstephan Unit
Research Center for Nutrition and Food
Science, Technische Universität München
Alte Akademie 10, 85354 Freising
Germany

Johan De Boever
Institute for Agricultural and Fisheries
Research
Animal Sciences Unit Scheldeweg 68
9090 Melle
Belgium

Leon de Jonge
Animal Nutrition Group
Wageningen University PO Box 338
6700 AH Wageningen
The Netherlands

Felicity Jackson
Manager, Nutrition Laboratory
Institute of Food, Nutrition &
Human Health
Private Bag 11222, Riddet Rd
Massey University Palmerston North 4474
New Zealand

Harinder P.S. Makkar
Animal Production Officer
Animal Production and Health Division
Food and Agriculture Organization of the
United Nations
Viale delle Terme di Caracalla
00153, Rome, Italy

Chris Piotrowski
Director, Aunir
Aunir - a division of AB Agri
The Byre, Pury Hill Business Park
Alderton, Nr Towcester
Northants, NN12 7LS
England

Acknowledgements

We thank Dr. Jim Balthrop for preparing the initial draft. Special thanks are also due to Ms. Felicity Jackson and Mr. Leon de Jonge for their untiring efforts to collate the information from other contributors and to bring the contents to a uniform format. We are also grateful to Prof. Tim Herrman for his suggestions during the initial phase of the manual preparation. Excellent support provided by Mr. Simon Mack, former Chief of Livestock Production Systems Branch (AGAS); Philippe Anker, Current Chief of AGAS and Samuel Jutzi, former Director of Animal Production and Health Division is highly appreciated.

Glossary of Terms

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.

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.

Coefficient of Variation (Relative Standard Deviation). The standard deviation divided by the mean and multiplied by 100.

Control Chart. A graphical method for recording measured values which, by using control limits, helps determine whether a process is steady and 'on target'. All control charts have three basic components:

A centreline, usually the mathematical average of all the samples plotted. An upper and lower statistical control limit that define the constraints of common cause variations, and the performance data plotted over time. The use of statistical process control charts allows for the monitoring of variation in laboratory analyses, over a specified time period.

Document. A controlled written policy, procedure, or work instruction that defines what people do and how to do it. Controlled means that the document states who wrote or authorised the policy or procedure, when it was issued and states any 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.

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.

Limit of Quantification (LOQ). The lowest experimentally measurable signal obtained for the actual analyte using a particular procedure. The LOQ is defined as the average mean of the blank plus ten standard deviations of the mean of the blank.

Linearity. Where a series of points show less than 3% deviation from a straight line.

Outlier. An observation which deviates so much from other observations as to arouse suspicions that it was generated by a different or erroneous procedure.

Precision. A measure of the scatter of the data around the average.

Proficiency Sample (External Quality Assurance Sample). Samples provided by external source in order to compare laboratory results between laboratories and may be used as an internal quality control sample.

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

Quality Control. Activities used to monitor a process or to check a result and provide assurance that all activities are performing within pre-determined limits set by the laboratory.

Records. Can be electronic or paper. Examples include chain of custody paperwork, sample results, 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).

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.

Working control. An internal quality control sample, of known value, analysed with each group of samples in order to monitor the performance of the method and analyst (see Table 2).

Contents

Introduction

Availability of animal feed and efficient feeding are the foundations of successful livestock production. The feeding of a balanced ration and correct feed formulation increases animal productivity, quality of product 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 undeveloped countries, the harmonising of Quality Assurance approaches is imperative.

A robust Quality Management System provides the mechanism to ensure that all these criteria are met and provides a system to constantly monitor laboratory results and identify opportunities for improvement.

A Quality Management System provides management, staff and customers with confidence that all technical, administrative and human factors that influence the quality of the results being generated are under continuous supervision with the aim to prevent non conformity and identify opportunities for improvement.

This manual has been prepared to describe a Quality Management System that may be used by animal nutrition/feed analysis laboratories and serve as a reference source which specific laboratories can use to implement protocols appropriate to their specific situations. However the principles laid down are generalised and may not apply to every laboratory situation.

The Quality Management System described in this manual is based on ISO 17025:2005 principles 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 by the laboratory's customers. This policy is achieved through the commitment of management and staff at all levels to apply laboratory practices that ensure the quality of testing services and of the 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 laboratories on which they can develop a Quality Management System which will meet the requirements of the international standard.

The manual has been divided in two main sections. Part I presents general aspects of quality assurance procedures and good laboratory practices that must be put in place in the feed analysis laboratory. Part II contains some basic procedures for determination of nutrients and mycotoxins. The methods described for various analytes have been taken from official recognised methods as well as from the laboratories whose representatives

contributed to the production of this document. The analysts in these laboratories have been using these methods for many years and the methods have proved reliable. However, other methods or variants of the methods presented in this manual may also be used.

It is planned to include a number of important techniques for feed additives, microbiological agents, drug residues and other undesirables and associated quality assurance approaches in the next edition of the manual.

PART I

Quality assurance procedures and good laboratory practices

Setting up a quality laboratory system

QUALITY AND QUALITY CONTROL SYSTEMS

This section explains what is meant by Quality and Quality Management System and how this will impact on and improve working in a laboratory.

What does Quality mean?

Quality is not easy to define but it needs to be defined by an accredited laboratory. It can mean different things to different people. However, in all aspects of business 'Quality' has become very important. Whether it is a manufacturing or a multi-disciplinary organisation, all successful organisations want to be associated with the word 'Quality'.

So what is Quality? A textbook definition is: *Quality is fitness for purpose.*

The International Standards Organisation (ISO) has produced a document entitled 'Quality Management Systems – Fundamentals and Vocabulary', in which the word 'Quality' is defined as: *Degree to which a set of inherent characteristics fulfils requirements.*

This clearly indicates that achieving quality means fulfilling requirements. The requirements may come from customers and in some cases from regulatory authorities.

How can Quality be achieved?

Quality is everyone's responsibility; it must be built in at every stage of the process, from identifying the customer's needs, through planning and implementation right up to the point of reporting analytical results.

In some cases, quality needs to be checked even beyond delivery to the customer since customer satisfaction can have an enormous impact on quality as perceived by them.

Making it happen!

It must be understood that quality does not occur by accident. The starting point is identifying the customer's needs and from that a plan must be considered for the processes and resources and application of monitoring controls. The analyst needs to be continually assessing his/her performance against his/her own objectives and standards to strive for improvement. Since quality does not occur by accident there is a need to establish an effective Quality Management System in order to ensure that requirements are fulfilled efficiently and effectively. This manual is a start to achieving this.

Quality Management System

A Quality Management System directs and controls an organisation with regard to quality by putting in place standard operating procedures (SOPs) to which everyone operates in a