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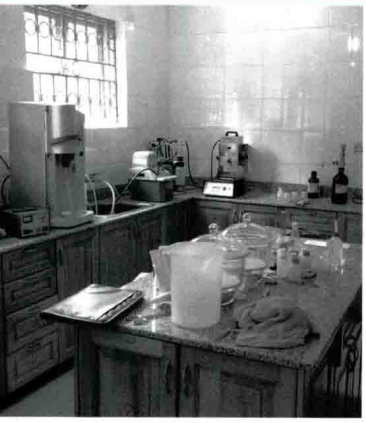

THE FEED ANALYSIS LABORATORY: ESTABLISHMENT AND QUALITY CONTROL

Setting up a feed analysis laboratory, and implementing a quality assurance system compliant with ISO/IEC 17025:2005

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FAO ANIMAL PRODUCTION AND HEALTH
guidelines

THE FEED ANALYSIS LABORATORY: ESTABLISHMENT AND QUALITY CONTROL

Setting up a feed analysis laboratory, and implementing a quality assurance system compliant with ISO/IEC 17025:2005

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Foreword

Feed has a fundamental influence on productivity, health and welfare of the animal. Feed quality influences animal product quality and safety, and the environment. To achieve balance among these parameters, the animal's nutritional requirements must be properly met.

Confidence in the nutritional information on any feed or feed ingredient provided by suppliers is critical for buyers because it provides a guarantee of feed quality. Current reports from many countries suggest that manufacturers and buyers do not always have confidence in the data provided from non-accredited laboratories, which can negatively affect market prices and international trade. It is therefore important that laboratories work towards adopting a Quality Assurance System for all of their routine feed analyses. This has been detailed in two FAO *Animal Production and Health Manuals:* No. 14, *Quality Assurance for Animal Feed Analysis Laboratories,* and No. 16, *Quality Assurance for Microbiology in Feed Analysis Laboratories*.

Not only must the methods used be of an internationally recognized standard, but all steps in the process, from the initial sample submission through to the final report preparation, must be traceable. An internationally accredited laboratory gives producers and buyers of feed a great deal of confidence in the data they receive. This provides wider market possibilities for feed manufacturers. Also, the right nutritional information about feed ingredients and feeds will enable preparation of balanced diets that meet the nutritional requirements to match the physiological stage of animals and to satisfy the farmer's husbandry objectives.

This document presents a step-by-step process to guide the laboratory management team through the various stages, from planning the feed analysis laboratory building and layout, to hiring suitable staff and choosing which methods to set up, with appropriate equipment requirements. A detailed guideline for initiating a Quality Management System starts with validation of methods, personnel and training; addresses systematic equipment maintenance, calibration, proficiency testing and quality control procedures; and final reporting and auditing, all culminating in a final accreditation inspection within an estimated four-year time frame.

The authors have extensive laboratory experience as well as personal experience with successfully bringing non-accredited laboratories up to an internationally recognized accreditation standard. The content of the document has been peer reviewed by a large number of experts and their suggestions incorporated. The guidelines presented will assist governments and feed manufacturers, as well as a range of institutions, including research and education, to work towards establishment of a feed analysis laboratory – whether as an integral unit or as an independent commercial laboratory – with internationally recognized accreditation.

Berhe G. Tekola
Director
Animal Production and Health Division

Abbreviations

A.U.	Absorption Unit
AAS	Atomic Absorption Spectroscopy
ANOVA	Analysis of variance
CRM	Certified Reference Material
CUSUM	Cumulative sum
FAO	Food and Agriculture Organization of the United Nations
FAO/IAEA	FAO/IAEA Agriculture and Biotechnology Laboratory
GC	Gas chromatography
GC-FID	Gas Chromatography-Flame Ionization Detector
GC-MS	Gas Chromatography-Mass Spectrometry
HPLC	High Performance Liquid Chromatography
IAEA	International Atomic Energy Agency
ICP	Inductively Coupled Plasma [Analysis]
ICP-AES	Inductively Coupled Plasma–Atomic Emission Spectroscopy
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
LC-MS	Liquid Chromatograph–Mass Spectrometer
LIMS	Laboratory Information Management System
LOD	Limit of Detection
LOQ	Limit of Quantification
MS	Mass Spectrometer
MS-MS	Sequential mass spectrometry
MU	Measurement of uncertainty
NIR	Near-Infrared Spectrometry
PR	Public Relations
PSG	Project Steering Group
QA	Quality Assurance
QMS	Quality Management System
R&D	Research and development
ROI	Return on Investment
SD	Standard deviation
SOP	Standard operating procedure
UV	Ultraviolet

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Chapter 1
Introduction

1.1 BACKGROUND

The importance of livestock production in developing countries is increasing due to growing demands for animal products, combined with demands for more sustainable agriculture. Globalization and increased demand for animal products also offer export opportunities, leading to improved welfare for people from the exporting countries. Key elements for success, however, are high productivity and low prices, coupled with high quality and safety of animal products. Chemical analyses of diets and animal products play an essential role in achieving optimal production and guaranteeing safety for consumers. In developed countries, it is common practice to undertake most of the analyses in accredited laboratories. The availability of this kind of service in developing countries is constrained due to fewer laboratories and a lack of infrastructure. This can lead to a lack of reliable data, which can make animal agriculture in developing countries much less competitively priced when compared with that in developed countries.

The situation in developing countries can be improved by increasing the number of laboratories and improving the quality of the available analytical services. The provision of relevant information and training can be used as a tool to improve the quality of the analytical services in these laboratories. For this purpose, an international group of laboratory experts participated in an FAO working group that led to the publication of two manuals describing quality assurance, safety issues and analytical methods: *Quality assurance for animal feed analysis laboratories* (FAO, 2011), and *Quality assurance for microbiology in feed analysis laboratories* (FAO, 2013). This group was also the starting point for an FAO network of international experts, aimed at improving analytical capability in developing countries.

Increasing the number of laboratories, however, is a challenging task. The initiative to start a laboratory lies with local stakeholders and is based on an investment decision. The high investment and the technical complexity can result in hesitation by stakeholders because of a lack of expertise.

1.2 AIM

The aim of this present document is to present guidelines for starting and running an animal feed analysis laboratory, including the implementation of quality assurance (QA) systems compliant with an international standard. To achieve this goal, the relevant information will be described and illustrated by giving examples wherever appropriate, which should lead to a better understanding by semi-technical persons and decision-makers.

1.3 A ROAD MAP OF THE DOCUMENT

The document is divided into three parts.

The first part (Chapter 2) describes the initial phase of building an animal feed analysis laboratory, a phase especially important for decision-makers and business developers. Some critical and crucial decisions have to be made during this phase, with such central questions as: *What should the laboratory do?* and *What are the chances of success in terms of being an economically viable unit?* To answer these questions, stakeholders should first undertake a market analysis and identify any potential customers, their particular requirements, and other business opportunities to make the project viable. This information is necessary to make a balanced judgement of the potential benefits or profits with respect to the investment required. This document addresses the issue from the point of view of different types of laboratory. The investments needed for facilities, equipment, consumables and labour (time and skill) will be given for the different types of analyses, including a global price indication. Using this information, stakeholders should be in a better position to calculate Return on Investment (ROI).

The second part (Chapter 3) of the document deals with the physical creation and running of the laboratory, and is especially important for financers and the laboratory staff. The first section deals, among others, with the physical creation of the laboratory, such as securing the land; building the laboratory, including the necessary facilities; employing suitable laboratory personnel; purchasing appropriate equipment; and organizing the laboratory (placement of various items of equipment and their safe operation). Special attention is given to pertinent legislation, and health and safety aspects. The second section focuses on the organization of the primary process, from receiving sample material to sending analysis reports and invoices, and management of the laboratory. Crucial elements, such as storage, planning, traceability and confidentiality, are highlighted, and examples of the related procedures described. Management aspects are separated into internal and external. Internal aspects focus on optimization, and increasing efficiency and quality of the laboratory processes. This also includes human resource management. External aspects focus on improving the market position of the laboratory, including enhancing contact with customers, identifying new customers, better positioning of the laboratory within the marketplace, establishing contacts with national and international networks on laboratory analyses, participation in conferences that address feed and food analysis issues, and exhibitions of laboratory equipment. Both aspects are important to ensure the successful running of the organization.

The third and final part of this document (Chapter 4) describes the implementation of a QA system, which is especially important for laboratory staff and the QA manager. The quality of the analytical results produced should be guaranteed to gain the confidence of customers. The implementation of a complete quality control system can take several years of experience and refinement before it can be accredited. In this document, activities and their time schedule are described for the implementation of quality principles with the aim of achieving laboratory accreditation according to ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories,* which is an internationally recognized standard for quality systems within testing laboratories. Additional information is also given about implementation of these principles in daily practice.

Chapter 2
Development of a business plan

2.1 INTRODUCTION

Preparation of a business plan is essential for the creation of a new laboratory. A business plan describes aims of the laboratory and a plan to realize them. It also assesses challenges in achieving the aims and making a profit, as well as identifying potential opportunities for the laboratory. The plan can be seen as a road map for the future laboratory to achieve its final goal. The physical creation of a laboratory needs a relatively large investment, and therefore a good business plan can also help to increase the confidence of potential investors. The realization of a business plan involves a range of experts, including marketing and technical specialists, to provide a realistic plan for the new laboratory on which the necessary investments can be based.

The absence of a business plan can lead to incorrect decisions regarding investments, or to missed opportunities, which could lead to a non-profitable outcome.

Two different areas of expertise are necessary:

- knowledge to assess the market situation and to identify opportunities and challenges; and
- laboratory knowledge to evaluate types and requirements of potential analyses and the estimation of laboratory costs.

A group to develop a business plan should be created to include personnel with expertise in both the above two areas. They should regularly interact while developing the plan.

A suggested approach to realize a business plan is described in the next section. This approach should not be seen as definitive, but rather as a possible tool to create a business plan. The example approach is limited to chemical analyses.

2.2 APPROACH FOR DEVELOPMENT OF A BUSINESS PLAN

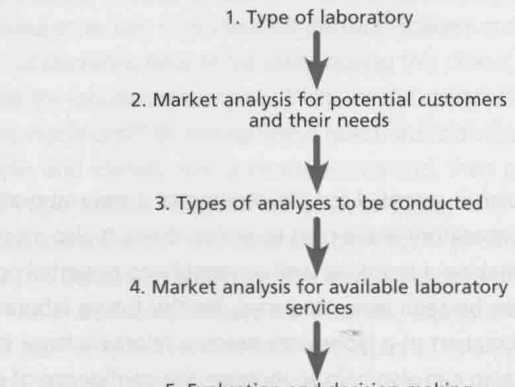
The key elements required to prepare a business plan are given in Figure 2.1.

2.2.1 Type of laboratory to be developed

The characterization of the laboratory to be created is the first important step. From a commercial point of view, a distinction should be made between a laboratory as a stand-alone unit, and one embedded in a larger organization. A laboratory could be one of five types:

- **Stand-alone commercial laboratories.** These laboratories have an independent judicial position, working on a commercial basis with the aim to make a profit. In practice this means that they largely analyse samples sent from commercial clients.
- **Laboratories integrated with feed producing units.** These laboratories are part of a larger organization, but operate as a separate unit within the total chain of quality control of animal diets and pre-mixes produced. In practice they are used for

FIGURE 2.1
Sequential steps in the development of a business plan



the control of feed ingredients and animal diet specifications. Sometimes they also provide services to others outside their own organization.

- **Laboratories integrated with research organizations.** These laboratories are used to analyse samples from experiments performed within a research organization. The analytical work conducted in these laboratories is a mixture of standard analyses and more specific research analyses in a wide range of matrices. These laboratories can operate as separate units or be fully integrated within a research division.
- **Laboratories integrated with educational organizations.** The primary function of these laboratories is to provide training opportunities for students. Students may also analyse their own research samples.
- **Government or reference laboratories.** The function of these laboratories is to be a reference for other laboratories and thereby assist in maintaining and improving the quality of analytical work conducted in the individual laboratories within a country. They are also used by the government for regulatory analyses regarding feed and food safety.

In some situations the laboratories connected to research and educational organizations also analyse samples from commercial clients.

2.2.2 Market analysis for potential customers and their needs

The next step is to identify and quantify potential customers and their needs. These could be producers or users of feed ingredients, such as feed industries, researchers, non-governmental and governmental organizations. The number and type of clients may vary between different locations and reflect the level and sophistication of agriculture and livestock activities in the region. Customers are critical for the revenue of the laboratory and therefore its commercial existence. Good market analysis is necessary to assess the opportunities for a new laboratory to be economically viable. This analysis should take into account the maximum acceptable duration for transport of samples to the laboratory

(ideally no more than one or two days). It should be noted that differences in regulations between countries may present difficulties in sending samples across international borders.

The market analysis should be performed using the steps presented below, starting with an initial analysis based on the current use of analytical services. This should focus on:

- Number and type of customers.
- Type of analyses and the amount spent on analytical services.
- Organization of the analytical services: in-house versus outsourced analysis of samples.

Customers can be divided into categories relating to the amount they are likely to spend per year on analytical requirements, such as small-scale farmers; small- and medium-scale feed manufacturing units; and large feed manufacturing mills. Analytical services should be divided into different types of analyses. An obvious division is to separate the analytical services into proximate analyses (i.e. the classic animal feed analyses) and advanced analyses that use sophisticated instruments (examples being minerals, amino acids and contaminants). The amount spent on each type of analysis can be roughly calculated by identifying the number of samples and the prevailing market prices.

A division between analytical services performed within the organization and those outsourced to independent commercial laboratories should be made. Some companies may have the capability to perform routine analyses in-house, such as nitrogen analysis, which is likely to continue even if a new laboratory offers the same service. The ratio between both types of services strongly affects the opportunities of the new laboratory.

The second step should assess additional and potential opportunities in the market that are likely to utilize the services of the laboratory being established. Attracting new clients should be a primary goal, and this could be achieved by offering a more comprehensive testing facility, faster turnaround time or shorter travel distance than is currently available in the area, or assisting with interpretation of the results and providing recommendations about ration formulation.

A critical evaluation should be undertaken to establish why these potential clients would use analytical services in the future, but are not currently using the services. Having the ability to perform some unique analyses offers clear opportunities for the laboratory and could strengthen its market position. Its realization, however, will have an impact on investments needed (see Section 2.2.3).

The third step is to investigate and predict future market developments. Some important points that can be addressed are:

- growth of the animal production sector;
- pressure to produce animal products efficiently and sustainably;
- national and international legislation for feed and product safety; and
- volume of feed or feed ingredient export.

These issues will require the generation of new information and data, and therefore the need for analytical services. As part of the market analysis it is important to seek advice from local councils as well as national regulators to understand market trends and possible changes to legislation. These should be taken into account at the planning stage. This market analysis should be performed for each type of laboratory.

2.2.3 Types of analyses

The types of analyses conducted by the laboratory affect both its market position in terms of attracting potential customers, and the investment needed. The types of analyses can be divided into five types:

Type 1. Proximate analyses
Type 2. Macro-minerals
Type 3. Micro-minerals at trace level
Type 4. Chromatographic analyses (e.g. amino acids, fatty acids)
Type 5. Chromatographic analyses at trace levels (contaminants such as aflatoxins, pesticides and pesticide residues, antibiotics, etc.).

The types of analyses will determine the investment needed. Proximate analyses are used for feed characterization for general nutritional parameters, and the capacity to perform these analyses should be seen as the minimum requirement for every laboratory. Other types of analysis are more specialized and need specific equipment and facilities. For minerals and chromatographic analyses, it is important to make a distinction based on the required detection limit of the samples to be analysed. Determination of trace levels are mostly performed to establish the presence or absence of a contaminant that could affect public health, which governments try to protect by legislation (e.g. aflatoxins, pesticides, pesticide residues and antibiotics). Consequently, these determinations not only require highly skilled personnel and sensitive and expensive equipment, but also demand a higher level of purity of chemicals used (including water) and clean work conditions to avoid contamination.

Types of laboratories can be tentatively categorized as:

- Basic nutrition laboratory performing only proximate analyses (Type 1 analyses).
- Laboratory conducting analysis of nutrients; performing proximate, mineral and chromatographic analyses (Types 1 to 4 analyses).
- Laboratory conducting analysis of nutrients and anti-nutrients (Types 1 to 5 analyses).

All animal nutrition laboratories should be able to perform proximate analyses, with the possibly of extending to analysis of other analytes in the future.

It is also possible for a laboratory to sub-contract some analyses if it is not economically viable to set up and maintain capability for all types of analyses (this saves customers the inconvenience of sending multiple samples and ensures the laboratory can still secure a portion of the work, and hence income).

In order to estimate the investment required to perform different types of analyses, a calculation of the cost to perform the proximate analyses as well as the cost to implement other types of analyses should be made. The cost calculation should include costs for facilities, equipment, personnel and consumables.

2.2.4 Market analysis for available laboratory services

The next step in the process is to examine the current market situation for performing analytical services, and the opportunities for changing this situation. The success of the new laboratory depends mostly on the opportunity to take over part of the existing market, so it is therefore important to investigate how much flexibility currently exists. This assessment should focus on the following issues:

- Estimation of the number and type of laboratories already present in a specific area. For the characterization of the laboratories, the division as earlier mentioned (Section 2.2.1) can be used. This analysis will lead to identification of laboratories that can be seen as competitors for the potential new laboratory.
- Identification and assessment of the relationship between the laboratories and the clients. This should give information on the amount different clients will spend on obtaining laboratory services. The relationship between clients and a laboratory will be based on the quality and promptness of services provided to a client. This will also determine their loyalty and personal preference towards a company. Company policy may dictate the flexibility each potential client will have to make a change in their out-sourcing of laboratory business. Some of this information may be commercially sensitive and difficult to obtain.
- Visiting potential clients as part of a Public Relations (PR) exercise can be valuable in establishing contacts in the industry and establishing an indication of the amount of analysis work that could be available and the type of service expected by the clients (e.g. are they dissatisfied with their current suppliers, and if so, for what reason?).

2.2.5 Evaluation and decision-making

The last step in the creation of the business plan is to bring together all the information collected in the previous steps to make an evaluation of the different options. For calculating profitability, the evaluation should estimate the potential revenues and costs. This should be done for the different types of laboratories in Section 2.2.1 above.

The calculation of the potential revenue should be based on the results of the market analysis for each of the clients (Section 2.2.2) and their relationship with the existing laboratories (Section 2.2.4). The first step in this calculation is to gather information on the different types of analysis and the amount a client pays to each of the laboratories in the region. The second step is to estimate how many potential clients would be willing to make a change and to procure services from the new laboratory, and estimate this potential revenue. This likely change can be expressed in terms of a probability factor with a scale from 0 to 1, with 0 being low probability of change to the new laboratory and 1 being a high probability of change. The total revenue is estimated by multiplying the amount spent by the probability factor. As there are a number of factors beyond the control of the laboratory, this figure will only provide an estimate, as an exact figure is difficult to derive. In general, clients that use more than one laboratory are more willing to switch to a new laboratory, compared with those that use only one, provided the new laboratory meets all their analytical needs.

Focusing on a new market can be much more profitable than looking at just the existing market, but it means more uncertainty because it depends on future plans of potential clients. Therefore, it is preferable to focus in the first instance on potential customers within the present market.

The total costs should also be calculated for all the different types of analyses. A good approach is to calculate firstly the costs to perform only the proximate analyses, followed by an estimation of the additional costs to perform other, more advanced, analyses. Costs will vary widely between countries, depending on freight costs, currency exchange rates, availability of suitable equipment or of high grade consumables, and labour costs.

The expected profits for the different options can be calculated from the predicted total revenue and costs. Calculation of profit, however, is based on various input variables that contain uncertainties. A sensitivity analysis can easily be performed by changing the value of input variables and assessing the effect on the calculated profit. This analysis should be limited to those variables that contain the highest uncertainty and therefore have the greatest effect on the accuracy of the calculation. Some examples of such variables are the probable costs and the prices of analyses charged by other laboratories. The evaluation of this uncertainty can be performed by estimating the difference between the predicted profit and a non-profit situation.

The new laboratory should be careful if using the market price for calculating the revenues because it will be competing with other, established laboratories. The new laboratory should avoid using prices that are too low in order to capture a part of the market: a reduction in prices might increase the volume of work, but the consequences could be a decrease in profit as a result of prices with too little profit margin. Also, it could lead to a general 'price war' amongst laboratories, with destructive consequences. In addition, laboratories might find it difficult to raise prices after a certain period.

The final result of these calculations are values for the profitability of the laboratory under different conditions, expressed as an average value with a confidence interval. The range of this confidence interval reflects mainly the uncertainty in the estimation of the potential revenues. The profitability is often expressed as Return on Investment (ROI) which is related to the investments required. The decision-makers and investors will use these values to make decisions regarding the investment in the new laboratory. Depending on the type of laboratory (see Section 2.2.1), however, the decisions could be made in different ways:

- **Stand-alone commercial laboratories.** The decision will be based purely on the level of profitability and its confidence interval. The uncertainty expressed in the range of the confidence interval will positively affect the margin of profit that investors demand.
- **Laboratories integrated with feed producing units.** The decision should primarily be influenced by the profit a feed producer is likely to make from the feed manufacturing activity. In this case, an alternative approach is to compare the costs of the laboratory against those for outsourcing the analyses to be undertaken for effective running of the feed manufacturing unit. A laboratory integrated into the feed manufacturing unit has several benefits, such as a quick turnaround time, not dependant on any outside laboratory, and better quality control of the products. These benefits should also be quantified and taken into consideration when making a decision.
- **Laboratories integrated with research institutes.** The decision will primarily be influenced by the additional value the laboratory brings to the research conducted in the institute. Although such laboratories can also perform analyses for commercial clients, practice shows that these laboratories often have difficulty competing with stand-alone commercial laboratories, mainly due to the high throughput of the latter and thus lower unit costs per analysis. Nevertheless, research laboratories should also try to generate additional revenue by attracting commercial clients. The additional