SOUTHERN AFRICA TRADE HUB

Technical Report:

Assessment of Aflatoxin Testing Facilities in Zambia and Malawi

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LIST OF ACRONYMS

FDCL	Food and Drug Control Laboratory, Ministry of Health
CARS	Chitedze Agricultural Research Station
COMESA	Common Market for Eastern and Southern Africa
DARS	Department of Agriculture Research Services
EAC	East African Community
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
GAP	Good Agricultural Practice
GC-MS	Gas chromatography–mass spectrometry
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis of Critical Control Points
HCC	hepatocellular carcinoma
HPLC	High Performance Liquid Chromatography
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
MBS	Malawi Bureau of Standards
ppb (µg/kg)	parts per billion
PQPS	Plant and Quarantine Phytosanitary Services, Ministry of Agriculture
RUF	Ready to use foods
ROSA	Rapid one step assay
SADC	Southern African Development Community
SATH	Southern African Trade Hub
TLC	Thin Layer Chromatography
UPLC-MS	Ultra High Performance Liquid Chromatography – Mass Spectrometry
UPS	Uninterrupted Power Supply
US	United States
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
VNL	Valid Nutrition
ZABS	Zambia Bureau of Standards
ZARI	Zambia Agricultural Research Institute, Ministry of Agriculture

EXECUTIVE SUMMARY

This report describes the outcome of an assessment on aflatoxin testing facilities in Zambia and Malawi during October and November 2011. The assessment was carried out by an independent consultant.

The objective was to assess the status of the aflatoxin testing facilities in Zambia and Malawi and their ability to provide commercially acceptable aflatoxin testing services. The report gives a summary of the outcomes of the assessment in Section 2 and also discusses the findings in more detail in Section 3.

The report makes a number of recommendations on possible interventions to address the shortcomings identified.

1. INTRODUCTION

The United States Agency for International Development's (USAID) Feed the Future program has two essential aims:

- Addressing the root causes of hunger;
- Establishing a lasting basis for change by aligning USAID's resources with country-owned processes and sustained, multi-stakeholder partnerships.

The Feed the Future program in Southern Africa is targeted at improving livelihoods of people involved in production and beneficiation in selected agricultural value chains. In Southern Africa, the USAID bilateral missions in Mozambique, Malawi and Zambia have drawn up country Feed the Future strategies. Prioritized projects in selected value chains are all focused on delivering program goals.

The overall objective of the USDA Sanitary and Phytosanitary (SPS) work in Southern Africa is based on the broad objectives of Feed the Future regional program. Specifically, it draws direction from the Feed the Future strategy guidelines which emphasize the role of national and regional missions in supporting Feed the Future efforts. A major emphasis of the Feed the Future program is ensuring improved availability and access to safe food by the populations of the focus countries. It makes an underlying assumption that growing cross-border trade will help spur and sustain demand for commodities that countries produce as well as raise the standards of domestic animal, plant and human health. SPS concerns in constraining trade regionally have been identified as key issues that need to be addressed in the framework of SPS annexes of the Southern African Development Community (SADC) Protocol on Trade as well as the proposed Tripartite Agreement between SADC, the Common Market for Eastern and Southern Africa (COMESA) and the East African Community (EAC).

In a complementary program, the Southern African Trade Hub (SATH) seeks to increase economic growth through enhancing competitiveness and trade in selected value chains. Amongst broader project objectives, the project includes three objectives relating to staple foods:

- New Trade Linkages Established and Greater Competitiveness in Staple Foods and other Strategic Value Chains
- Increased Use and Availability of Financial Products and Services for Trade and Investment
- Increased Investment through Targeted Promotion Efforts

Market, quality and safety standards continue to play a critical role in determining if export products actually make it into global markets. Increasingly, however, quality and standards compliance are specified not only for products and quality management systems, but now also for laboratory services (ISO/IEC 17025[1]).

SATH commissioned this assessment in order to determine approaches to enhance regional laboratories' capacity to comply with regional and international market standards, including agricultural standards, particularly relating to aflatoxin testing services. The

[1] International Organization for Standardization - General requirements for the competence of testing and calibration laboratories. www.iso.org

presence of aflatoxin in groundnuts and maize is a constraint to trade in the region and internationally. The presence of accredited aflatoxin testing services are a critical requirement for growth in trade of these commodities. The study will inform further interventions required in order to achieve SATH staple food objectives.

1.1. Background and General Information

Aflatoxin is one of the important components which form part of a group of chemicals commonly referred to as Mycotoxins. These naturally produced fungal metabolites are highly toxic and possible carcinogens. They are known to cause immune-system suppression, growth retardation, liver disease and death in both humans and domestic animals.

Mycotoxin contamination is generally not appropriately controlled and regulated in Africa unless the product is exported. Rural and urban African consumers are exposed to mycotoxin-contaminated foods with significant negative impacts on health. As a result, an estimated 4.5 billion people living in developing countries worldwide may be chronically exposed to aflatoxin through their diet. In the European Union (EU), maximum residue limits set for aflatoxin B_1 in foods destined for human consumption is 2 µg/kg (parts per billion). The South African regulations, according to the Foodstuffs and Cosmetics Act (Act No 54 of 1972), stipulate the following: 15 µg/kg total aflatoxin for peanuts intended for further processing and 10 µg/kg for total aflatoxin in all foodstuffs with a 5 µg/kg level for aflatoxin B_1 in foodstuffs. Since these toxins cannot be sensed by the consumers of the contaminated food product(s), the problem goes mostly undetected. The high incidence of liver cancer in Africa indicates that it might be severe. Aflatoxins in large doses can cause acute liver cirrhosis and death. During 2004, in Kenya 125 deaths occurred out of 317 reported cases of aflatoxicosis. Chronic sub-lethal doses are more insidious due to their immunological and nutritional consequences and all doses increase the risk of liver cancer (hepatocellular carcinoma - HCC). A strong synergy is observed between hepatitis B and C infection, aflatoxin ingestion and liver cancer. The rate of liver cancer is 16 times higher in Mozambique than in the United States (US).

Aflatoxins are regulated in parts per billion (ppb) ranges, the measurement of which requires sophisticated equipment. In addition, for export, certification testing laboratories and tests need to be accredited by an internationally recognized certification body of which there are few in Africa. In Southern Africa there are significant gaps in the status of aflatoxin testing, which need to be formally quantified in preparation for formal interventions to address them.

The physical assessment of 8 aflatoxin testing facilities (4 each in Malawi and Zambia) took place during October and November 2011 to determine:

- The demand and supply for aflatoxin testing services, both current and projected
- The current capability of the laboratories in terms of:
    - Facilities – are the buildings suitable to accommodate the laboratories?
    - Laboratories – are the laboratories suitably organized and equipped for their operational activities?
    - Equipment – is the equipment available suitable for the job, operational, maintained, calibrated and in general good condition?

- Personnel – what is the current training status of the personnel, are the training records available and are there future training plans in place?
- Management – are there formal documented management policies in place to support the activities of the laboratory?
- Funding – is there sufficient provision in the budget to support the testing facility, maintain, facilitate and expand operations, equipment and facilities?
- Capacity – can the laboratory handle the current workload with the facilities available; is there a need and or possibility to increase the current capacity?

The outcomes of the assessments are reported as follows: **Section 2** of this report consists of a summary in table format and **Section 3** contains more detailed discussions on the individual laboratories and recommendations.

2. SUMMARIZED REPORT

During the assessments and discussions with the various people involved in the activities of the testing facilities, there were concerns which repeatedly came to the surface and should therefore be considered as *generic* issues which need serious attention:

2.1. Funding – One of the Root Problems in Most of the Laboratories

Most of the equipment, especially the more sophisticated equipment in the laboratories responsible for aflatoxin testing, was donated. The international community donates expensive, technological advanced equipment to the laboratories. In most cases they do not have the funds for consumables (including analytical standards and reference materials), maintenance, trouble shooting, service of the instruments, calibration, etc.

In almost all of the laboratories visited, the basic infrastructure such as reliable electricity supply and acceptable water quality is not available due to financial and other constraints.

Different options to address these financial constraints need further investigation and will be discussed in more detail in Section 3 of this report.

Chances of achieving and maintaining ISO 17025 accreditation for under-funded laboratories are very slim. The first priority should be to address the basic infrastructure challenges, only then the focus can move to training needs, documented quality systems, upgrade of testing equipment and ultimately compliance with ISO 17025 requirements.

2.2. Laboratory Etiquette – Cleaning and Good Housekeeping

For any analytical testing facility to function properly, it should not be cluttered with empty chemical bottles, broken down equipment, boxes, files and other non-essential items. A chemistry laboratory covered in dust cannot provide reliable testing results and will not comply with ISO 1725 requirements.

Equipment not cleaned after use causes corrosion, rust and decay. Laboratory equipment such as water purifying systems which are not regularly cleaned and maintained reaches a stage where it is impossible to restore it to a good working condition. This broken down equipment adds to the clutter and the inefficiency of the laboratory. The training of laboratory personnel to adhere to the basic principles of good laboratory practice and housekeeping has to be one of the first priorities.

2.3. Laboratory Management for Better Efficiency

Customers will not continue to submit samples for analysis to laboratories which cannot supply them with reliable results within an acceptable timeframe. In some cases, customers have to wait up to eight weeks for results and even then they express their doubts over the accuracy of the results.

Accreditation to an international standard such as ISO 17025 is not a prerequisite to operate efficiently. The challenge in most of the laboratories visited is to ensure that the laboratory management has a proper understanding of the requirements of the laboratory. A proper management system will pave the way for customer recognition, which is the basis for survival of a commercial laboratory. A successful and sustainable accreditation system is only possible under good laboratory management. The importance of this cannot be emphasized enough.

2.4. Factors beyond the Control of the Laboratory

During the interviews, it became clear that there are certain issues which are beyond the control of the laboratory. These issues need to be considered when looking at possible interventions. Better long- and medium term planning can go a long way to relieve these pressures.

Most of the servicing and calibration of the laboratory equipment cannot be performed by local service engineers, the technicians must either be flown from Europe, the US or South Africa or the equipment sent overseas for repair. The possibility of having a local engineer or engineers trained to perform at least some of these duties needs to be considered to address this issue.

The cumbersome Government procurement processes cause serious delays in the delivery of consumables, equipment and spare parts. One of the possible solutions to be investigated is a national ‘spares bank’ for critical spares on equipment from the same supplier used in different laboratories.

The erratic water and electricity supply is probably one of the biggest challenges outside the control of the laboratory. Even the laboratories with stand-by electricity generators and reservoirs have to deal with the added challenge of fuel shortages and bad quality water.

Extremely dusty environmental conditions during certain seasons of the year demands extreme care in the cleaning procedures of the laboratory. Some of the laboratories are situated in open field environments which aggravates this challenge. Sophisticated analytical equipment such as those donated to the laboratories is very sensitive to these conditions and would therefore require additional servicing and maintenance which adds to the already high running costs of these laboratories.

2.5. Laboratory Assessments, Simplified Evaluation Report

The tables below give a summary of the assessment outcomes for easy comparison. A more detailed discussion of the individual laboratories is available in PART II of this report. Please note that the information in the tables is based on observations and subjective evaluations but provide a means of getting a good idea of the current status of the laboratories.

The criteria used for the scores:

Poor: conditions are unacceptable

Average (avg): conditions are not poor, but need a lot of attention

Good: workable, but needs attention

Excellent (exl): comply with requirements

Table 1: Laboratories assessed in Malawi and Zambia

Laboratory	Abbreviation
Chitedze Agricultural Research Station – Lilongwe, Malawi	CARS
International Crops Research Institute for the Semi-Arid Tropics – Lilongwe, Malawi	ICRISAT
Valid Nutrition – Lilongwe, Malawi	VNL
Malawi Bureau of Standards – Blantyre, Malawi	MBS
Zambia Agricultural Research Institute, Ministry of Agriculture - Lusaka, Zambia	ZARI
Plant and Quarantine Phytosanitary Services, Ministry of Agriculture, Lusaka, Zambia	PQPS
Food and Drug Control Laboratory, Ministry of Health, Lusaka, Zambia	FDCL
Zambia Bureau of Standards, Lusaka, Zambia	ZABS

Table 2: Services

	CARS	ICRISAT	VNL	MBS	ZARI	PQPS	FDCL	ZABS
Lighting	avg	avg	good	avg	avg	avg	poor	good
Water	poor	poor	poor	poor	avg	avg	poor	good
Water reservoir	poor	poor	poor	poor	poor	poor	poor	Good
Electricity	poor	poor	poor	poor	poor	poor	poor	poor
Electricity standby	avg	avg	poor	poor	avg	avg	poor	good
Uninterrupted Power Supply (UPS)	avg	poor	poor	poor	poor	poor	poor	avg
Cleaning	good	good	good	poor	avg	avg	poor	good
Air conditioning	avg	poor	avg	avg	poor	poor	poor	good
Housekeeping	avg	avg	good	poor	avg	poor	poor	poor
Conclusion	*avg*	*avg*	*avg*	*poor*	*avg*	*poor*	*poor*	*good*

Table 3: Buildings

	CARS	ICRISAT	VNL	MBS	ZARI	PQPS	FDCL	ZABS
Clean exterior	avg	avg	good	poor	avg	avg	poor	avg
Clean interior	poor	avg	avg	poor	avg	poor	poor	avg
Peeling paint	avg	avg	avg	avg	good	good	poor	good
Roof leaking	avg	avg	good	avg	avg	avg	poor	avg
Floors	avg	avg	good	avg	avg	avg	poor	good
Dust	poor	avg	avg	poor	poor	poor	poor	avg
Hygiene	poor	avg	avg	poor	avg	avg	poor	good
Hand wash	poor	avg	avg	avg	avg	poor	poor	good

basin								
Emergency shower	poor	poor	poor	poor	poor	poor	poor	poor
Space for expansion	avg	avg	poor	avg	avg	poor	poor	avg
Conclusion	*avg/poor*	avg	*avg/poor*	*avg/poor*	*avg*	*poor*	*poor*	*avg/good*

Table 4: Equipment

	CARS	ICRISAT	VNL	MBS	ZARI	PQPS	FDCL	ZABS
Suitability/range	good	good	avg	poor	good	poor	avg	good
Maintenance	avg	avg	avg	poor	avg	poor	poor	good
Servicing	avg	avg	avg	poor	avg	poor	poor	good
Clean equipment	avg	avg	good	poor	avg	poor	poor	good
Operational	avg	avg	good	poor	avg	poor	poor	avg
Accessories	good	avg	avg	poor	good	poor	poor	avg
Computer back-up	poor	poor	poor	avg	avg	poor	poor	good
Conclusion	*avg*	*avg*	*avg*	*poor*	*avg*	*poor*	*poor*	*good*

Table 5: Laboratories

	CARS	ICRISAT	VNL	MBS	ZARI	PQPS	FDCL	ZABS
Lay out/Space	avg	avg	poor	poor	avg	poor	poor	avg
Workbenches	poor	avg	avg	avg	avg	avg	poor	good
Floors	avg	avg	avg	avg	avg	avg	poor	good
Cupboards	avg	avg	avg	avg	avg	avg	poor	good
Electrical outlets	poor	poor	avg	avg	poor	poor	poor	avg
Distilled water	avg	poor	poor	poor	avg	poor	poor	good
De-ionized water	poor	poor	poor	poor	avg	poor	poor	good
Gas supply	avg	poor	avg	avg	avg	poor	poor	avg
Instrument labs	avg	avg	poor	poor	avg	poor	poor	good
Preparation area	poor	avg	poor	poor	poor	poor	poor	avg
Cleaning area	poor	poor	poor	poor	poor	poor	poor	avg
Housekeeping	avg	avg	avg	poor	avg	poor	poor	good
Conclusion	*avg*	*avg*	*poor*	*poor*	*avg*	*poor*	*poor*	*good*

Table 6: Management

	CARS	ICRISAT	VNL	MBS	ZARI	PQPS	FDCL	ZABS
System in place	poor	poor	poor	poor	poor	poor	poor	avg
Quality procedures	avg	poor	poor	avg	poor	poor	poor	good
Operational procedures	avg	poor	poor	avg	poor	poor	poor	good
Methods	good	good	good	avg	avg	poor	avg	good
Records	poor	poor	poor	avg	poor	poor	poor	good
Audits	poor	poor	avg	poor	poor	poor	poor	avg
Proficiency testing	poor	poor	poor	poor	poor	poor	poor	avg
Inter-laboratory comparison	poor	poor	poor	poor	poor	poor	poor	avg

Conclusion	*poor*	*poor*	*poor*	*poor*	*poor*	*poor*	*poor*	*avg/poor*

Table 7: Personnel

	CARS	ICRISAT	VNL	MBS	ZARI	PQPS	FDCL	ZABS
Suitability	good	avg	avg	avg	avg	poor	avg	good
Qualifications	good	good	good	good	good	good	good	good
Numbers available	avg	avg	avg	avg	avg	avg	poor	good
In-house training	avg	avg	avg	avg	avg	poor	poor	good
Training Programmes	avg	avg	poor	poor	avg	avg	poor	avg
Lab etiquette	avg	avg	avg	poor	avg	poor	poor	good
Neatness	good	good	good	poor	avg	avg	poor	good
Conclusion	*avg/good*	*avg/good*	*avg/good*	*avg/poor*	*avg*	*avg/poor*	*poor*	*good*

Table 8: Finances

	CARS	ICRISAT	VNL	MBS	ZARI	PQPS	FDCL	ZABS
Government grants	avg	avg	poor	avg	avg	avg	avg	avg
Privately funded	avg	avg	avg	avg	avg	poor	poor	poor
Self-generated	poor	poor	poor	poor	poor	poor	poor	poor
Constraints	avg	avg	avg	avg	avg	avg	poor	avg
Conclusion	*avg*	*avg*	*avg/poor*	*avg*	*avg*	*avg/poor*	*poor*	*avg/poor*

Note: 'poor' for constraints above means many financial constraints inhibit laboratory operations and performance.

Table 9: Capacity

	CARS	ICRISAT	VNL	MBS	ZARI	PQPS	FDCL	ZABS
Current capacity	avg	avg	avg	poor	avg	poor	poor	good
Potential capacity	exl	good	good	good	good	avg	avg	exl
Conclusion	*avg*	*avg*	*avg/poor*	*avg*	*avg*	*avg/poor*	*poor*	*good*

2.6. Conclusions

All the laboratories visited suffer from severe financial constraints. Sophisticated equipment is donated to the laboratories, but the basic support structures are not in place with the consequence that the laboratories are not functional and the equipment has, in some of the laboratories, deteriorated to an extent where it will be very costly to get it in a working condition again or in some cases like with water purification systems, completely impossible.

The only laboratory visited with the potential to become an ISO 17025 accredited aflatoxin testing facility with the necessary capacity to maintain such a system would be the laboratory at ZABS. A considerable amount of work is however needed to establish such a system, but with the current capacity in terms of facilities, people and instrumentation, it would be possible. The biggest challenge is not laboratory accreditation, but ensuring the sustainability of such a system.

For the other laboratories assessed, the focus should rather be on finding solutions to get at least some testing capability established as the first phase of the project. It is clear that the solution to the lack of capacity is a multi-facetted one and will need to be addressed in phases. It will certainly not be a ’one size fits all’ solution, but through a coordinated process – several of the laboratories’ challenges can be addressed through a single solution either for the country or even for the region.

2.7. Common observations and concerns

There are some observations and concerns which were common throughout almost all the laboratories visited and were confirmed in the discussions with people involved in the management of the testing facilities. High quality equipment is donated, but often without consideration of practical implications such as:

- Equipment is sometimes delivered without all the necessary accessories to be fully operational and the laboratories do not have the funds to add the additional items. As a result, some of these pieces of equipment have been standing for months or even years without any analyses being performed on them. The dusty conditions in the laboratories causes decay, with huge cost implications to get the instruments operational again.
- In some instances, the electricity requirements of the instruments and the available supply in the facility is not compatible (120V vs 220V). Equipment used under these circumstances will burn out. In most of the laboratories they do not even have the funds to purchase transformers to overcome this problem.
- The servicing and repair of the more sophisticated pieces of equipment (and even some of the less sophisticated ones) require service engineers from either Europe or South Africa. Local service engineers are not trained to provide such specialized services and do not have easy access to spare parts. Maintenance schedules are available in some of the facilities, but are not adhered to as a result of a lack of funds or a lack of discipline or both. No evidence of preventative maintenance and regular calibration processes could be found in any of the laboratories visited.
- Since most of the equipment from foreign countries is not equipped with the plugs compatible with the local plug outlets, the plugs need to be replaced. Sometimes bare wires are pushed into the sockets of the plug outlets with the obvious safety hazard implications. Over and above the safety hazards, this practice has detrimental effects on the useful lifetime of the equipment and most importantly, on the accuracy of the results.
- The operating manuals of some of the pieces of equipment are not in English and as a result, instruments are not operated in the correct manner, which causes breakdowns. These broken down instruments are not fixed (see the reasons discussed above) and are also not removed from the laboratories, adding to the clutter and the general ineffectiveness.
- Buildings and facilities are in general in a poor state of maintenance including peeling paint, leaking roofs, decaying wood and in general very dusty. Fortunately, in some of the laboratories, there was evidence of cleaning taking place.
- Witnessing of the testing procedure was part of the request to visit the laboratories. Only one of the laboratories visited was able to demonstrate the testing procedure.

None of the other testing facilities were able to demonstrate any testing, not even the sample preparation procedures. All these laboratories indicated that they do not have the necessary consumables to conduct any testing at all. It was very evident that no testing had taken place in months. At the time of the assessments, and during the discussions with the management of the laboratories, all the laboratories explained that they were waiting for analytical standards, solvents, other consumables and somebody to fix the instruments.

- On the day of the assessments, at least three of the laboratories did not have any electricity and in the cases where a back-up generating system was available, there was no fuel available to make use of this option.
- The laboratory personnel in most of the laboratories have the necessary qualifications and should be able to perform the analyses, but supervision and a properly documented system is needed to ensure that the testing is performed correctly. In general, there is a lack of proper laboratory management. In the majority of the laboratories, no evidence could be provided of training records or a technical training program for the people in the laboratory.
- The organization and the general housekeeping in the laboratories are not good. Storage spaces for glassware, chemicals and equipment is generally poor. The workbenches are used as storage space which limits the actual workspace to prepare the samples and perform the analyses.
- Records or inventory lists of equipment could not be supplied by any of the laboratories visited. From an environmental health and safety point of view, major adjustments are needed to ensure a compliant laboratory environment. No evidence could be supplied on the safe handling of hazardous waste and or training in the safe use of chemical/hazardous substances. These are critical elements of laboratory management which have to be addressed.
- In most of the laboratories, dedicated instrument laboratory space is available. Unfortunately, corrosive chemicals are stored in the same room with sensitive and expensive equipment. Calibration records for instruments such as balances could not be provided. Even the most expensive and sophisticated instruments are not cleaned and correctly stored after use. Chemical build up on instruments and layers of dust are more prevalent than absent.

3. DISCUSSION ON INDIVIDUAL LABORATORIES VISITED AND RECOMMENDATIONS

3.1. Chitedze Agricultural Research Station – Lilongwe, Malawi

The Department of Agriculture Research Services (DARS) is a technical department in the Ministry of Agriculture and Irrigation. DARS is mandated to conduct research and provide regulatory and advisory services to farmers on all crops and livestock, except tobacco, tea and sugarcane. DARS conducts research in all agricultural and related fields through seven research oriented commodity groups: (i) plant protection, (ii) cereals, (iii) grain legumes, oilseeds and fibers, (iv) horticulture, (v) livestock and pastures, (vi) soils and agriculture engineering and (vii) technical services.

These departments are headed by a Director reporting directly to the Principle Secretary of the Ministry of Agriculture. Chitedze Agricultural Research Station has National Research coordinators for cereals, grain legumes, oilseeds and fiber crops, soils and engineering and technical services. Mycotoxin research and regulation is conducted under soils and agricultural engineering in close cooperation with the plant protection group.

Interviews were conducted with Dr. Francis Maideni, station manager for Chitedze and also national coordinator for the cereals group and Dr. Wilkson Makumba, the national research coordinator for soils and agricultural engineering. The mycotoxin laboratory falls under Dr. Makumba. Both these people interviewed showed commitment to support the mycotoxin testing activities. They are well informed and understand the importance of having the capacity to perform mycotoxin analyses. In principle, the research scientist in the laboratory has the support from management needed to establish the necessary capability. Management does not, however, have a detailed understanding of the requirements necessary to achieve this. The daily challenges within the laboratory are not well understood and therefore not addressed. Their vision of *being a center of excellence in agricultural research leading to the generation of cutting edge technologies* would be difficult to achieve if the basic infrastructure in the laboratories does not exist.

The brand new equipment donated by the EU include an Ultra High Performance Liquid Chromatography – Mass Spectrometry (UPLC-MS), post column derivatisation system, two High Performance Liquid Chromatography (HPLC) systems and a water purification system. Even though the mass spectrometry system is equipped with an uninterrupted power supply (UPS), the power supply of the facility is so unreliable that the supplier of the instruments (service engineers from South Africa) suggested that the risk is too high to use the mass-spectrometer. Currently the system is used as an UPLC with a fluorescence detector.

The quality of the water to be fed into the water purification system is not good at all. The ion-exchange cartridges on the system are very expensive and will have to be replaced at regular intervals. Alternative measures such as in-line filters and an upgrade to the existing water distillation unit to prepare better quality water to feed into the system were suggested.

Once the instruments are commissioned (at the time of the assessment, most of the equipment were not unpacked or commissioned), the challenge of lack of consumables will have to be addressed. The people in this laboratory have a good scientific background: Mr. Limbikane Matumba is currently busy with his PhD studies and therefore has a good incentive to get the chromatographic and mass-spectrometry equipment operational and validate the methods to do the practical work for his studies. He was trained in Austria and would be able to utilize the instruments to their potential provided that he has the basic infrastructure available.

If a good documentation system is not developed, the operation of this laboratory will only be centered around one person and once he leaves, the laboratory and equipment will stop functioning. To create a sustainable solution, the focus should therefore be on developing the basic infrastructure and a properly documented management system for the laboratory.

3.2. ICRISAT – Lilongwe, Malawi

The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) is a non-profit, apolitical, international organization devoted to science based agricultural development.

Research is done for the development of crop varieties resistant to diseases and pests, and tolerant of drought and heat.

For the purpose of screening seed samples for the presence of aflatoxin residues, they have a laboratory equipped with an ELISA system. On the day of the assessment, no tests were performed in the laboratory since most of the technical people were in the field conducting field trials. Mr. Limibikani Matuba from the research station explained the process since he was previously involved in the screening of seed samples for aflatoxin using ELISA. No documentation could be provided on the standard operating procedures or methods followed in this laboratory. Maintenance and calibration records were also not available. Mr. Wills Munthali, a scientific officer, was also interviewed.

Unfortunately the analyst usually performing the tests was not available to demonstrate the procedure as followed by the laboratory. The laboratory is equipped with the basic instrumentation needed for screening of samples. In the absence of a well-documented system, and the unavailability of laboratory personnel to be interviewed, only the basic laboratory facilities were evaluated.

In general, the laboratory facilities did not appear to be in a poor condition although it was extremely dusty. The same challenges exist with regards to power supply and maintenance of the equipment. Fortunately most of the equipment used in this facility is less sensitive to power interruptions. This laboratory can be considered fit for the purpose it was designed for but still needs a lot of attention to ensure reliable test results.

3.3. Valid Nutrition - Lilongwe, Malawi

Valid Nutrition manufactures a range of highly fortified nutritional pastes for the prevention and treatment of malnutrition. These products are made in the countries in which they are needed, thereby stimulating the local economy as well as providing life-saving products at affordable prices.

Valid Nutrition produces and distributes, either directly, or through collaborative arrangements with third parties, its own branded ready-to-use foods (RUFs) under the Valid Nutrition brand name in Malawi. All Valid Nutrition products follow a common manufacturing standard that is based upon the principles of ISO 22000:2005 Food Safety Management Systems. This requires all manufacturing sites to follow a documented set of procedures that define the quality and safety standards for each product and the conditions under which they are produced. A fundamental requirement of this approach is for the implementation of Hazard Analysis of Critical Control Points (HACCP) as the primary tool in food safety management.

As part of the HACCP program, samples of the raw materials as well as the final products need to be tested. Each consignment of raw materials is tested for the presence of aflatoxin using the ELISA screening method. The additional analyses required for quality control purposes are subcontracted to Malawi Bureau of Standards and Intertek. Annually, they have their final product tested for pesticide residues, veterinary drug residues, heavy metals and other contaminants. These analyses are outsourced to other laboratories.

They are still in the process of validating the ELISA screening method. A new analyst was appointed a month before the assessment and she is in the process of being trained to perform the aflatoxin testing. She has a microbiological background and has a good understanding of laboratory testing in general. For her to be able to produce reliable and consistent accurate results, she will have to be trained on this specific methodology. There are key differences between the requirements of chemical and microbiological testing. On the day of the assessment, the performance of the method was witnessed and recommendations made on critical steps in the method which can contribute to the certainty of the measurement.

The outcome of the test results generated on the day of the assessment confirmed the concerns about the accuracy of the results which will have to be addressed. Most of the basic equipment needed to perform the aflatoxin testing is available and the overall housekeeping in the aflatoxin testing laboratory is good.

Participation in proficiency schemes and the inclusion of certified reference materials as part of the method validation process and ongoing proof of competency will have to be first priority. Both the quality assurance and the factory managers understand the importance of reliable results for quality control purposes. All the personnel interviewed showed commitment to addressing the problems identified during the assessment. With the necessary training and guidance, this laboratory should be able to perform the aflatoxin testing on a level required for the quality control purposes for which it was designed.

The physical laboratory space as well as the human resource capacity will have to be expanded and improved to be able to handle larger volumes of samples.

The quality control laboratory at Valid Nutrition is in the process of investigating the option of developing the capability to test for melamine using a screening kit. At the time of the assessment, they presented an extensive list of instrumentation, general laboratory glassware and consumables due for delivery within the next few weeks. With this equipment, they will be able to expand their testing ability to include a range of nutritional analyses. The laboratory floor space is in the process of being expanded. Once the equipment has arrived and the floor space is available, major interventions will be needed to commission the equipment and to develop and validate the methods.

The existing quality system in place can serve as the basis for this process, but the expertise of a very knowledgeable person (specialist in the field of chemical analysis and the implementation of quality systems for testing laboratories) will be required on site. Most of the employees working in the factory do not have any scientific qualification or experience, the expansion of the testing capabilities will therefore need additional qualified personnel. Although the purpose of the assessment was to focus only on the aflatoxin testing capability, the additional planned activities in this laboratory might impact on the capacity of the aflatoxin testing and were therefore also taken into consideration.

3.4. Malawi Bureau of Standards (MBS) – Blantyre, Malawi

During the discussions and the assessment of the aflatoxin testing facilities, the following people were present: Willy Muyila, Deputy Director General, Isaac Chirwa, Divisional Manager – Chemical Technology, and Stephen Chalimba, Divisional Manager – Engineering Technology.

As an introduction to the discussions, some background information was presented on the activities of the South African Grain Laboratories (SAGL) with special reference to the role as the National Reference Laboratory for the Grain Industry in South Africa. Based on the fact that the purpose of the visit to the laboratory was focused on the assessment of the aflatoxin testing capabilities of the laboratory, a significant portion of the time was dedicated to discussions around the technical requirements with regards to mycotoxin testing.

Information was shared on the current testing capabilities of the MBS laboratory including the specific methodology applied, the volumes of samples currently being analyzed, the commodities being tested, the mandate of the laboratory, the human resource capacity and the future plans to expand the capacity in line with the mandate of the laboratory. Some time was spent on discussions around the importance and availability of proficiency schemes as a tool to prove competency of the testing facility. The cost implications associated with maintaining an ISO 17025 accredited testing facility was also discussed in detail.

The consultant was informed of the prospect of an EU funded project to upgrade the current facilities, but the uncertainty of the timelines for the finalization of such a project necessitates the continuation of interventions to get the current activities aligned with ISO17025 requirements. The selection of a preferred method between the current TLC (not operational because of problems with the scanners) and HPLC (donated to the laboratory by Pfizer during 2009, but not operational because of leaks, etc.) were discussed, focusing on the benefits and disadvantages of both techniques. The running costs of the different techniques were also discussed.

The challenges with regards to basic services such as reliable electricity supply, high purity water and the availability of maintenance services, including spare parts, were covered in detail. The training needs of the personnel involved in the aflatoxin testing and different training options were discussed.

The roles of the MBS in relation to other aflatoxin testing facilities in Malawi as well as the responsibilities associated with those roles were discussed. The possible benefits of using upgraded and well-maintained instrumentation within an accredited method (e.g. aflatoxin testing) for other applications such as fortification analyses (e.g. vitamins) were mentioned. The main aim will therefore be to get the aflatoxin testing methodology accredited under ISO 17025 before any of the additional possibilities will be explored.

During an extensive inspection of the actual laboratory facilities, detailed information was shared on the current status of the equipment and the reasons for the non-operational equipment were discussed, including possible solutions going forward. The laboratory visit also included an evaluation of the quality documentation with special focus on the implementation and review processes. A number of recommendations were made to ensure a more efficient implementation process.

In the closing meeting, the following recommendations and possible solutions were discussed:

- The main objective would be to get the current HPLC system in a good working condition again – this will require funding to source the necessary spare parts and inputs from both a qualified service engineer and a specialist analyst.

- Currently, no reliable supply of deionized water is available. The system in the laboratory which has not been maintained is beyond repair and will have to be replaced.
- The current HPLC system is equipped with only a UV detector and for the determination of aflatoxin using HPLC a fluorescence detector will need to be added to the current system. Fortunately, upgrades to and spare parts for the system donated to the laboratory in 2008 should still be available. Subsequent discussions with the suppliers of this equipment confirmed this.
- Ideally the laboratory would need to be equipped with more than one HPLC system to ensure uninterrupted delivery of results in case of a breakdown.
- The option of getting one or more of the current engineering personnel trained on specialized equipment such as HPLC and GC-MS instruments needs to be explored. This should cut down on maintenance costs and down time when the services of external service engineers are required.
- Linked to this initiative, the option of a supply of critical spare parts to be maintained in-house should also be considered.
- The training options for the analysts performing the aflatoxin testing should ideally include both exposure to laboratories operating under ISO 17025 accreditation and the expertise of external specialist(s) spending some time in the MBS laboratory.
- The option of training in the form of video conferencing should also be investigated.
- The lack of sufficient funds to cover the maintenance costs and cost of consumables (running costs) was highlighted.
- There exists a relatively well documented quality system within the laboratory, but it is not implemented in the laboratory, neither is it reviewed or maintained.
- An overall culture of good laboratory practice, housekeeping and responsibility to keep a quality system intact is lacking.
- Evidence of an inventory of the equipment in the laboratory and maintenance and calibration schedules could not be provided at the time of the assessment.
- Training schedules of the laboratory personnel were also not available for evaluation.

3.5. Zambia Agricultural Research Institute (ZARI) – Lusaka, Zambia

ZARI provides high quality, appropriate and cost effective services to farmers, generating and adapting crop, soil and plant protection technologies.

Their mission is to contribute to the improvement of the welfare of the Zambian people through the provision of technologies and services that enhances household, food, security and equitable income generating opportunities for the farming community and agricultural enterprise.

The laboratory visit covered all the testing facilities, including the aflatoxin testing laboratory. The mycotoxin testing laboratory at NISIR was undergoing major renovations and at the time of the assessment, thus there was no functional laboratory to inspect. They indicated that the plan was to be operational again by the middle of January 2012.

The aflatoxin testing laboratory was assessed in detail. At the time of the assessment, no aflatoxin testing was performed using the UPLC-MS system in the laboratory. Tembo Howard, who is the responsible analyst in this laboratory, was interviewed to establish the reasons for the equipment not being used to its full potential. The same challenges which were mentioned at all the previous laboratories visited came to the surface. Consumables, which include the mobile phase for the instrument, the analytical standards to determine the aflatoxin residues, the analytical column to separate the components on the instrument, and the solid phase extraction columns needed for the clean-up of the samples were not available.

Reliable power supply and good water quality were also not readily available. The HPLC system to be used for the aflatoxin testing is not dedicated for this purpose and there are other priorities such as veterinary drug and pesticide residue determinations which enjoy preference over the aflatoxin testing.

Sample preparation and sample clean-up facilities are not adequate. There is a risk of contamination where different matrices and active ingredients are analysed on residue levels in the same area. The mandate of this laboratory facility is to provide analysis results as part of research projects and this can create problems with priorities when samples needs to be analysed for different research projects and also the routine monitoring samples for aflatoxin residues. The validation requirements for methods used for research projects and routine monitoring purposes are different and it might be difficult to accommodate both using the same testing facility.

3.6. Plant Quarantine and Phytosanitary Services (PQPS) – Lusaka Zambia

The PQPS section is responsible for inspections of imported and exported agricultural products. They have inspection points at all the ports of exit and entry in the country. The facility was built a few years ago and was funded by the Netherlands. It includes a small laboratory with a few fridges, freezers and microscopes.

The facility is relatively well cared for, but they do not have the capability to screen for the presence of aflatoxin levels in agricultural commodities. Based on the reasons as explained above, they cannot rely on the central research laboratories at Mount Makulu and expressed the need to establish a small screening facility for aflatoxin testing. Mount Makulu is dependent on borehole water and the reservoir system is not fully operational yet. The national grid supplies the electricity and interruptions are frequent. Any interruption of the power supply also affects the water supply, leaving the facility paralyzed.

As indicated in the discussion of the capabilities of ZARI, PQPS cannot be positioned to take responsibility for routine product testing since their mandate is research and inspection to assist agriculture in the country. The recommendation would therefore be to focus on the development of a basic fit-for-purpose screening facility to be able to screen for the presence of aflatoxin levels in agricultural products. Quantification and confirmation of the aflatoxin residues can then be referred to a laboratory such as the Zambia Bureau of Standards (ZABS) once their testing procedures have been established.

3.7. Zambian Bureau of Standards (ZABS) – Lusaka, Zambia

During the visit and assessment, interviews and discussions were held with the following people: Andrew Chipongo, Laboratory Analyst responsible for quality assurance, Ray

Kamela, Senior Laboratory Analyst, and Frederick Hamutunga, Metrology Manager. The laboratory manager, Nikodemus Malisa, was unfortunately not available, but briefed the laboratory personnel on the purpose of the visit and assessment.

ZABS is a statutory entity and is the standards body of the Zambian Government.

The offices and testing laboratories are accommodated in a solid brick office block with ample windows for daylight penetration and ventilation. The area around the building is very dusty, which creates a problem with dust in the laboratories, but the housekeeping in the laboratories assessed is generally acceptable.

A reservoir on the premises ensures uninterrupted water supply although the quality of the water sometimes creates problems as a result of particles which need to be filtered out. The electricity supplied by the national grid is supplemented by a standby generator in case of power failures. On the day of the assessment, there was a power failure but the generating system also had problems and the laboratories were therefore not operational.

The air conditioning system in the form of individual split units for each laboratory works well but needs regular maintenance as a result of the dusty conditions outside the building.

The sample preparation area for aflatoxin testing is relatively well equipped, but is shared with sample preparation activities for the determination of other active ingredients, which creates a risk of contamination. Since the space allocated for this purpose is ample, this problem can be addressed by rearranging the activities.

There is a separate instrument room for the UPLC system. The instrument was not operational at the time of the assessment and they indicated that the service engineer from South Africa was meant to come and do the final commissioning within the next week or two.

No method validation had been done on the instrument or sample. The sample clean-up columns were available and well within the expiry dates. The other consumables needed to perform the testing and method validation have to be acquired through the normal supply channels and were not available. The same challenges that were identified in the other laboratories around the financial constraints affecting the maintenance, servicing and day to day operations of the laboratory exist.

A well-documented quality system exists, but the implementation still needs attention. The training needs of the people in the laboratory also need to be addressed. Personnel must receive practical training to fully utilize the new sophisticated equipment.

Currently, most of the equipment is brand new, but provision for the maintenance and service needs to be included in the future plans.

This laboratory has the potential to become ISO 17025 compliant with the necessary assistance. Although major interventions will be needed, the basic system exists on which such interventions can be based.

3.8. Foods and Drug Control Laboratory (FDCL) – Lusaka, Zambia

The FDCL of the Ministry of Health are situated on the property of the University Teaching Hospital of Lusaka. They are mainly responsible for regulatory work, testing samples provided by police for forensic purposes. They are accommodated in very old and poorly maintained buildings. The outside and inside are in a state of despair: it is dirty with peeling paint, leaking roofs and potholed floors. The perimeter of the building is bare earth which adds to the dust accumulating in the laboratories.

The laboratories are in a poor state. On the day of the visit, there was no electricity and the laboratories are not equipped with back-up generators. This situation is a regular occurrence. The water supply should theoretically not be a problem since the water is supplied via a reservoir on the premises, but problems with leaking tanks result in unpredictable and erratic water supply.

In the absence of air conditioners in the laboratories, open doors and windows are the only means of ventilation in the laboratories, which results in everything, even the instruments in use, being covered under a layer of dust.

Interviews were held with Margaret Mazhamo, Manager, and Gertrude Mundia, Principle Analytical Chemist. The method currently employed for the determination of aflatoxin levels is thin layer chromatography and the plates are prepared in-house. The analyst performing the tests is well trained, but the lack of basic infrastructure makes it impossible to produce reliable results. On the day of the visit, no documentation on the management system, quality control processes or training records could be provided. According to the people involved in the testing, they experience major challenges to procure the consumables needed to perform the analyses. They do not have any analytical standards available; the last time they were able to order standards was during 2009. Since then, results are reported without any analytical standards to verify the accuracy of the results.

An HPLC, which was earmarked for vitamin analyses as part of a maize meal fortification project, was donated to the laboratory during 2007. The project was suspended and the instrument has never been used. Currently, it is standing in a 'laboratory' which looks like a chemical storeroom with the instrument covered in a layer of dust. If this instrument can be restored to good working condition, it might be possible to validate and implement a method for the determination of aflatoxin residues using HPLC with fluorescence detection.

Before any investments are made in terms of improvements to the testing methods and or instruments, the facility has to be upgraded to provide the suitable environmental conditions to support the testing activities. The laboratory is 100% dependent on Government funding and in cases where customers pay for analyses, the prices are predetermined and approved by Government and do not even cover the basic costs of the analyses.

3.9. Commercialization – Supply and Demand

Based on the fact that almost all the laboratories visited were not performing any test work at the time of the assessment as a result of the reasons discussed above, it would be difficult to assess the number of samples the laboratory would be able to analyze once their systems are up and running. The cost structure (price per sample) will be determined by the volumes analyzed and the volumes analyzed will be determined by the capacity of the laboratory in terms of the throughput.

The SAGL's model as described below can serve as an example to use as basis for the development of a revenue model for the different laboratories in Zambia and Malawi.

The cost calculation model currently in use at the SAGL (an independent laboratory, but also a company without gain which has to be commercially self-sufficient without Government funding), is based on the following principles:

Historical data is used to determine the number of analyses included in the equation. The price per sample is determined by taking the following into consideration:

- The number of samples invoiced;
- The direct and indirect costs (including the depreciation of the equipment);
- The ‘market-relatedness’ of the prices;
- The number of control samples (quality assurance samples) is not included in the cost calculation equation;
- Where applicable (e.g. chromatography/mass spectrometry analyses) a sliding scale is applied based on:
  - The number of samples submitted simultaneously
  - The batch size (number of samples analyzed in one batch)
  - Costs are recovered on the first sample analyzed (single sample price).

A portion of the samples analyzed at the SAGL for the presence of mycotoxin residues forms part of research and monitoring projects performed with the financial support of the Grain Trust in South Africa. The budgets of these project proposals are based on the cost structure as explained above. Indicative pricing and sample volumes for SAGL are:

	LC-MS/MS Analyses	**ROSA Screening**	**Total Sample Analysis Income**
Average Price/ Sample (USD)	US$197	US$88	
Average Number of Samples per Year	450	700	
Total	**US$88,650**	**US$61,600**	**US$150,250**

Current and projected sample volumes for Zambia and Malawi would be substantially lower. The volumes of samples submitted to the laboratories in Malawi and Zambia for analysis will be enhanced by and in most cases determined by the following factors:

- Regulations/Legislation of each particular country;
- Regulations/Legislation of the country of export in case of agricultural product exports;
- Food safety programs such as HACCP, GAP (Good Agricultural Practice) and GMP (Good Manufacturing Practice);
- National monitoring programs;
- Size of the local industry; and
- Requirements for the production and marketing of functional food products.

The SAGL sample analyses income table indicates that even with relatively high sample volumes, income may be insufficient to sustain a purely commercial laboratory service focused on aflatoxin testing. SAGL is able to operate as it receives subsidies from the Grain Trust and provides a range of other sample services.

4. RECOMMENDATIONS

The major challenges, which were the same for all the laboratories visited, are the lack of:

- Basic infrastructure such as water and electricity to support efficient testing activities;
- Technical support to maintain, service and calibrate testing equipment, in most cases really sophisticated equipment donated to the laboratories;
- An understanding of the requirements of a quality system such as ISO 17025;
- Documented system, both technical and management;
- Basic understanding of good laboratory practices and good laboratory housekeeping requirements – good laboratory etiquette and work ethics; and
- Practical hands-on training to utilize sophisticated equipment and to be able to do troubleshooting.

These challenges will have to be addressed in phases to ensure a sustainable solution. Different options have to be considered since some of the solutions might not be the same for all the different testing facilities. In some cases one solution might work for different facilities. Further investigation of the possible solutions suggested will be needed in order to determine the associated costs and thus, viability.

Option I:

An option would be to create an "Africa" laboratory under the management of an ISO 17025 accredited facility in South Africa to perform the analyses and train the analysts while the basic infrastructure is rebuilt in Zambia and Malawi. The most critical equipment in this laboratory must be similar to the equipment in their laboratories.

Analysts from the different laboratories in Malawi and Zambia then work in this laboratory and analyze the samples from their countries under these controlled conditions and report reliable results. This will expose the analysts to a system where they don't have to deal with the normal challenges which they encounter on a daily basis in their laboratories, but rather focus on the critical issues related to the accuracy of the results generated. The idea is to build the capacity by training laboratory personnel who will be able to go back to their countries with a good understanding of what is required for a laboratory to generate consistent reliable results.

Parallel with this process, the basic infrastructure in the laboratories in Malawi and Zambia should be upgraded by implementing sustainable solutions. These solutions should typically include the establishment of alternative methods for reliable electricity supply such as solar power, good quality water supply and proper environmental control in the laboratories. Once the infrastructure problems have been addressed, the analysts can return to their laboratories to implement the processes in which they have been trained.

Simultaneous with this process, selected engineers from Malawi and Zambia can then receive intensive training on the more specialized testing equipment such as HPLC and GC systems. This intervention should address the problem of high costs associated with flying out service engineers and should also cut down on instrument down times.

Coupled with the training of service engineers, the option of keeping a 'spares bank' for critical spares for equipment also needs to be explored.

The SAGL would be prepared to operate such a laboratory on behalf of the project.

Option II:

The second option is that a technical specialist or specialists be appointed to develop the laboratories on site. Such a technical specialist should spend at least six months to two years at the laboratories in Malawi and Zambia.

This person must have:

- good managerial and organizational skills;
- the ability to address the basic infrastructure challenges;
- a good basic knowledge of instrumentation and able to perform troubleshooting and basic maintenance;
- must have expert knowledge of the analytical and quality procedures; and
- must be able to train the staff.

There can also be a combination of options I and II where a specialist is appointed to manage the development of the laboratories on site while the initial analyses and advanced training are conducted in South Africa.