AOAC INTERNATIONAL AFRICA SECTION

White Paper

The AOAC Africa Laboratory Performance Benchmarking Program

A collaborative approach to driving and delivering effective and sustained improvement in analytical laboratories

Prepared by:
AOAC INTERNATIONAL Africa Section Method Alignment Committee

AOAC INTERNATIONAL
AFRICA SECTION

Association of Analytical Communities Africa Section

The AOAC Africa Section is a sub-organisation of the AOAC INTERNATIONAL. It is a not-for-profit organisation based purely on the active volunteer work of scientists and like-minded stakeholders.

The Section serves as an effective vehicle to drive the improvement of analytical competence and capabilities as well as improving the standards and performance of food testing labs in this region – be it private, research, academic or Government. This platform can also foster more public-private engagements, bringing tremendous benefits for the consumers and economies in this region.

This Section aims to achieve its goals through collaboration, training & education, analytical methods development & harmonisation, the extension of the scope of Official Methods (to include indigenous foods where required).

The AOAC Africa Section aim to serve as an independent and impartial scientific advisory body, while engaging laboratory support services providers to develop the infrastructure necessary to ensure easy access to reagents, consumables, instrumentation and maintenance, all of which are required to sustain testing performance standards.

COMMUNITY

A platform to connect to members across the African continent and AOAC INTERNATIONAL. Members are encouraged to provide input on priorities, methods and their experiences. Members feedback is integrated into the Executive Committees' actions and decision-making.

KNOWLEDGE

As a Member, you will have access to the latest knowledge and professional development tools to harmonise laboratory standards, and are welcome to contribute to them, with the aim of establishing robust industry standards.

VALUE

Benefit from relationships with targeted manufacturers and support providers. In addition, through access to conferences and training, Members receive value-added return on your membership investment by participating in these offers.

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Summary

AfCFTA will cover policy areas such as regulatory measures covering sanitary standards and technical barriers to trade, which will increase output in services, manufacturing, and natural resources industries.

The Association of Analytical Communities – Africa Section provides a platform for regulatory, testing and control scientists to be able to interact and exchange ideas and best practices to improve the standard and performance of their processes within the region. Now that the African Continental Free Trade Area (AfCFTA) agreement has created the world's largest free trade area, (in terms of the number of participating countries), the importance of harmonizing practices and processes has become even more urgent. AfCFTA connects 1.3 billion people across 55 countries with a combined gross domestic product (GDP) of US$3.4 trillion. In order to unlock its full potential, much depends on significant policy reforms and trade facilitation measures. This agreement will cover policy areas such as regulatory measures covering sanitary standards and technical barriers to trade, which will increase output in services, manufacturing, and natural resources industries.

One of the most important drivers of economic development in the region is Agricultural trade. The agricultural economy involves entire populations from subsistence to commercial farming, hence allowing a wider participation in reaping of the benefits. In order for all stakeholders to fully access the agricultural value chain and markets, commodities must be of acceptable quality and conform to food safety and quality regulations. Each country signatory to AfCFTA has its own food safety regulations and instruments of monitoring and enforcement. Most regulations within the region are based on Codex Alimentarius Guidelines or are directly adopted from EU or US regulations. Conformity to these regulations is achieved through laboratory testing supporting inspection and surveillance programs.

Capacity Building

To build capacity in the laboratory testing service sector in the region, the AOAC Africa Section launched the Laboratory Performance Benchmarking Program, which aims to determine the baseline testing capability of laboratories in the region, identify the root causes of poor performance, and close the gaps through direct mentorship of participating laboratories.

The role of routine laboratory testing services is critical for the development of the region's agro-based economies. In addition to laboratory testing, the inspection and certification of agricultural commodities and agro-based products must comply with regulations. The basic food regulatory standards in the region are based on the Codex Alimentarius Guidelines (unless otherwise specified). Adherence to these standards is critical for acceptance and pricing by recipients, so testing laboratories must provide proof of conformity to these regulations and do so under an acceptable standard. Testing laboratories should adhere to the universally accepted ISO/IEC 17025 standard and be accredited. Test methods should at a minimum be validated and, ideally, be included in the scope of the accreditation. The laboratories must be periodically assessed for performance under ISO/IEC 17025 to ensure that they generate universally comparable results. This is one of the greatest needs in the region, that methods must yield results to a comparable minimum performance. To achieve this, it is important to train analytical scientists in the appropriate methods. To build capacity in the laboratory testing service sector in the region, the AOAC Africa Section launched the Laboratory Performance

Benchmarking Program (LPBP), which aims to determine the baseline testing capability of laboratories in the region, identify the root causes of poor performance, and close the gaps through direct mentorship of participating laboratories. A diagrammatic representation of the AOAC Africa Section LPBP is shown in **Figure 1**.

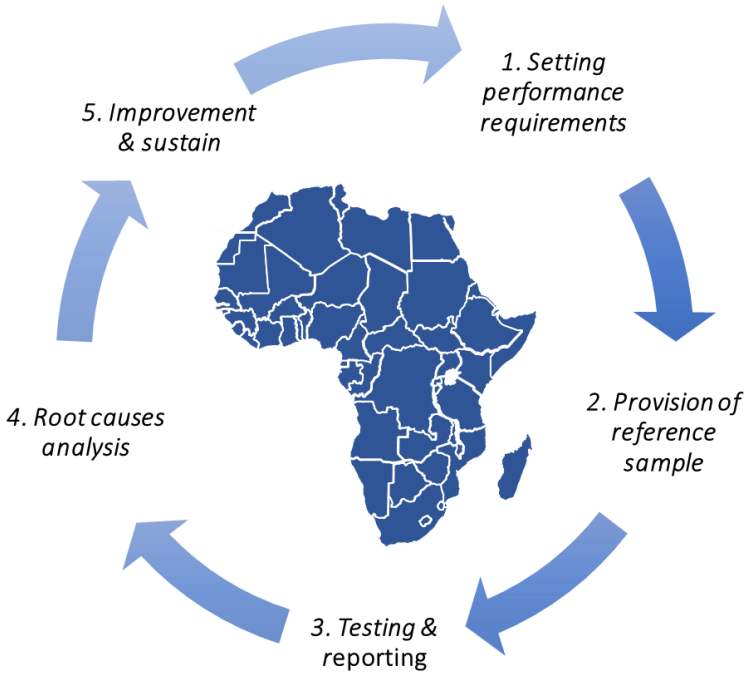

Figure 1. Shows the five stages of the AOAC Africa Section Laboratory Performance Benchmarking Process.

The AOAC Africa Laboratory Performance Benchmarking Program (LPBP)

> ***The protocol invited participating laboratories to use their existing methods of analysis, as employed in routine testing. The method used, whether in-house, from literature, or from standard methods was to be reported.***

The LPBP started by determining the baseline testing capability of laboratories in the region, with the main objective of identifying key analytes and their analytical methods that require special attention. The key analytes were defined based on their importance for public health and trade and included aflatoxins (in peanut slurry and maize), mycotoxins (in peanut slurry and maize), and vitamins and minerals (iron, zinc, calcium, potassium, and phosphorus) in fortified maize. To establish a baseline performance expectation based on regulatory requirements and product standards, the Standard Method Performance Requirements (SMPRs) were set for each of the analytes in various matrices. The SMPRs evaluated specific method performance criteria, which included:

- Accuracy
- Precision
- Limit of Detection
- Operational Range

The protocol invited participating laboratories to use their existing methods of analysis, as employed in routine testing. The method used, whether in-house, from literature, or from standard methods (such as AOAC, ISO, CEN, etc.), was to be reported. Results should have been reported in triplicate, with 3 independent samples analysed on 3 different days.

The results submitted by the participating laboratories were compared to the target performance and reported as "pass" or "fail" based on their actual performance. In the first round of the AOAC Africa Laboratory Performance Benchmarking Program, 38 food testing laboratories from 8 African countries took part.

Peanut slurry (levels 1 and 2) and maize samples were distributed to all registered laboratories in October 2021. The aflatoxin results for peanut slurry (in triplicate) were obtained from 84% of registered laboratories. The standard analytical method performance requirements for the quantification of total aflatoxin and aflatoxin B_1 in peanut slurry was defined as shown below in Table 1.

Table 1. Standard (target) analytical method performance requirements for the quantification of total aflatoxin and aflatoxins B1, B2, G1 and G2 in the AOAC LPBP peanut slurry samples.

Aflatoxins B_1, B_2, G_1, G_2		**Total Aflatoxin**
Operational Range (ppb)	0.1–50 ppb	1–100 ppb
Recovery (%REC)	70 – 125%	70 – 125%
Repeatability (%RSD)	<25%	<25%
Measurement Uncertainty	44%	44%

The assigned values of for the peanut slurry samples are presented in Table 2.

Table 2. Aflatoxin concentration levels in the AOAC LPBP Peanut slurry samples.

Aflatoxin	Concentration (ppb) Level 1	Concentration (ppb) Level 2
B1	29	3.53
B2	9.4	0.69
G1	13.5	2.71
G2	6.7	2.43

The overall performance for the accuracy of quantification of aflatoxins in peanut slurry is shown in Figure 2. The results showed that 64.7% the participating labs achieved the target performance for AFB_1, while 54.5%, 63.6% and 53.8% of labs achieved the target performance for, AFB_2, AFG_1 and AFG_2, respectively.

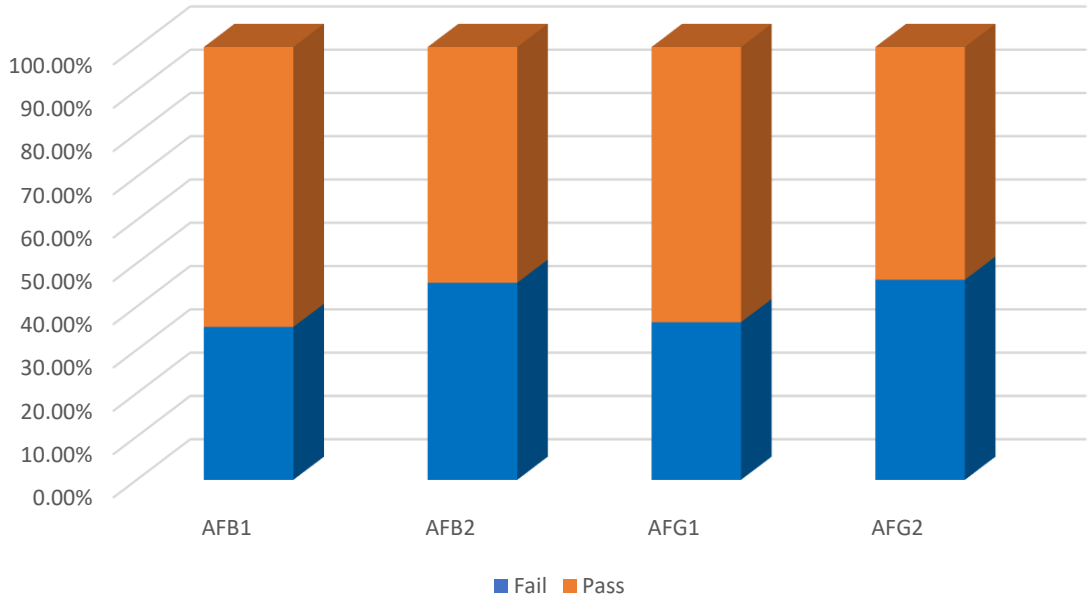

Figure 2. Shows the overall accuracy performance of the participating laboratories when compared to the target method performance for the quantification of aflatoxins B1, B2, G1, and G2 in peanut slurry.

Figure 3 illustrates a general need for method improvement to achieve acceptable method performance in terms of accuracy. This study shows that between 30% and 45% of the laboratories have poorly performing methods as depicted by the blue bars.

Mycotoxins in maize: Naturally incurred standard reference samples were given to the participating laboratories and analysed according to the agreed protocol (three times in duplicate on three separate days) in order to generate the method performance data. The Standard Method Performance Requirement for the detection and quantification of 6 different mycotoxins, [AFB_1); Total Aflatoxins, Ochratoxin A (OTA), Deoxynivalenol (DON), Zearalenone (ZEA) and Fumonisins (FBs)] are shown in Table 2.

Table 2. Standard method performance requirement for AFB1, Total Afla, OTA, DON, ZEA and FBs based on regulatory standard.

	AFB_1	**Total Afla**	**OTA**	**DON**	**ZEA**	**FBs**
Operational Range (ppb)	0.1–50	1–100	0.1–50	50–5000	5-300	10–5000
Recovery*	70 – 125%	70 – 125%	70 – 125%	80 – 120%	80 – 120%	80 – 120%
Repeatability	<25%	<25%	<25%	<25%	<25%	<25%
Measurement Uncertainty	44%	44%	44%	44%	44%	44%

Of the participating laboratories, 85% submitted results for Total Aflatoxin, 55.5% submitted results for AFB_1 and 22.2% submitted results for other mycotoxins (OTA, ZEA, DON and FBs). The levels of participation are shown in Figure 2. While most of the participating laboratories submitted results for the Aflatoxins, only a relatively low number of labs submitted results for the other mycotoxins. This implies that most of the participating laboratories lack the capacity to quantify other important mycotoxins.

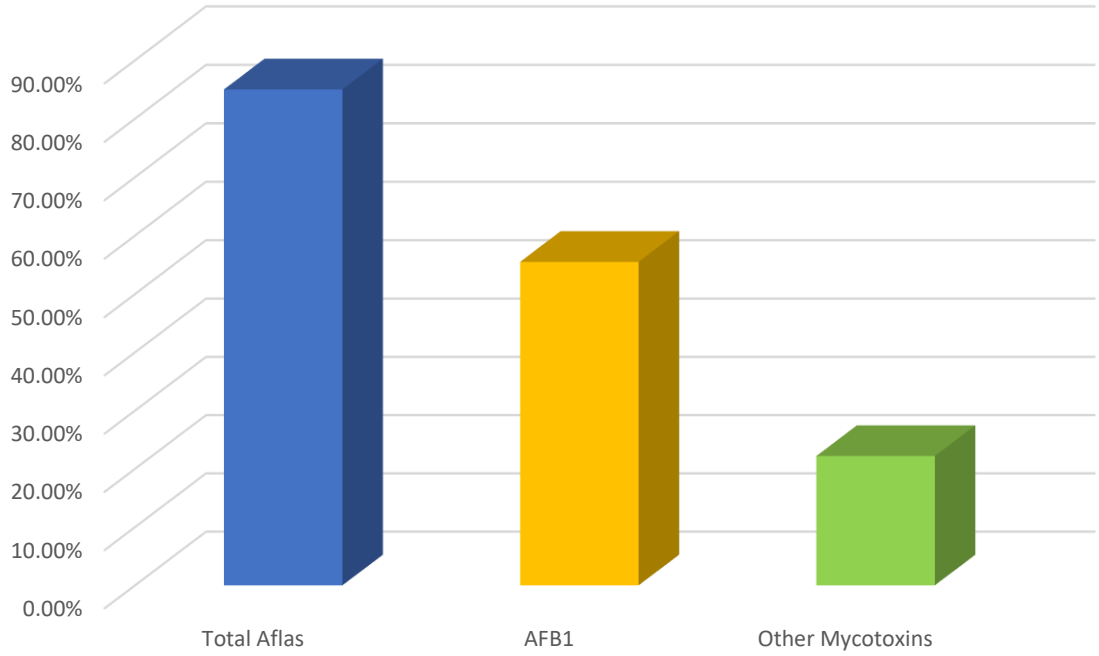

Figure 3. Shows the percentage of the participating laboratories that submitted results for Total Aflatoxins, AFB1 and other mycotoxins (OTA, ZEA, DON and FBs).

The Assigned Values for each mycotoxin in the maize sample i.e., AFB_1, Total Aflatoxins, OTA, ZEA, DON, and FBs were 29.4 ppb, 35.6 ppb, 4.1 ppb, 58 ppb, 144 ppb and 5,621 ppb, respectively. The overall performance of the laboratories for the quantification of mycotoxins in maize is shown in Figure 4.

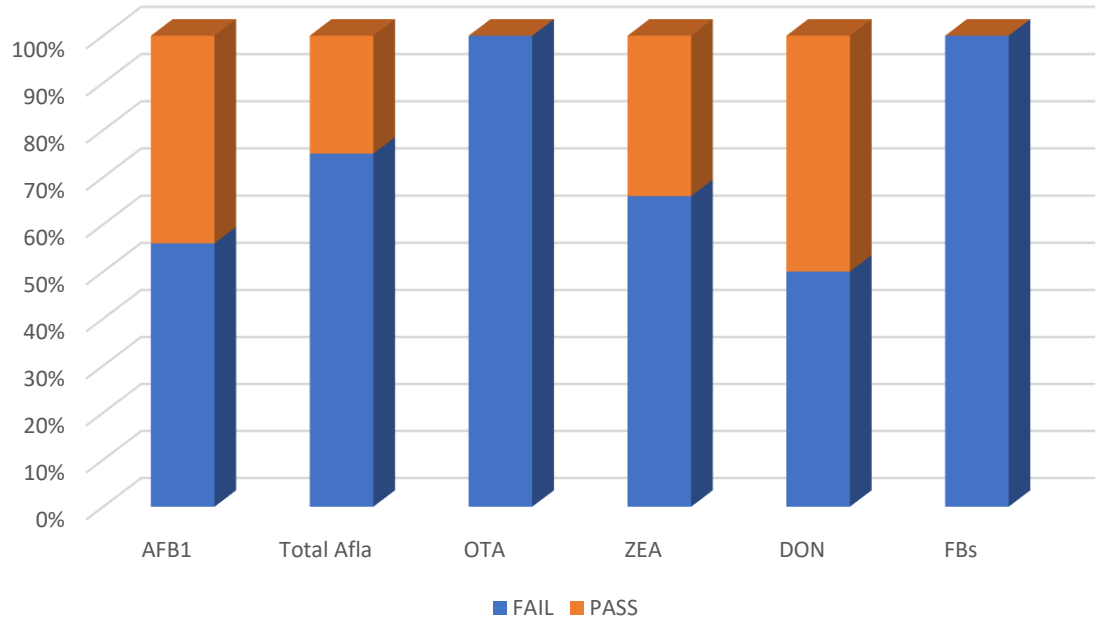

Figure 4. Shows the percentage of laboratories achieving the target accuracy performance. Results reported as PASS achieved the target performance while those reported FAIL did not meet the target accuracy performance.

The results shown in Figure 3 show that there are significant deficits in the reliability of the results for mycotoxins in maize. While there was overall better performance for Total Aflatoxins and AFB1, 70% and 50% of the results respectively, were not reliable i.e., failed to achieve the target standard method performance. The overall performance for the other mycotoxins were considerably worse.

The results show that only a very few of the participating laboratories achieved the target performance for OTA, ZEA, DON and FBs in maize. These results show that of the laboratories that participated in the AOAC Africa Section LPBP, only a relatively small number of laboratories had the capacity and capability to quantify other mycotoxins (other than Aflatoxins), and of these laboratories, only a very few achieved the target method performance. For the trade of safe foods within the Africa Continental Free Trade Area (AfCFTA), it is imperative that laboratories in our region expand their current capacity and capability for multi-mycotoxins quantification as well as identify the root cause(s) of poor performance and use these findings to improve their analytical method performance.

Nutritional analysis of Maize: Standard reference samples of ground yellow maize fortified with vitamins A (retinol), B1 (thiamine), B2 (riboflavin), B3 (niacin) and B6 (pyridoxal 5'-phosphate), and minerals (iron, zinc, calcium, potassium, and phosphorus) were sent to the participating laboratories where they were analysed according to the agreed protocol (as previously described). The assigned values for ash, moisture and protein content were 2.837 g/100g, 4.00 g/100g and 13.34 g/100g, respectively. The assigned values for vitamins A, B1, B2, B3 and B6 were 0.788 mg/100g, 0.387 mg/100g, 0.91 mg/100g, 6.778 mg/100g and 0.96 mg/100g, respectively. The assigned values for iron, zinc, calcium, potassium, and phosphorus were 8.39 mg/100g, 5.85 mg/100g, 305 mg/100g, 663 mg/100g and 525 mg/100g, respectively. The Standard Method Performance Requirements for the detection and quantification of the above-mentioned target nutritional analytes are shown in Tables 3, 4, and 5.

Table 3. Shows the Standard (or target) analytical method performance requirements for protein, ash and moisture content in fortified maize flour.

Parameter	Target performance
Recovery	90 – 110%
Repeatability (RSDr) Ash	3.4%
Repeatability (RSDr) Moisture	3.2%
Repeatability (RSDr) Protein	2.7%

Table 4. Shows the Standard (or target) analytical method performance requirements for iron, zinc, calcium, potassium, and phosphorus content in fortified maize flour.

Parameter	Target performance
Analytical Range	1 – 250 mg/100g
Limit of Quantitation (LOQ)	1.0 mg/100g
Recovery	90 – 110%
Repeatability (RSDr)	1 – 10 mg/100g ≤10%>10 mg/100g ≤ 5%
Reproducibility (RSDR)	1 – 10 mg/100g ≤10%>10 mg/100g ≤ 5%

Table 5. Shows the Standard (or target) analytical method performance requirements for vitamins A, B1, B2, B3 and B6 content in fortified maize flour.

Parameter	Target performance
Analytical Range	1 – 250 mg/100g
Limit of Quantitation (LOQ)	1.0 mg/100g
Recovery	90 – 110%
Repeatability (RSDr)	1 – 10 mg/100g ≤10%>10 mg/100g ≤ 5%
Reproducibility (RSDR)	1 – 10 mg/100g ≤10%>10 mg/100g ≤ 5%

The results submitted by the participating laboratories show that 78%, 86% and 100% of the labs testing for protein, moisture, and ash content respectively, achieved the target analytical method

performance. This is shown below in Figure 5. These results show that 22% and 14% of the labs did not meet the target performance for protein and moisture content respectively.

The results submitted for the minerals showed that many of the participating laboratories did not achieve the target performance. The results show that 65%, 63%, 50%, 82% and 78% achieved the target performance for iron, zinc, calcium, potassium, and phosphorus respectively. This is shown in Figure 6.

The percentage of participating laboratories achieving the target performance for vitamins in fortified maize is shown in Figure 7. The results show that none of the labs achieved the target performance for vitamin A, while 58% achieved the target performance for vitamins B1 and B2, 76% achieved the target performance for B3 and only 40% achieved the target performance for B6.

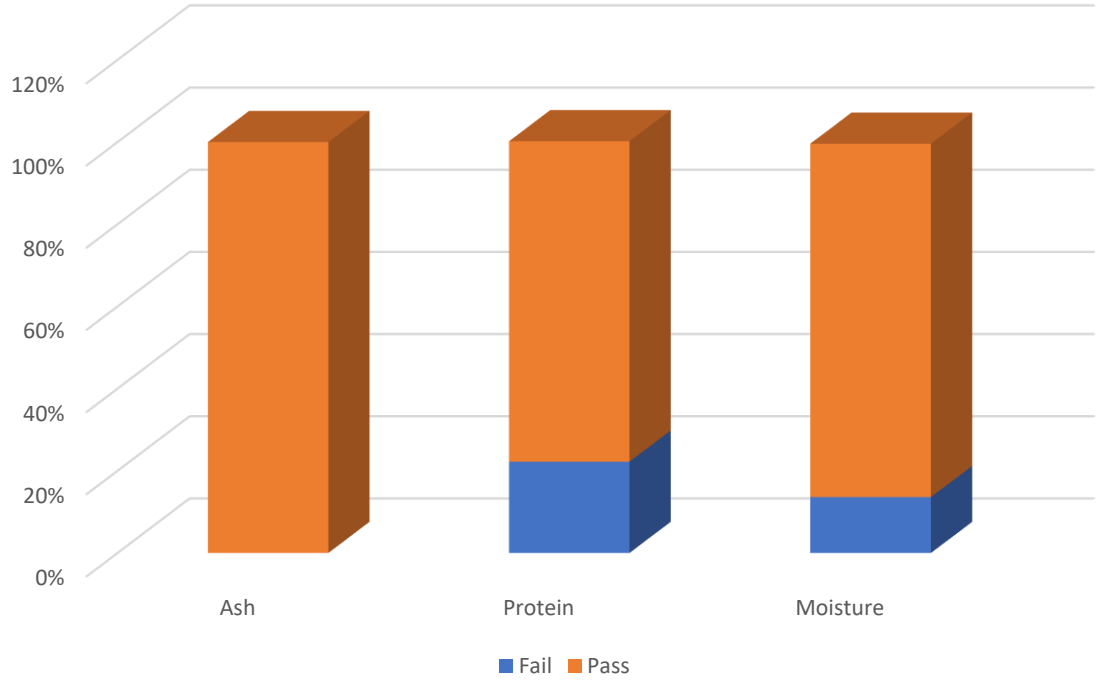

Figure 5. Shows the overall performance of the participating laboratories that analysed ash, moisture and protein content in fortified maize standard reference samples. Laboratories achieving the target performance is classified as PASS while those not achieving the target performance is classified as FAIL.

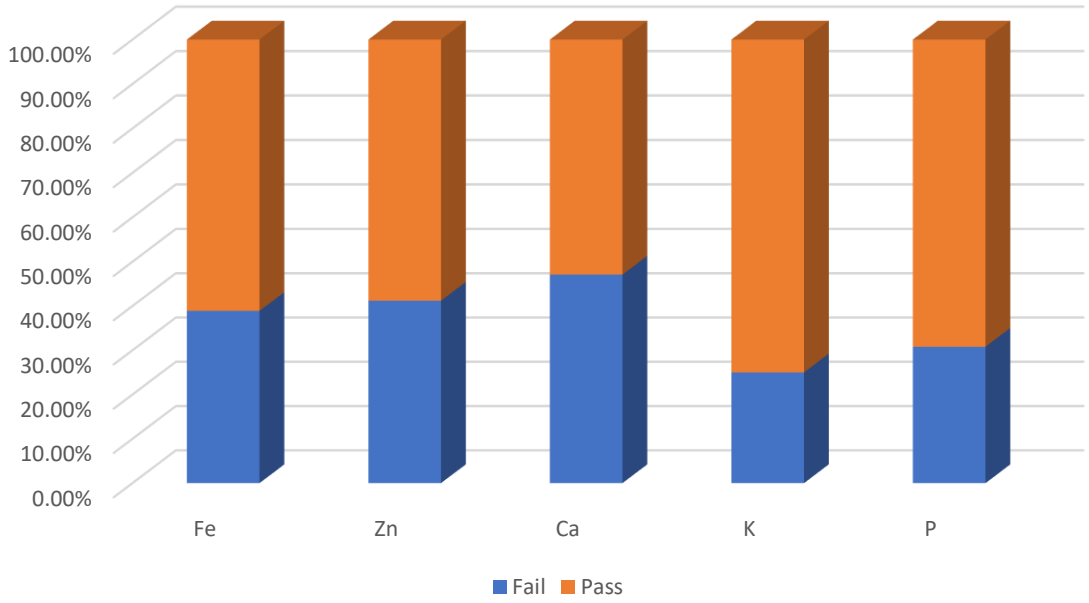

Figure 6. Shows the overall performance of the participating laboratories that analysed iron, zinc, calcium, potassium, and phosphorus in fortified maize standard reference samples. Laboratories achieving the target performance is classified as PASS while those not achieving the target performance is classified as FAIL.

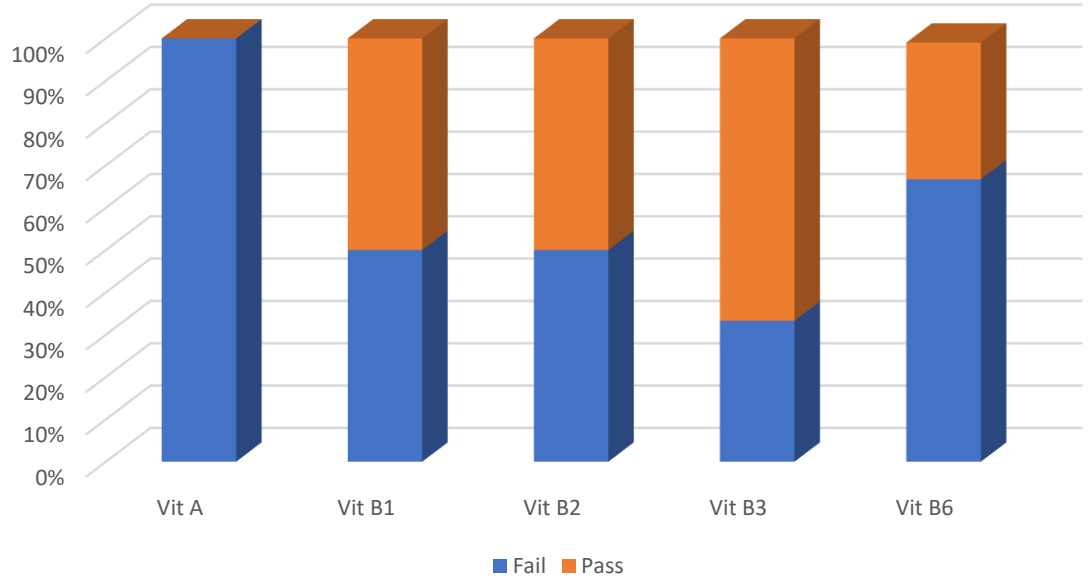

Figure 7. Shows the overall performance of the participating laboratories that analysed vitamins A, B1, B2, B3 and B6 in fortified maize standard reference samples. Laboratories achieving the target performance is classified as PASS while those not achieving the target performance is classified as FAIL.

Primary causes of unsatisfactory performance

In order to support laboratories in identifying the root cause of poor performance, training on problem solving and root cause analysis was provided to laboratories.

The primary objective of the AOAC Africa Section LPBP is to evaluate the performance of laboratories in the region, determine the root causes of poor performance and work directly with

laboratories to implement corrective actions that will result in the overall continuous improvement of the performance of laboratories in our region. Following the performance evaluation phase, laboratories were required to identify and report the causes of unsatisfactory performance.

In order to support laboratories in identifying the root cause of poor performance, training on problem solving and root cause analysis was provided to laboratories. The training provided a structured and systematic approach to problem solving and continuous improvement. The primary causes of unsatisfactory performance of this cohort of participating laboratories were reports as follows:

(i) pre-analysis i.e., poor sample handling, unsuitable storage, poor physical infrastructure
(ii) analyses phase i.e. poor homogenisation prior to subsampling, inefficient extraction, instrument not calibrated, use unsuitable analytical method, competence of Laboratory Analysts (not adequately trained) and
(iii) post analysis phase (transcription error in reporting in wrong/unusual units, and absence of adequate report quality verification process before results are reported.

Conclusion

The outcome of the AOAC INTERNATIONAL Africa Section Laboratory Performance Benchmarking Program, which focuses on the real-time measurement of the key performance characteristics of some agreed tests of certain food matrices, has highlighted the importance of measuring the overall performance of analytical methods and their application, as well as the reliability of the results produced by many of our laboratories, whether ISO 17025 accredited or not.

In order to support the agricultural-based economic growth plan for Africa and to facilitate the trade of safe and quality foods under AfCFTA (encompassing ARSO's one standard, one test, one certificate accepted everywhere principle), the AOAC Africa LPBP provides an excellent independent platform to raise the standards and performance in laboratories as well as giving confidence to analytical services users.

Based on the findings presented in this white paper, we believe that adopting (and expanding) such a program for laboratories in our region will help them to identify deviations in their overall performance and their root causes, thereby allowing them to carry out focused improvement activities to achieve the target performance as required for regulatory conformity compliance. It can also serve to inform users of analytical services of the analytical method-specific performance rating (a qualitative measure) of the laboratory services provider, thereby building confidence in test results, reducing the likelihood of results-related disputes and the associated financial and reputational losses that can occur as a result of such disputes. In order to support the agricultural-based economic growth plan for Africa and to facilitate the trade of safe and quality foods under AfCFTA (encompassing ARSO's one standard, one test, one certificate accepted everywhere principle), the AOAC Africa LPBP provides an excellent independent platform to raise the standards and performance in laboratories as well as giving confidence to analytical services users.

We are therefore inviting all food testing labs in the region to participate in the AOAC Africa Section LPBP.

It is important to note that the LPBP is not a proficiency test scheme, nor does it replace the ISO/IEC 17025 requirement for participation in an ISO/IEC 17043 accredited P-Test scheme. However, laboratories can use the participation in the LPBP to demonstrate active participation in multi-lab testing programs as required by the ISO/IEC 17025 standard.

Acknowledgements

The AOAC Africa Section Method Alignment Committee would like to acknowledge the support of USDA-USAID Land O'Lakes TRASE project for supporting the participation of laboratories in Kenya, Uganda, Tanzania, Burundi, and Rwanda, as well as facilitating the training on problem solving and root cause analysis delivered to these laboratories.

We would also like to acknowledge the contribution of the National Metrology Institute of South Africa in providing the reference samples used in this pilot round of the AOAC Africa Section Laboratory Performance Benchmarking Program.

END.