ARF/EA–REVIEW OF ECSA-HC FOOD FORTIFICATION ACTIVITY

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ACRONYMS

AED  Academy for Educational Development
CAC/GL  Codex Alimentarius Commission Guidelines
CDC  U.S. Centers for Disease Control and Prevention
CIDA  Canadian International Development Agency
CoA  certificate of analysis
CoC  certificate of conformance
COMESA  Common Market for Eastern and Southern Africa
CRG  Commodities Reference Guide
CV  coefficient of variation
DHS  Demographic and Health Survey
EAC  East African Community
ECSA-HC  East, Central and Southern African Health Community
FAO  Food and Agriculture Organization of the United Nations
FAOSTAT  FAO Statistics–Food Balance Sheet
FBRC  Food Biosciences Research Centre
GAIN  Global Alliance for Improved Nutrition (Swiss NGO)
GH Tech  Global Health Technical Assistance Project
GMP  good manufacturing practice
HBS  household budget survey
HIES  Household Income and Expenditure Survey
IDD  iodine deficiency disorder
IEC  information, education and communication
ISO  International Organization for Standardization
KEBS  Kenya Bureau of Standards
KEMRI  Kenya Medical Research Institute
kg  kilogram
KNBS  Kenya National Bureau of Statistics
LPT  laboratory proficiency testing
MDG  Millennium Development Goal
mg  milligram
MI  Micronutrient Initiative (Canadian NGO)
MoA  Ministry of Agriculture, Animal Industry & Fisheries (Uganda)
MoH  Ministry of Health
MPHS  Ministry of Public Health and Sanitation
EXECUTIVE SUMMARY

An independent assessment team was tasked with reviewing USAID/EA progress, achievements, and food fortification plans being implemented in the ECSA region by means of document review, interviews with key stakeholders, e-mail correspondence, and field work (in Kenya and Uganda).

Four key areas had been identified by USAID/EA and implementing partner AED/A2Z. These areas were “Policy and Standards,” “Food Control,” Laboratory Proficiency Exercises,” and “Estimating Impact of the Food Fortification Program.”

POLICY AND STANDARDS

The assessment noted that adoption and/or adaptation of standards and regulations have significantly increased in the EA region, with Uganda (slightly more advanced) and Kenya leading the way. Based on the ECSA guidelines developed by the Standards Setting Technical Workshop in 2007, these standards remain introspective, and the team could find no evidence of cross-border collaboration outside of those workshops.

Industry involvement has been critical to the progress that food fortification has made within the region, and industry appears to have been involved at all stages of this process.

Although Uganda and Kenya are well advanced, their incorporation of food fortification policy within their own national food policy remains at draft level, even though in neither case have technical problems been an issue. Tanzania is only now reviewing its policies. Lesotho, Swaziland, and Mozambique fortify wheat flour and maize meal in accordance with South African regulations for cross-border trade. Lesotho and Swaziland have the same products available in the local markets, but this is less evident in Mozambique. Zimbabwe used to enrich maize meal and wheat flour for marketing purposes, as the mills were owned by South African companies. For Malawi and Zambia the team received mixed signals—sugar and maize meal appear to be fortified, but the quantities of pre-mix entering the countries raises questions about the status, as has the attitude of Zambia’s Ministry of Health on flour fortification.

The key constraint was, and remains, the excessive degree to which the food control inspectorate (Food Control) wants staple foods to be monitored and controlled. Because Food Control fears that consumers might receive an overdose of micronutrients, it views fortified foods as a safety risk.

The assessment team was convinced that the ECSA activities funded by USAID and technically supported, initially by MOST (USAID’s micronutrient program) and currently by A2Z, have been the prime movers both within and between countries. In fact, it is highly unlikely any activity would have emerged without this initiative.

FOOD CONTROL

While the assessment team confirmed that some training has been instituted within Food Control, the level of this training has generally been overstated by the inspectorate. The team noted that ECSA has produced training materials for food control inspection, although there has been limited dissemination of these materials, probably for financial reasons. ECSA-HC plans to improve dissemination in the coming months.

To some extent food inspection has been strengthened, but this component should be considered a work in progress. The team believes this area will be significantly strengthened very shortly.
One particular document, *Quality of Fortified Foods in Uganda, National Monitoring Report 2007–2008*, was identified as documentary evidence of food control activities, although the team realizes that further documentary evidence may exist but could not be found.

Compliance to standards on salt was demonstrated, mostly because of the years of work UNICEF has spent in this area. Compliance could not be established for other fortified products, even though laboratory data demonstrated otherwise. However, the team would question any reliance on the laboratory data at this stage of the project. Nevertheless the Ugandan report mentioned above states that most salt and oil available in Ugandan markets are being fortified.

**LABORATORY PROFICIENCY TESTING EXERCISE**

Food laboratories participating in the Laboratory Proficiency Testing Exercise (LPT) have improved their skills in testing fortified foods. However, the team could not find data to establish whether these laboratories actually tested for micronutrients before the LPTs or are using the exercises as practice. Regardless, this activity has clear benefits for food control purposes.

It was not possible to assess improvement in the knowledge and skills of laboratory personnel because the baseline was unknown. Nevertheless there appears to be improvement, based on discussions with the laboratory staff. From its experience, the team would venture to state that further improvement should begin to become more evident.

Likewise, it was impossible for the team to determine if the reliability of the laboratories has improved due to their participation in the ECSA LPT exercise, because no data existed before and what exist now are limited. At the least, the existence of the LPT establishes that a procedure and a system have been implemented to assess laboratories’ performance. The reliability of laboratory results remains a work in process. However, the results do not lack value: they demonstrate to government and food control senior management that sole reliance on analytical data for the purposes of logo permissions and enforcement is highly questionable (not forgetting that these analysis samples can be considered as representative, unlike the samples inspectors normally take).

**ESTIMATING THE IMPACT OF THE FOOD FORTIFICATION PROGRAMS**

The assessment team could not find sufficient information to estimate intake of fortified foods in Kenya, but the team was advised that the consumption of fortified wheat flour and maize meal is below 10% of the population, and even if fortification were made mandatory, this number would only rise to 20%. In Uganda the situation was different for oil. According to the Uganda Food Consumption Survey of September 2009, 90% of oil consumed by the vulnerable group is fortified.

Although there are no estimates of the level of demand for fortified foods in Kenya, the Uganda Food Consumption Survey of September 2009 attempted to estimate Ugandan demand by focusing on the use at the household level of salt, oil, sugar, wheat, and maize flour, which are the selected vehicles for food fortification programs. A high proportion of the 949 households interviewed reported using edible oil (presumed to be fortified). The only tool available in Kenya and Uganda which, if expanded, could be used to estimate demand of food vehicles used for fortification (oil, wheat flour, maize flour, and sugar) is the Household Income and Expenditure Survey (HIES).

The team found that ECSA is in the process of assisting member states to collect data in order to determine national availability, accessibility, and consumption of staple foods.

The team found no data or generalized information for estimated micronutrient intake or any data that could aid in estimating intake.
POLICY AND STANDARDS CONCLUSIONS

The assessment team noted that policy development for food fortification has not been a cause-and-effect issue. It has been a reactive, rather than proactive, process and therefore has neither hindered nor helped food fortification efforts. For instance, usually policies (cause) guide the development of standards and regulations (effects). In Kenya, however, the situation is one where standards and regulations (effects) will guide policy formulation (cause). This is a clear case of retrospective policy development. Thus it cannot be said that policy facilitated the fortification process. Nor can it be said that policy hindered the process. Furthermore, the absence of a food and nutrition or fortification policy has not necessarily prevented fortification of foods in Kenya. Fortification has proceeded and expanded because of health realities and needs. Tight standards and regulatory mechanisms for fortification have been instituted because of the understanding that fortification of foods in Kenya is a practice that is here to stay.

The assessment team concluded that food fortification has been viewed as health, manufacturing, and consumption concerns rather than a policy concern. Salt iodization presents the best case. One compelling reason for producing the Uganda Food and Nutrition Policy in 2005 was to help the Government, food industry, and health practitioners focus attention on the nutritional and health needs of Ugandans. To this end, USAID support of ECSA food fortification activity has greatly contributed to increased awareness of the benefits of food fortification, and to the acceleration of regional and national policy development and monitoring of fortification programs in the region. This is evidenced by the level of interest among all the member states that are now pursuing food fortification policy options promoted by the ECSA/USAID food fortification program. While policy in Uganda has been decided, Kenya has not yet formulated its food fortification policy. However, the team found that establishment of standards and regulations is moving ahead of policy development. It is therefore possible that Kenya’s policy may be shaped by inputs from the ECSA/USAID program.

FOOD CONTROL CONCLUSIONS

The assessment team noted that Food Control falls under multiple regulations and regulators; as a result, it is fragmented and has a tendency to over-control. Further fortification was considered by Food Control to be a safety risk because there is a perceived risk of overdosing micronutrients to the consumer.

The team observed that food control inspectors use inadequate sampling protocols which are unsuitable for quality assessment, and that inspectors place undue reliance on wet chemistry when assessing compliance issues and have little knowledge about the industries they must monitor. During industry inspections the team saw that industry had more than adequate documentation to demonstrate they are fortifying food in accordance with the standards.

Of particular concern is the fact that Food Control monitors fortification pre-mix on a “conformance to specification” basis, with no attention to “fitness for use,” i.e., the ability of the pre-mix to deliver the required level of micronutrients at the point of consumption. This could be remedied by Food Control or some other competent body by registering pre-mix suppliers and testing the pre-mix for stability under typical environmental conditions.

LABORATORY PROFICIENCY TESTING EXERCISE CONCLUSIONS

The number of LPT participants increased from 2 to 11 in Round 3, and testing covered both qualitative and quantitative techniques for Vitamin A in sugar and oil, iodine in salt, and Vitamin A and iron in wheat flour and maize meal.

The assessment team observed, however, that many laboratories are not following explicit instructions on how to conduct trials, although the team did see visible signs of increased capacity.
and capability. The information generated by these trials was not, however, disseminated widely enough.

ESTIMATING THE IMPACT OF THE FOOD FORTIFICATION PROGRAMS’ CONCLUSIONS

The assessment team concluded that the lack of a database is a significant obstacle to estimating demand for and consumption levels of fortified foods in Kenya and Uganda. The team believed that, if expanded, the Household Income and Expenditure Survey (HIES) modules in Kenya and Uganda could provide the data needed to estimate consumption and intake of fortified foods.

The team considered it unfortunate that the knowledge and technical expertise at the ECSA regional universities were not being tapped to help develop databases on food fortification programs. University participation would provide more depth over and above the ECSA inputs because the universities have greater skills and technical and institutional capabilities than ECSA does. This is an opportunity which should be maximized to add value to past and current ECSA efforts.

The team believes that USAID placement of A2Z within the ECSA secretariat has been critical in assisting ECSA member states in data collection to determine national availability, accessibility, and consumption of fortified staple foods. Based on the team’s findings, this project is key to expanding knowledge, practice, and benefits of addressing micronutrient deficiency in the region.

Important as it is, social marketing as a strategy for stimulating demand is not fully understood and has been under-developed and inappropriately implemented in Uganda. Currently, food fortification is being implemented more as an information, education and communication (IEC) intervention rather than a behavior change component. Consumers need to adapt to eating foods rich in micronutrients, which will increase the quality of their health, instead of just being made aware of available options for their dietary intake. Professionally directed social marketing will help consumers to understand the need to incorporate fortified foods in their diet.

The assessment team makes the following recommendations:

- ECSA should work closely with the Council of Ministers for Health and Trade to explore ways of handling proposals for mandatory fortification and harmonization of standards, and how these would affect trade relations in the region.

- Investment in capacity development at all levels should take center stage in strengthening program implementation and fortification processes. This calls for intensive capacity-building interventions, which should involve an exchange of experiences at regular intervals so that countries with more successful programs can see their successes replicated. Institution-based, on-the-job, and in-house training at key levels can go a long way in imparting fortification skills and technological updates. Regular contacts and engagement between industry and regulatory government bodies through National Fortification Alliance exchange sessions and consultative meetings can greatly improve government-industry relationships.

- ECSA should identify, document, and disseminate best practices in food fortification programs in the region, with a view to having them replicated.

- Operations of the National Fortification Alliances should be strategically constituted and strengthened to enable them more effectively to coordinate and advise fortification programs.

- The task of estimating demands and intakes should be left to the Bureaus of Statistics, which should consider adapting the available tools or incorporating the necessary consumption of fortified foods and intake of micronutrients into their HIES modules. USAID should initially fund training of bureau staff to adapt or modify tools to capture the required data.
Inspectors must be encouraged not to rely on sample analysis. This can be accomplished by discussing the following points with senior management officials of the respective regulatory bodies:

- Reminding officials that an alternative monitoring strategy—the paper trail—exists, and is written into their respective mandates.
- Making officials aware of the limitations of laboratory analysis.
- Ensuring that officials understand that fortification is not a safety risk to the public.

As neither industry nor the Bureau of Standards is capable of prescribing a pre-mix formulation designed to meet the relevant standard for wheat flour and maize meal, the ECSA/A2Z should help them to do this.

ECSA/A2Z should provide guidelines on registering pre-mix suppliers, which should include parameters such as demonstrated stability of Vitamin A in a powder food vehicle under tropical conditions and the identification of other potential “markers” if quantitative testing is required. If, however, the paper trail is used as a monitoring technique, this will enable more frequent inspections of production facilities, if required, and so decrease the need for quantitative testing, which can be expensive.

As some quantitative testing will still be required, the LPT exercises should also include pre-mix within the ring trial and, when staff have become sufficiently competent, the inclusion of borderline samples to establish whether laboratories are capable of making compliance issue decisions (for prosecution) or not. In addition, investigation of substantial variations in some results (e.g., Vitamin A in sugar) should be conducted.

The issue of legislated maximum micronutrient contents should be addressed at the next regional workshop as compliance criteria of quality.

Since different regional standards exist because of varying views on the nutritional needs of each country, ECSA should engage the respective Ministries of Trade to forestall any negative trade issues—possibly by agreeing on a range of micronutrient requirements rather than trying to establish identical requirements.
I. INTRODUCTION

PURPOSE
The purpose of this review is to provide the United States Agency for International Development regional office for East Africa (USAID/EA) with an independent assessment of the progress, achievements, and plans of the food fortification activity being implemented by the East, Central and Southern Africa Health Community (ECSA-HC) with USAID funding.

In conducting the assessment, the team will:

- technically assess the progress of the food fortification activity to date and its contribution toward achieving the stated results.
- highlight achievements and recommend the improvements needed to achieve results.
- review current plans and propose strategies to estimate the demand, use, consumption, and potential benefit of the food fortification program as a public health intervention. The assessment team will synthesize data on current consumption patterns, conduct field interviews to estimate demand and potential benefit, and make recommendations for the future design of the ECSA food fortification program.

BACKGROUND
The USAID/EA definition of East African countries consists of Burundi, the Democratic Republic of Congo (DRC), Djibouti, Ethiopia, Kenya, Rwanda, Southern Sudan, Tanzania, and Uganda.

Similarly, ECSA–HC consists of Kenya, Lesotho, Malawi, Mauritius, Mozambique, Seychelles, Swaziland, South Africa (RSA), Tanzania, Uganda, Zambia, and Zimbabwe. RSA appears to be playing a decreasing role within ECSA, while participation has increased from Angola, the DRC, Eritrea, Ethiopia, Madagascar, Rwanda, and Southern Sudan, which are looking to ECSA for assistance in developing a food fortification infrastructure compatible with that being developed in East Africa.

METHODOLOGY
The methodology used during the assessment deviated slightly from that originally anticipated because the following representatives were unable to accompany the assessment team during field work due to other commitments:

- A senior Government official in Kenya and Uganda to provide access to both Government offices and private companies for interviews (A2Z functionaries assigned to ECSA and Uganda made the necessary contacts).
- The ECSA Nutrition Advisor to reinforce collaboration and achieve buy-in for regional fortification efforts (the A2Z functionary assigned to ECSA played this role).
- The USAID/EA MCH advisor will be an integral member of the team with a role specified through the team planning meeting.
- The USAID/Washington A2Z Agreement Officer’s Technical Representative (AOTR) will be a member of the team with a role specified through team planning meeting.

The assessment team therefore consisted of the two external members plus the A2Z Regional Fortification Advisor in the ECSA-headquarters in Arusha, Tanzania, and the A2Z Food
Fortification Officer in Uganda. The team did not consider this deviation from the original planning to be significantly detrimental and so advised Washington when the issue of adequate support was raised.

The SOW provided a set of illustrative questions (below) discussed in two team planning meetings (one with USAID and one with ECSA/A2Z), which were extended to cover a broader view of policy than merely governmental policy. It was recognized at these planning meetings that Task 4 may be based more on assumptions than on facts.

**TASK 1: POLICY AND STANDARDS**
The team’s aim was to determine the extent to which the food fortification project has influenced changes in government food fortification policies within East African countries and throughout the ECSA-HC region.

- Are member countries adopting standards and regulations that will promote food fortification within countries and across borders in the East African region?
- In the past these countries did not have food fortification policies, yet some manufacturing companies claim to fortify some foods. The assessment should determine whether or not governments, in enacting policies, have involved the private sector (manufacturing companies).
- What is the status of the food fortification programs, policy development, and implementation process in each country and across borders?
- What were the key policy enablers and/or constraints to implementing food fortification programs in the ECSA-HC region?
- To what extent has the ECSA-HC regional activity on food fortification influenced the introduction or scaling up of fortification programs within countries and across borders?

**TASK 2: FOOD CONTROL**
The team’s aim was to determine the extent to which governments in the region have adopted and implemented food fortification guidelines and standards on food control.

- Are food inspectors trained in food control procedures at factories, importation sites, and retail stores?
- Have the food inspection actions been strengthened by this project?
- Have reports about food control been published and disseminated?
- To what extent do manufacturers strategically communicate information on their fortified foods?
- Are the basic detectable nutrients in fortified products meeting the fortification standards?

**TASK 3: LABORATORY PROFICIENCY TESTING EXERCISE**
The team’s aim was to examine whether the analytical capabilities of the food control laboratories involved in the food fortification programs have been strengthened.

- Have the participating laboratories in the proficiency network acquired new analytical skills useful for the control of fortified foods?
• Have the laboratory personnel improved in their knowledge and skills as compared with those before the introduction of this project?
• Is the reliability of the laboratory results better now than before?

**TASK 4: ESTIMATING THE IMPACT OF THE FOOD FORTIFICATION PROGRAMS**

The team’s aim was to make specific recommendations to improve data collection to estimate the demand, use, consumption, and potential benefit of the food fortification programs in vulnerable population groups.

• To what extent are fortified foods reaching vulnerable groups (defined as children under the age of five and women of reproductive age)?
• What tools are in place to estimate demand?
• What is the level of demand for fortified foods in the region, and what are the proposed strategies and methodologies for estimating demand?
• Does information exist to begin the process of estimating intake? How can the project use the information from household income expenditure surveys?
• What is the nutritional impact of the estimated additional micronutrient intakes?
• Do any/all children under the age of five and women of reproductive age have access to any commercially fortified foods in the selected countries?

The ECSA/A2Z planning meeting identified key informants to receive face-to-face interviews, and USAID provided a further list of potential informants, some of whom were in the same organization as those interviewed but in different sections, who could be reached via e-mail.¹ The e-mail list targeted those involved in the actual implementation of intervention programs, as well as those responsible for more regional policy; however, some contacts were not made because colleagues were not at their desks.

The questions sent were as follows:

Note: These questions relate to any and all countries within ECSA, so some questions may be applicable in Country X but not in Country Y.

1. Do you use fortified foods in your program?
2. If so, is this fortified food sourced locally, from USAID, or from any other source? Which foods are fortified?
3. If sourced locally, who fortifies the foods for you?
4. Who sources and pays for the pre-mix—you or the manufacturer?
5. What is the pre-mix formulation that is being used? Does it follow the USDA Commodities Reference Guide (CRG)?
6. Who monitors fortification compliance on your behalf?
7. Are standard operating procedures (SOPs) established? If so, can we have a (preferably electronic) copy?

¹ COMPETE; FAO; FEWS; Kenya Food Security; Regional Food Security & Nutrition Working Group; RELPA/PACAPS; UNICEF; USAID and WFP.
8. Do you report information relating to your fortification activities? To whom?

9. Do you feel/believe the value of fortification is understood by the vulnerable groups?

10. Are you aware of the ECSA food fortification project?

11. What is the relationship between your fortification practice with any government body such as the Ministry of Health or the Bureau of Standards?

12. Do you provide any education to accompany your distribution, i.e., written, verbal, public campaign?

13. Does fortification affect your production costs to a significant extent?

14. How are these costs, if any, met?

15. Do you believe there are linkages between fortification and HIV/AIDS and reproductive health—if so, what do you think they are?

16. What are the topical, critical issues in food fortification within your organization?

17. Do you have any HIES or HBS data we can access?

18. Do you have any food consumption data (excluding FAOSTAT) we can access, particularly in relation to rural versus urban consumption, and consumption within a household?

Note: These questions relate to any and all countries within ECSA, so some questions may be applicable in Country X but not in Country Y.

1. Are data on food security available and, if so, can we access them?

2. Does a regional policy for food security exist within ECSA or is it purely country-based? (We are asking ECSA the same question.)

3. Can we access that policy or policies?

4. Are resources (funds, materials, products) allocated to improving the nutritional status of vulnerable groups adequate?

5. What is the strategy, if any, for promoting demand for fortified foods?

6. If the above does not exist, who do you think should be responsible for developing such a strategy?

The team also reviewed documents collected from ECSA, USAID, various government departments, other donor agencies, and the Internet, as recorded in Appendix C.

Industry assessment was restricted to Kenya and Uganda.
II. FINDINGS

OVERALL

TASK 1: Policy and Standards

The team’s aim was to determine the extent to which the food fortification project has influenced changes in government food fortification policies within East African countries and throughout the ECSA-HC region.

The review, modification, adoption, and/or adaptation of standards and regulations have significantly increased in the EA region, with Uganda (slightly more advanced) and Kenya leading the way. Based on the ECSA guidelines developed by the Standards Setting Technical Workshop in 2007, these standards remain introspective, and the team could find no evidence of cross-border collaboration outside of those workshops.

Industry involvement has been critical to the progress that food fortification has made within the region, and industry appears to have been involved at all stages of this process.

Although Uganda and Kenya are well advanced, their incorporation of food fortification policy within their own national food policy remains at draft level, even though in neither case have technical problems been an issue. Tanzania is only now reviewing its policies. Lesotho, Swaziland, and Mozambique fortify wheat flour and maize meal in accordance with South African regulations for cross-border trade. Lesotho and Swaziland have the same products available in the local markets, but this is less evident in Mozambique. Zimbabwe used to enrich maize meal and wheat flour for marketing purposes, as the mills were owned by South African companies. For Malawi and Zambia the team received mixed signals—sugar and maize meal appear to be fortified, but the quantities of pre-mix entering the countries raises questions about the status, as has the attitude of Zambia’s Ministry of Health on flour fortification.

The key constraint was, and remains, the excessive degree to which Food Control wants staple foods to be monitored and controlled. Because the inspectorate fears that consumers might receive an overdose of micronutrients, it views fortified foods as a safety risk.

Beyond a shadow of a doubt, the ECSA activities funded by USAID and technically supported by MOST and A2Z have been the prime movers both within and between countries. In fact, it is highly unlikely that any activity would have emerged without this initiative.

TASK 2: Food Control

The team’s aim was to determine the extent to which government authorities in the region have adopted and implemented food fortification guidelines and standards on food control.

Some training has been instituted within Food Control (although this has generally been overstated), and ECSA has produced training materials for food control inspection, although there has been limited dissemination of these materials, probably for financial reasons. ECSA-HC plans to improve dissemination in the coming months.

To some extent food inspection has been strengthened, but this component should be considered a work in progress. The team believes this area will be significantly strengthened very shortly.

One particular document, Quality of Fortified Foods in Uganda, National Monitoring Report 2007–2008, was identified as documentary evidence of food control activities, although the team realizes that further documentary evidence may exist but could not be found.
The food industry has not communicated information to the government about the industry’s food fortification practices.

Compliance to standards on salt was demonstrated, primarily due to the years of work that UNICEF has spent on this issue. Compliance could not be established for other fortified products, even though laboratory data demonstrated otherwise. However, the team would question any reliance on the laboratory data at this stage of the project. Nevertheless the Ugandan report mentioned above states that most salt and oil available in Ugandan markets are being fortified.

**TASK 3: Laboratory Proficiency Testing Exercise**

The team’s aim was to examine whether the analytical capabilities of the food control laboratories involved in food fortification programs have improved.

Food laboratories participating in the Laboratory Proficiency Testing Exercise (LPT) have improved their skills in testing fortified foods. However, the team could not find data to establish whether these laboratories actually tested for micronutrients before the LPTs or are using the exercises as practice. Regardless, this activity has clear benefits for food control purposes.

It was impossible to assess improvement in the knowledge and skills of laboratory personnel because the baseline was unknown. Nevertheless there appears to be improvement, based on discussions with the laboratory staff. From its experience, the team would venture to state that further improvement should begin to become more evident.

Likewise, it was impossible for the team to determine if the reliability of the laboratories has improved due to their participation in the ECSA LPT exercise, because no data existed before and what exist now are limited. At the least, the existence of the LPT establishes that a procedure and a system have been implemented to assess laboratories’ performance. The reliability of laboratory results remains a work in process. However, the results do not lack value: they demonstrate to government and food control senior management that sole reliance on analytical data for the purposes of logo permissions and enforcement is highly questionable (not forgetting that these analysis samples can be considered as representative, unlike the samples inspectors normally take).

**TASK 4: Estimating the Impact of the Food Fortification Programs**

The team’s aim was to make specific recommendations to improve data collection to estimate the demand, use, consumption, and potential benefits of the food fortification programs in vulnerable population groups.

The assessment team could not find sufficient information to estimate intake of fortified foods in Kenya, but the team was advised that the consumption of fortified wheat flour and maize meal is below 10% of the population, and even if fortification were made mandatory, this number would only rise to 20%. In Uganda the situation was different for oil. According to the Uganda Food Consumption Survey of September 2009, 90% of oil consumed by the vulnerable group is fortified.

There are no estimates of the level of demand for fortified foods in Kenya. The Uganda Food Consumption Survey of September 2009 attempted to estimate Ugandan demand by focusing on the use at household level of salt, oil, sugar, wheat, and maize flour, which are the selected vehicles for food fortification programs. A high proportion of the 949 households interviewed reported using edible oil (presumed to be fortified). The only tool available in Kenya and Uganda which, if expanded, could be used to estimate demand of food vehicles used for fortification (oil, wheat flour, maize flour, and sugar) is the Household Income and Expenditure Survey (HIES).
The team found that ECSA is in the process of assisting member states to collect data in order to determine national availability, accessibility, and consumption of staple foods.

ECSA project reports indicate that HIES can be used to:

- provide training on the use of data obtained from regular household surveys for estimating consumption of food vehicles identified for fortification, and possibly for identifying others (ECSA, supported technically and financially by A2Z, provided such training in Uganda in April 2009).
- estimate expenditure patterns relating to fortified foods.
- determine rural and urban distribution of fortified foods.
- establish prevalence rates of specific fortified foods.
- help program managers to define interventions and gaps.

The team found no data or generalized information for estimated micronutrient intake or any data that could aid in estimating intake.

Likewise, the team could find no consolidated national or segregated data. At the current levels of food fortification programs in East Africa, commercially fortified foods are not necessarily penetrating remote rural areas (although, as stated earlier, in Uganda it is estimated that 90% of oil consumed by this group is fortified).

**TASK 1: POLICY AND STANDARDS**

Policies can act as an enabling environment for behavior change and program implementation in the manufacturing, supply, and consumption of fortified foods. The policies which affect food fortification are largely those of governments, usually embedded in acts, standards, and regulations. Another set of policies are those of the funders of food production and food and nutrition programs. Food processing and manufacturing industries may also have their own policies, which usually address quality, health considerations, and maximization of profits through the sale of their products. All sets of policies, standards, and regulations relating to food fortification must be flexible, adaptive, and complementary. The team looked for evidence not only of government policies, but also of policies of government partners and other stakeholders and how they support and reinforce one another.

Donors and international agencies tend to tailor their interventions to respond to the policies, standards, and regulations of governments. The assessment team found that the principal international players in food fortification in Kenya and Uganda are USAID, the United Nations World Food Program (WFP), the United Nations International Children’s Emergency Fund (UNICEF), the United Nations Food and Agriculture Organization (FAO), the World Health Organization (WHO), Micronutrient Initiative (MI) (a Canadian NGO), and Global Alliance for Improved Nutrition (GAIN) (a Swiss NGO).

A significant indicator of the adoption of policies, standards, and regulations promoting food fortification in ECSA countries was found in the number of ECSA-HC countries participating in the implementation of the ECSA food fortification project. When the project began in 2004, only one member country, Zambia, had a food fortification policy governing standards and regulations. Within five years the project had influenced policy development and the adoption of standards and regulations for food fortification in nine countries—Botswana, Kenya, Lesotho, Malawi, Mozambique, Swaziland, Tanzania, Uganda, and Zimbabwe. Fortification of salt with iodine has been mandatory in all ECSA countries since the early 1990s.
With the exception of Zambia, which restricts importation of Kenya’s sugar because it is not fortified, the team did not find any explicitly prohibitive country policies that would affect regional trade in fortified foods.

Ministry of Health officials in Uganda are convinced that removal of the remnants of trade policy barriers and restrictions will broaden the sale and consumption of fortified foods across borders within ECSA, and will also help harmonize fortification standards in the region. ECSA should prepare a brief for the Regional Health Ministers meeting so that attendees can deliberate and make the necessary recommendations to their governments regarding the relaxation of restrictions on import of staple foods.

The above precautionary action seems increasingly likely, as data collected during the 2nd ECSA Regional Workshop in 2004 indicated that the East African Community (EAC) had a 25% import duty on maize meal and no agreement on import duties for wheat flour. Subsequent to that workshop, import duties of 60% and 50% were declared in the EAC Common External Tariff of December 16, 2004, which tends to support the impression the team received during the field work.

So far, there appear to be uniform movements toward mandatory fortification in the region. As already mentioned, fortification of salt with iodine is mandatory in all ECSA countries while the identified food vehicles for fortification—sugar, maize meal, vegetable oil, and wheat flour—are the same in all these countries.

Legislation in Kenya permits, but does not require, mandatory fortification except for iodization of salt. The draft Food and Nutrition Policy, which incorporates food fortification and upon which the Ministries of Health and Agriculture are jointly working, has not been finalized. Fortification of oil is not covered in the Act.

Fortification standards have been developed for salt, sugar, oil, wheat flour, and maize meal. Chapter 254 of the Kenyan Food, Drugs and Chemical Substances Act (Rev. 1992) also mentions enrichment of wheat and 2492 and salt. This has now been superseded by KS 229:2009. The Act is currently being considered for amendment to refer to fortification only as in the relevant standards as directed by the Minister.

The assessment team was informed that Kenya has micronutrient guidelines that aim to introduce mandatory fortification by the end of 2010. This may coincide with enactment of the Food and Nutrition Policy. The team was assured by MoH officials that Kenyan industry is ready for these developments.

The Uganda Food and Nutrition Policy (UFNP) was published in February 2005. It identifies twelve intervention focus areas, including food processing and preservation, food standards, quality control, and health. In highlighting the determinants of food and nutrition insecurity, the UFNP states:

In Uganda many families/households suffer from micro-nutrient deficiencies. One third of the disease burden attributable to childhood and maternal under-nutrition in Uganda is due to deficiencies in the micronutrient quality of that food. This can easily and inexpensively be addressed by salt iodization, fortification of commonly consumed commercial foods, and supplemental doses of Vitamin A and iron for women and children.

Thus the policy underscores the need for consumption of fortified foods. Since the launching of the UFNP, efforts have been made to ensure that fortified foods in the market are safe and contain

\[\text{thiamin (4.5–5.5 ppm), riboflavin (2.7–44.4 ppm), niacin (33.5–44.4 ppm), and iron (28.5–36.5 ppm).}\]
adequate nutrients in accordance with national standards. So far, fortified edible oils, fats, and salt in the Uganda market do meet national standards. Such foods (with the exception of salt) are labeled with the fortification logo which has now been registered. Adaption of ECSA standards is being advocated. Adherence to these standards is monitored and regulated by the Uganda National Bureau of Standards (UNBS), which collaborates with the Uganda Industrial Research Institute (UIRI) for additional analytical support. UIRI is considering a feasibility study of fortifying matooke (steamed green plantain, a staple in Buganda and widely consumed in many parts of Uganda).

Uganda developed a Food and Nutrition Strategy and Investment Plan in 2005 which emphasizes reducing micronutrient deficiencies through salt iodization and fortification of commonly consumed commercial foods.

The review, modification, adoption, and/or adaptation of standards and regulations have significantly increased in the EA region, with Uganda and Kenya leading the way. Based on the ECSA guidelines developed by the Standards Setting Technical Workshop in 2007, these standards remain introspective, and the team could find no evidence of cross-border collaboration outside of those workshops.

From discussions with the National Fortification Alliances, review of government policy documents (usually drafts), and the standards developed by the relevant Standards Bureaus, it appears that both Kenya and Uganda have extensively involved industry and other stakeholders, i.e., academia, consumers, traders, and representatives of donor and/or implementing partner organizations. In fact, some interviewees told the team that they felt the consultative process was “democracy gone too far” and that “we should just get on with it”—implying that government was not being strong enough and that the process was taking too long.

A more serious question was whether the policy-making process has included the most representative decisionmakers. While senior decisionmakers were present during the early days of the process, they increasingly resorted to “alternates” to represent them. Typically, alternates did not have the mandate to make decisions or the political and/or technical capability to actively participate. As a result, the consultative phase of policy and standard development has become increasingly drawn out.

The team also heard during the interviews that the development of food fortification initiatives hinged more on personalities than institutions. The vast majority of members of the consultative and development process are passionate about their activities but there appears to be no institutional adoption. A particular point of frustration for many interviewees was when an individual member of a sub-committee would be replaced because he/she had changed jobs or been promoted, upon which the process would return to Stage One because the new member did not agree with the proposed strategy.

The team will use the term “standard” because the vast majority of readers are more familiar with this term than with “technical regulation.” A discussion of the difference appears in Appendix C.

Another term that produced confusion was the word “fortification” itself. The team heard numerous references to “fortified foods” when what the speaker was referring to a foodstuff with some vitamins and/or minerals added for marketing reasons.

The team also noted the inconsistent use of language in the Kenya Standards—namely the use of “fortification” and “enrichment” and the permission to use the logo. Examples of this are

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3 See the Micronutrient Initiative reports for further discussion of this point.
provided in Appendix D. A2Z has taken note of this development and intends to bring the matter up for discussion at the next ECSA regional meeting, if not sooner.

It appears that both the Kenya Bureau of Standards (KEBS) and UNBS have taken a cut-and-paste approach to standards development—almost certainly due to workload constraints—which could cause confusion during cross-border trade. For example, while UNBS has altered a few of its compositional requirements to reflect the moisture basis upon which specific analysis is performed, both agencies make extensive use of the terminology “m/m” (“mass for mass,” also known by the term “as is”). This terminology is generic and used as such by the Codex Alimentarius Commission (CAC) because different countries use a different moisture basis for different analyses and Codex expects them to clarify this themselves. It is also technically incorrect to set a technical requirement for compliance, especially for products such as wheat flour and maize meal that are hygroscopic, i.e., products that gain or lose moisture depending on ambient environmental conditions. Interpretation of analytical results using standards containing such statements would prove unduly complex for the analyst, the food control inspectorate and industry.

The assessment team examined the relative positions of the ECSA recommendations on fortification levels and those adopted by Kenya and Uganda, which diverge to varying degrees, as well as the differences this will entail in the pre-mix formulations. As this was outside the scope of the report (but likely to be the subject of future deliberations), this discussion can be found in Appendix E. This issue is a major concern because the delay in initiating wheat flour and maize meal fortification in Kenya has been caused in part because KEBS did not feel competent to formulate the required pre-mix and wanted industry to carry out this task. Industry equally did not feel competent to do so and passed the task to the pre-mix suppliers, who formulated the pre-mix against what was, at that point, considered the target micronutrient content of wheat flour and maize meal. Unfortunately, the target content, when finally promulgated (being more in line with the ECSA recommendation), was different from the original both in formulation and dosage level. (It was only during a recent MI fortification capacity-building exercise that this oversight was identified.)

The team found some indication of a guarded stand-off between industry and government institutions that was caused by imposition of several intrusive regulations promoted by the Bureaus of Standards, revenue authorities, and customs and drugs regulatory departments in both Kenya and Uganda. These regulations should be reviewed and probably modified in order to allow manufacturers to fit comfortably in the fortification process. The primary role of governments and their agencies should be to facilitate, rather than impede, the operations and functioning of private-sector organizations. Where possible, governments should grant incentives to companies that are in the business of improving the nutritional value of dietary products for citizens of those governments.

Industry involvement has been critical to the progress that food fortification has made within the region, and industry appears to have been involved at all stages of this process.

Although there are actual or planned food and nutrition policies and other acts in the ECSA member states, fortification remains largely voluntary. The team believes that the ECSA secretariat may advocate for certification of manufacturers that meet ECSA and country standards.

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4 Personal communication, Omar Dary.
In Kenya the team observed the persistence of the freely used claim by some manufacturing companies that they fortify some foods. This is demonstrated by the language used in some product labels such as *Pro-Vitamin A, Rich in Vitamin A, Enriched with Vitamin A and more.* Clearly, the discussion of regulation of allowable claims is a topic that deserves attention.

Kenya’s Ministries of Health and Agriculture have yet to demonstrate fully that they are making efforts to implement the MoH flagship project of “facilitating manufacturers to improve health through food fortification” (Kenya Ministry of Health, *Medium Term Plan 2008–2012*). If such facilitation were to be undertaken, the two ministries would gain a higher level of commitment, which would help manufacturers in overcoming difficulties. The only facilitation strategy lies within the purview of the National Fortification Alliance, whose meetings and interactions can be structured to review continuously the concerns of the manufacturers, which the Alliance can then present to government institutions for consideration. Currently, the private sector is involved in consultative, advisory, and review meetings for developing Kenya’s Food and Nutrition Acts. MoH officials in Uganda also reported that food manufacturers were involved in developing the Food and Nutrition Policy and enacting the Food and Nutrition Bill.

In terms of fortification status and implementation, Uganda and Kenya are well advanced, although in both countries food fortification policy (incorporated into the National Food Policy) remains at draft level. In both cases this is not due to technical issues. Tanzania is only now reviewing its policies and other issues.

It is widely recognized that ECSA has been the prime mover in initiating scaling-up food fortification operations within the region, successfully building upon foundations laid by other projects (MOST in Uganda and MI in Kenya) within specific countries. ECSA appears now to have developed, with technical support from USAID/EA and A2Z, a workable model that should be transferable from one country to another. Thanks to its high level of funding, the GAIN program has further enhanced this scale-up. Perhaps one of the most important lessons learned in the region comes from the early work in Uganda by MOST in which the program supported the development of a business plan and a five-year strategy to enable the country to apply for a GAIN grant. Regardless of whether a country is successful in its GAIN application, the development of such a business plan should be specifically incorporated into the ECSA model.

The placement of A2Z within ECSA was a strategic masterstroke because it has nearly seamlessly joined political expertise with technical expertise. However, the team questions if this symbiotic relationship is being fully exploited since the team perceived that ECSA may not have staff with sufficient technical expertise and/or experience to ensure that the transfer of institutional knowledge is achieved. Again, the team is concerned about fortification being more about personalities than institutions—the loss of any key personnel (and that number is remarkably small) would be a major setback to regional and national activities. The development of institutional knowledge needs to be urgently addressed. The team was told that ECSA is planning to address this problem by organizing a training of local professionals in food fortification skills and creating a roster of local experts in this field.

In a similar vein the team noted that while USAID, ECSA, A2Z, GAIN, and, increasingly, the Flour Fortification Initiative are the major players in food fortification capacity-building in the region, other players are also active in what are probably more targeted programs, e.g., CIDA funding MI activities on salt in partnership with UNICEF; FAO and WHO supporting food safety training, and so on.

All of these donors/implementing partners have different priorities and/or policies regarding their activities. For example, some will fund specific fortification activities but not programs, some will fund only specific countries not regions, and some will fund particular food vehicles but not others. The team believes there is a risk that partners may even give differing messages to a
country. If that is the case, then ECSA should take the lead in bringing partners to the table with the aim of achieving a consensus that activities should complement countries’ efforts and that partners should not insist on divergent approaches. Similar activities in West Africa should also be monitored for possible conflicts.

The result of all this activity is a fragmented approach to fortification capacity-building exercises. More importantly, the targeted nature of these projects means that there appears to be no follow-up on past activities, which thus may require further funding. ECSA is in a unique position to lead countries in the coordination of all these efforts and initiatives.

Consider the following example: A donor/implementing partner trains an individual in a particular task, who returns to his/her place of employment only to be promoted, relocated, or who changes his/her job. While the donor/implementing partner believes that task is still being performed by the trainee, in reality that institutional gap has just become vacant again. The team believes that two separate courses of action are required. First, the donors/implementing partners should, at a minimum, disseminate information on their activities, or, preferably and if appropriate, invite a representative of other donors/implementing partners to observe and participate in that activity, because it is important to recognize the efforts and achievements already made in the region. Second, the donor/implementing partner should follow up with the representative (a) to ensure that the activity has been of benefit, and (b) to ensure that the representative still occupies the same position.

The Ministry of Public Health and Sanitation (MPHS) in Kenya has plans to enhance the level of food fortification through:

- upgrading its advocacy program and promoting dialogue with the Government and other stakeholders to boost efforts at promoting and scaling up food fortification.
- mobilizing resources to build a strong base for food fortification activities.
- training in monitoring of fortification efforts, which will establish a robust database that can be used for decision-making in implementing fortification programs.
- undertaking coordinated and focused social marketing, which will help the National Food Fortification Alliance (NFA) to reach diverse target groups and increase their demand and consumption of fortified foods.
- formalizing the composition and functions of the NFA so that it can play a more effective role in coordinating implementation of fortification programs.
- lobbying the Government to eliminate unnecessary bureaucratic procedures that hamper implementation of fortification programs.

To date, the focus in Kenya is first to prepare industry to manufacture more fortified foods, and then to stimulate consumer demand for fortified foods. Factory visits are being conducted by KEBS every six months as part of the quality assurance process. Market surveillance is also being carried out by KEBS, which is in the process of establishing a specific unit for that task. Market surveillance by the MPHS is inconsistent. Community monitoring of salt proceeds through Reach Every District (RED), reaching five schools per district.

In Uganda it appears that the major micronutrient deficiencies result from insufficient intake of Vitamin A, iron, and iodine in the local diet. The team found that a number of strategies are being applied to manage the situation, including annual Vitamin A supplementation during “child-days-plus” for children and mothers; fortification of salt with iodine; supplementation of iron tablets and fortification of staple foods for adolescent girls and lactating mothers. Sugar fortification is also being undertaken by Kendo Mills, which repackages sugar. Plans are at an advanced stage to

Bidco, Mukwano, and Mukono Oil fortify the foods they manufacture.

Using the five-year MOST project, USAID supported Maganjo Industries and United Nations General Assembly (UNGA) 2000 in fortifying maize flour, but fortification stopped when the project ended in 2006 because these manufacturers could not afford the cost of pre-mix and the schools could buy cheaper flour elsewhere without the pre-mix. Because this project lacked built-in consumer education and advocacy, it was therefore not demand-driven.

MoH officials expressed concern that no standards yet exist for some foods that are widely consumed, such as millet, cassava, Tilda rice, and matooke (plantain) flour. UIRI is considering innovations regarding fortification of matooke flour, but there is no official position on this yet. It must be noted that it will be important to establish consumption levels first.

In order to monitor the food fortification program, various monitoring activities are performed by different stakeholders so as to ensure that adequate fortification takes place at all times. In Uganda the food control system is headed by the Health Inspectorate of the Ministry of Health (MOH) in collaboration with the Uganda National Bureau of Standards (UNBS), the Uganda Industrial Research Institute (UIRI) Laboratory, and the National Drug Authority (NDA), among other partners. Supervision of all fortification works in the country is coordinated by the National Working Group for Food Fortification (NWGFF) whose secretariat is at the MOH. (Ministry of Health, Food Fortification Program, National Monitoring Report, 2007–2008.)

The director of Uganda’s Agricultural Research Institute credited USAID’s MOST and A2Z projects with laying strong foundations for fortification programs in Uganda and providing the momentum which is now driving the subsequent fortification interventions. Working jointly and closely with the Government, A2Z, and other national organizations, the GAIN project has built on these earlier USAID-funded fortification efforts to strengthen the fortification programs through procurement of pre-mix for wheat flour; procurement of micro-feeds; provision of training on fortification; and providing Mukono Oil Industries with a pre-mixing tank and Vitamin A, as well as training its staff in monitoring and feedback.

There are a number of concerns encountered by the team that must be highlighted and that have affected or continue to affect food fortification programs, policy development, and the implementation process. The team found program implementation to be proceeding reasonably well, although there are numerous human resources (HR) and institutional-capacity development shortfalls stemming from technical inadequacies at ECSA, MoH, the Bureaus of Standards, and industry. Investment in capacity development at all levels should take center stage in the work to strengthen program implementation and fortification processes. HR development and retention through training in order to sustain fortification efforts was cited as a something that remains an illusion in both Uganda and Kenya, except at the Uganda Bureau of Statistics (UBOS) where the team was told that this is not a big issue, even though UBOS could benefit from the training of more technically sound analysts. The training of trainers as a strategy for buttressing sustainability is not working well because those trained do not necessarily remain in their jobs to apply the skills and competency they have acquired.

The team found that there is no resource pool of experts to provide technical assistance in food fortification. While operating within constrained technical capacity consisting of one technical advisor and limited backstop, ECSA has managed to provide technical and implementation assistance to its member countries in various critical aspects of fortification. Efforts to strengthen technical expertise at ECSA and country levels could supplement the little that exists. One way of doing this is to develop and harmonize in-service training curricula and orientation of trainers...
with the requisite skills capacity for all components of fortification. ECSA-HC has already started work on this area, based on recommendations of a regional workshop convened in Nairobi in October 2009.

The Bureaus of Standards and Statistics have received minimal support from governments, donors, and fortification partners to consult with the universities, research institutions, and food fortification experts in the region and abroad to ensure that the outcomes of their tests, analyses, and surveys are adequately verified. The team also found that universities in the ECSA region had not been sufficiently encouraged and supported to mainstream food fortification technology in their food technology and food and nutrition science courses. Upon the team’s suggestion, ECSA-HC has agreed to support the food fortification training course for university professors.

Institutional development of standards and statistics bureaus to strengthen data collection, recording, analysis, processing, dissemination, and use across the ECSA region—through the supply of processing and storage equipment, development of robust fortification databanks, establishment of inter-bureau referral and reference networks, and systems that encompass monitoring, evaluation, tracking, communication, and feedback systems—has not been undertaken.

Strengthening of public-private sector linkages and operations was found to be slow. Currently, fortification programs lobby governments through the ECSA Health Ministers Forum to mainstream and institutionalize National Food Fortification Alliances within their governments and to provide the necessary budgetary allocations for the operations of the Alliances. The Alliances could coordinate activities for targeted consumer education and social marketing and consult with governments to introduce non-punitive operational profiles at their Bureaus of Standards, in order to help make the bureaus operate as facilitative units for industry in implementing fortification.

Looking forward, ECSA describes its strategy, through its reports, as:

- strengthening food control efforts using the Uganda model.
- encouraging more industries to join fortification.
- strengthening Laboratory Proficiency Testing (LPT).
- assisting countries through National Fortification Alliances (NFA) to build food fortification, nutrition, and micronutrient databases.
- organizing specific training courses for university professors in order to create a roster of local consultants and experts.
- strengthening and building the capacity of NFAs.

The key to implementing food fortification is to identify a champion in each of the sectors involved in the fortification program. The key constraint was, and remains, the fastidiousness with which Food Control wants staple foods to be monitored, since the inspectorate still views fortified foods as a safety risk. The best way to overcome this attitude is for governments and food manufacturers to acknowledge that fortification is considered one of the most cost-effective approaches to addressing widespread micronutrient deficiencies. In this way governments begin to view food fortification as a key strategy for improving the nutrition of their citizens.

In addition to Government responsiveness, the enthusiasm of the Kenyan private-sector manufacturers has been instrumental in driving policy development for fortification. Availability of partner and donor support has also aided policy development.
What has spurred policy development for food fortification in Uganda is the understanding that a massive micronutrient deficiency exists, as reported in the Uganda Demographic and Health Survey (UDHS) of 2006, and that food and nutrition are crosscutting, multi-sectoral issues which have advocates in many sectors. The National Food Fortification Alliance includes influential private-sector companies that are the main advocates of food fortification and help move the policy development agenda forward.

The team encountered a series of obstacles to implementing food fortification programs in Kenya. Lack of the financial and human resources needed to manufacture fortified foods by the food processing industries, and to stimulate demand for fortified foods and manage food fortification programs, was cited as the leading constraint. The Government lacks the capacity either to engage with industry or to facilitate and monitor the implementation of policy guidelines. So far, there are no designated and technically qualified contact persons to manage the Government interface with the industry. Because they are overwhelmed, the few government inspectors focus more on fault-finding and other non-facilitative aspects of inspection. There is no coordinated support for small-scale flour millers in the rural areas where the majority of Kenyans consume maize meal. Social marketing is underdeveloped because of the absence of functional strategies for consumer mobilization and education. The Ministry of Public Health and Sanitation has substandard management and coordination capacity, while the Fortification Alliance (which, if strengthened and streamlined, could be the key driver of fortification) is but a loosely constituted body with no clear operational format. The mid-level health and agricultural training institutions lack explicit micronutrient and fortification components in the basic training curricula for nutrition and food science students, while the available nutritionists and food scientists do not benefit from food fortification knowledge and skills updates.

The obstacles to policy development in Uganda include inadequate monitoring of food fortification programs and an inactive national food fortification alliance, which needs to be revitalized and strengthened. Lack of a food fortification strategy was cited as an impediment to viable advocacy, social marketing, and communication strategies programs. In addition, the team was told that Uganda also lacks viable fortification data for policy advocacy. Furthermore, because there is no national consensus on fortification, buy-in for food fortification is lacking.

Beyond a shadow of a doubt, the ECSA activities funded by USAID and technically supported by MOST and A2Z have been the prime movers both within and between countries. In fact, it is highly unlikely that any activity would have emerged without this initiative.

A review of literature and country reports presented by ECSA indicate that ECSA has made good progress between 2004 and 2009 in preparing member governments to implement start-up and scale-up of national fortification programs. To this end, ECSA has assisted in developing technical capacity in the areas of regulation and food control through regional workshops. Good partnerships, collaboration, and operational linkages have been established with development partners USAID, UNICEF, GAIN, and MI. Discussions are ongoing with GAIN on implementation and other interventions, as are discussions with the World Bank and CDC for strengthening food control, and monitoring and evaluation. ECSA has engaged industry and encouraged it to join fortification efforts. Financial and technical resources have been mobilized to support the regional initiative by hiring a food fortification advisor to facilitate regional collaboration and coordination. Advocacy materials on food fortification have been developed.

In addition to assistance with analysis of the existing standards, ECSA has provided financial and technical support in the preparation, production, and training in the use of a standards manual for Kenya (although the manual has not yet been disseminated due to lack of funds). Zambia is currently revising the sugar fortification manual, while Tanzania is revising the wheat flour and oil fortification manuals. With support from A2Z, ECSA has spearheaded the development of 17
food control manuals for salt, oil, sugar, maize flour, and wheat flour, and provided training in the use of these manuals.

ECSA has provided support for the analysis of existing testing capacity in the region through training of laboratory analysts, establishing a Laboratory Proficiency Testing (LPT) scheme among laboratories in five countries, and developing a manual on testing procedures. In collaboration with MI, ECSA conducted an assessment of industry capacity to fortify foods in the region. Food industry mapping—production, consumption, and trade (imports and exports) of staple foods—has been completed. Development of policies and legislation covering the food industry has also been mapped, and a study has been conducted of costs associated with food fortification in Kenya, Tanzania, and Uganda.

ECSA has also provided support to several countries to form public-private partnerships through the establishment of National Fortification Alliances (NFAs), which oversee implementation of food fortification activities in the countries.

**Policy and Standards Conclusions**

1. Policy development for food fortification has not been a cause-and-effect issue. It has been a reactive, rather than proactive, process and therefore has neither hindered nor helped food fortification efforts. For instance, usually policies (cause) guide the development of standards and regulations (effects). In Kenya, however, the situation is one where standards and regulations (effects) will guide policy formulation (cause). This is a clear case of retrospective policy development.

2. The absence of a food/nutrition or fortification policy has not necessarily prevented fortification of foods in Kenya. Fortification has proceeded and expanded because of health realities and needs; practice has therefore run ahead of policy.

3. Tight standards and regulatory mechanisms have been instituted for fortification because of the acceptance that food fortification in Kenya is here to stay.

4. Where standards and regulations derive from a policy, they can hinder fortification when the policy, standards, and regulations are misinterpreted or when their enforcers overstep their mandates.

5. Because policy development has not been proactive, policy has not informed food fortification processing and consumption, as would generally be expected.

6. Fortification of food has been more of a health, manufacturing, and consumption concern than a policy concern. Salt iodization is the best example of this.

7. A compelling reason for producing the Uganda Food and Nutrition Policy in 2005 was to help the Government, food industry, and health practitioners focus attention on the nutritional and health needs of Ugandans because it was realized that one third of the disease burden attributable to childhood and maternal under-nutrition in Uganda was due to deficiencies in the micronutrient quality of the foods which Ugandans were consuming.

8. USAID support to ECSA food fortification activity has greatly contributed to increased awareness of the benefits of food fortification, and to acceleration of regional and national policy development and monitoring of fortification programs in the region. This is evidenced by the level of interest among the ECSA member states that are now pursuing food fortification policy options promoted by the ECSA/USAID food fortification program. While policy in Uganda has been decided, Kenya has not yet formulated its food fortification policy. However, the team found that establishment of standards and regulations is moving ahead of
policy development. It is therefore possible that Kenya’s policy may be shaped by inputs from the ECSA/USAID program.

**TASK 2: FOOD CONTROL**

As the assignment progressed (and from studies conducted for Micronutrient Initiative\(^6\)), the issues relating to food control listed below made it necessary to modify the team’s approach to discussing food control.

- Food is covered by a plethora of regulatory mechanisms, including Acts of Parliament, regulations promulgated under various Acts, and specifically developed standards. The number of regulatory mechanisms was difficult to determine, but is typically rather high. For example, in South Africa there are at least 14 regulatory instruments and eight regulators (including sections of the Department of Agriculture—Veterinary, Fisheries, Water Affairs, and Agriculture—which deal with unprocessed foods except for biotoxins, which are dealt with by the Council for Scientific and Industrial Research; the Department of Health which deals with processed foods except for canned fish, which is handled by the Bureau of Standards; and the Perishable Products Export Control Board, which handles exports).

- Industry is often confused by the myriad of regulations/regulators and often receives conflicting instructions from the different inspectors.

- The various regulatory authorities considered themselves, or wished to be perceived as, sources of support for industry, but the team noted that the competence of many of these regulatory authorities to carry out such a task was generally limited, and industry was also distrustful of such authorities.

In the team’s opinion, food fortification is over-controlled (food fortification being considered a safety risk), and too much reliance is placed on wet chemistry in monitoring. Monitoring and enforcement, a discipline important to industry as it ensures a level playing field, is part of the problem. For example, the team observed that various industries in Kenya and Uganda carried the respective Standards Mark indicating that regulatory authorities were satisfied with the overall production standards (two validation inspections are required per year). However, it was also noted that industry was either having problems keeping the respective fortification logo (oil industry) or had been refused permission due to fortification noncompliance (Kenya—wheat and maize mills). Note: Sugar is either being considered, or in early development in both countries; salt is not produced locally in Uganda for human food use; and Uganda, as of November 2009, is running proving trials on wheat flour initiated by GAIN.

The LPTs (discussed later in this report) indicate improving capability in oil (Vitamin A), sugar (Vitamin A), salt (iodine), wheat flour and maize meal (iron), but that capability was less evident for Vitamin A in wheat flour and maize meal. It is important to note that these LPTs are carried

\(^6\) The team gratefully acknowledges permission from Micronutrient Initiative to refer to the following documents:

out on well-prepared, homogeneous samples, so these results should be considered as best-case scenarios.

It appears that laboratories can test for a specific micronutrient with increasing reliability in certain food matrices but not in others, i.e., the flours and meals, which suggests that the laboratories are having problems with part of the methodologies (multiple methods are being used rather than the ECSA “standard method” as per the training manuals). However, the team recognizes that this is acceptable if the results are reliable and comparable—the problem is recognizing that one must compare the different methods. The weakness is most likely in the extraction phase of the method, as the team noticed that the laboratories have not yet reached a competency standard where they indicate important analytical qualifying information such as limits of detection, laboratory analytical error, coefficients of variation, recovery data, and results of internal control samples on their reports (all of which are important in interpretation of the analytical report).

The team is, however, of the opinion that laboratory competency is not the only major factor in the failure of the wheat and maize industry to achieve logo status. Of greater concern is the sampling protocol used by the food inspectors. The ECSA manuals for food inspections increase the intensity of sampling, but do not increase it enough.

To be fair, the inspectors are more familiar with ensuring food safety than, as is the case with food fortification, food quality. The inspectors also have recourse to national regulations, developed for safety assessment, which consider “any sealed package to be representative of the lot.” For example, inspection of a production facility means taking one or two sealed packages from the packing line. With liquids this is less of an issue, since homogeneity is far less of a concern. ECSA has produced manuals for overcoming these limitations, and training courses are being provided to the member countries.

However, inspectors should insist on taking samples from those the processor routinely collects during their normal QC/QA protocols, although it should be noted that both Standards Bureaus are signatories and active members of Codex and that the use of a “grab sample” is detrimental to the processor because the validity of the sample for quality assessment is highly questionable.

Interviews with KEBS inspectors revealed that the previously mentioned assignments initiated by MI have caused the inspectors to search for a satisfactory resolution to this situation. The ECSA manuals have also attempted to address the issue. For example, the Uganda Standards for salt (US 203) and sugar (US 510) provide instructions that lots exceeding 1,000 packs require sampling 10 packs—a move in the right direction. Still, the team was informed that in the event of a sanction and/or a prosecution (and both bureaus have their own prosecutors), the same sampling protocol would be followed despite its lack of international recognition and the implications under the WTO and its Technical Barriers to Trade (TBT) requirements.

From the MI work the team noted that the manufacturers routinely produce documentation that could be used as evidence that they have been practicing due diligence and have been adding the required quantity of fortification pre-mix as prescribed in the relevant standard. In fact, the manufacturers could readily produce hourly records of established QA protocols to challenge the evidence resulting from a single analysis from a single laboratory.

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7 Quote from the assessment team.
The above is of particular relevance since in both countries the inspectors have a legal mandate to access such information, as the following extracts demonstrate:

- “Require from any person the production of any book, notice, record, list or other document which is in the custody or under the control of that person or any other person on his behalf” and “Examine and copy any or any part of any book, notice, record, list or other document which appears to him to have relevance to his inspection or inquiry, and require any person to give an explanation of any entry therein, and take possession of any such book, notice, record, list or other document as he believes may afford evidence of an offence under this Act.” (Laws of Kenya, The Standards Act, Chapter 496 (rev. ed. 1981), sections 14(1)(d) and (e) respectively.)

- “Examine and make copies of acquire any book or records in relation to fortified foodstuffs” and “Interview any person or agent to determine whether these Regulations are complied with.” (“The Food and Drugs (Food Fortification) Regulations, 2005,” Uganda Gazette, 2:98, January 14, 2005.)

This clearly shows that monitoring and enforcement could be effectively carried out using an alternative strategy—namely following a paper trail—which would swiftly permit the introduction of fortified wheat flour and maize meal into the marketplace, with clear benefits for the social marketing strategies both countries are developing, but deferring the introduction of further fortified products until those bearing the relevant logo are available.

The team does not propose that efforts to increase laboratory capacity and competency be decreased (on the contrary, the team recommends that they be intensified), but rather that the current limitations of laboratory testing be recognized and that failure to comply with the relevant regulations be viewed as an artifact of that limitation. The capability of the inspectors to interpret analytical reports is also a concern that should be addressed.

To support this, the team refers to a study conducted in South Africa which demonstrated that internationally accredited (for vitamin and mineral analysis in grains and grain products) laboratories and various other laboratories from pre-mix manufacturers could reach a high level of consensus (typical coefficients of variation (CV) between laboratories of 10% to 12%, the CV within any laboratory was lower) on the composition of various fortification pre-mixes in original and adulterated form. However, those same laboratories could not reach consensus (typical CVs between laboratories of 40%; within any laboratory CVs were lower but higher than that achieved on the pre-mix) on laboratory-prepared, homogeneous (as per the ECSA LPT technique), finished products in both original and adulterated form. The potential for disputes both within and between countries on the analysis of fortified products is obvious.

Another factor to consider is illustrated in the following extract:

“The TBT Agreement also calls upon WTO Members to ensure, whenever possible, that the results of conformity assessment procedures of other Member Countries are accepted, even when they differ from their own, provided that the procedures give the same level of confidence. The purpose of this provision is to avoid multiple product testing (in both exporting and importing country markets), and its associated costs. However, it is acknowledged that in order to achieve acceptance, negotiations may be needed, primarily to ensure the continued reliability of conformity assessment results (the accreditation of conformity assessment bodies is a factor that can be taken into account in this regard). The

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TBT Agreement encourages these kinds of mutual recognition agreements between WTO Members.” (Guidelines on Food Fortification with Micronutrients. Edited by L. Allen, B. de Benoist, O. Dary and R. Hurrell. FAO/WHO, 2006, p. 328.)

Given the above, negotiations could be problematic.

The team also questions why Vitamin A—which is difficult to analyze and has a stability question mark over it—is used as a marker for fortification compliance on wheat flour and maize meal. If the industry can only procure pre-mix from registered suppliers, which Food Control can monitor, then the Vitamin A will have been added, and the laboratories will be able to check that fact more readily and with greater accuracy. The argument that Vitamin A is the most expensive micronutrient in the pre-mix and is therefore the one most likely to be subject to cheating is no longer valid. The use of total iron is also questionable due to variation in the intrinsic content of grain. Yet it is precisely these two factors that are delaying the roll-out of fortified grain products in the region. While there is currently no practical alternative to this approach, as long as analysis of the finished product is required, and accepting that the iron form in maize (NaFeEDTA) can be analyzed for specificity (unlike the ferrous fumerate used in wheat flour), the problems in relying on analysis as the sole determinant of compliance must be recognized.

Both Kenya and Uganda have established procedures to ensure that the pre-mix supplied to the food fortification program “conforms to specification,” as declared on the accompanying certificate of analysis (CoA). The team accepts that this is a typical practice exercised worldwide but, citing the South African study, points out that “conformance to specification” is not the same as “fitness for purpose,” which is significantly more important in ensuring that the relevant food fortification requirements are met, and that the primary objective of food fortification (actual delivery of micronutrients to the population) is the purpose.

To understand the difference between the terms “conformance to specification” and “fitness for purpose,” consider the manufacture of a concrete life-jacket for use at sea—it may conform to specification, but it would not be fit for its purpose.

As was investigated in the South African study, and discussed at the Second Technical Workshop on Wheat Flour Fortification in Atlanta (March 2008), the stability of Vitamin A in wheat flour and maize meal has implications for monitoring and enforcement by Food Control that have hitherto gone unchecked. In the South African study it was reported that when pre-mix was subjected to accelerated storage conditions (40°C and 75% relative humidity) in typical wheat flour and maize meal packaging (in paper bags rather than the pre-mix manufacturer’s original packaging), some disturbing observations were made. Some pre-mixes retained approximately 80% of their Vitamin A during the trial, while other pre-mixes, over the same period and under identical conditions, lost approximately 90% of their Vitamin A. These data justify the introduction of a stability test for Vitamin A in pre-mixes.

Under the current system of food control the pre-mix is occasionally tested for compliance upon arrival in the country—and could be tested at any time up to the “Best Before” or expiration date provided by the pre-mix manufacturer—and, in the experience of the team, is invariably found compliant.

However, even if Food Control did implement a system (similar to South Africa) in which stability and source of origin of micronutrient were addressed, the team noted that, at least, in the Kenya Standards Act, Chapter 496 Revised Edition 1981, a disclaimer has been incorporated in the Act i.e.
Part V—Miscellaneous—Section 17

“The fact that any commodity complies or is alleged to comply with a Kenya Standard or approved specification or has been or is alleged to have been manufactured in accordance with any such specification, or that a standardization mark is used in connexion (sic) with any commodity, shall not give rise to any claim against the Government, the Council, or the Bureau, or any member or employee thereof.”

Essentially this means that industry cannot pass responsibility on to the regulatory authority unless the latter includes in the standard a requirement that the fortification pre-mix not only comply with certain compositional requirements, but that it also conform to specific performance criteria. While the manufacturer would remain unable to raise any claim, it would at least be able to defend itself under due diligence principles.

The problem is twofold. First, the industry assumes that Food Control has approved the use of the pre-mix for the purpose intended by that industry (which is what industry does itself—it checks the raw material against contract specifications and for fitness for purpose), although checking pre-mix for such criteria is well beyond the capabilities, or reasonable expectations, of the food industry. Second, Food Control believes that (a) the fortified product should be “true to label” for the duration of the shelf life of the product, and (b) it is the processor’s responsibility to ensure that this is so.

Given the above information on Vitamin A stability and the distribution chain, it is clear that industry is being left open to possible prosecution on two, perhaps three, criteria over which it has little, if any, control. First, manufacturers have erroneously assumed that Food Control has assessed the pre-mix as being “fit for purpose” (a responsibility Food Control does not want to assume). Second, despite marking their products as required (e.g., stating storage conditions, etc.), manufacturers have no control over their fortified product once they leave the factory or distribution warehouse. They cannot therefore ensure that their storage criteria are complied with. Third, Food Control assumes that because a fortified product is in a package carrying a brand name, it is actually that company’s product, although it is not unknown for unscrupulous retailers to place an inferior product inside another company’s packaging. Some products can be sold with tamper-proof seals, but this is not possible for all products.

South Africa has amended its food fortification regulations to require suppliers of pre-mix to state confidentially to the regulatory authority the source(s) of origin of their micronutrients and to provide verified stability data on those micronutrients. While South Africa conducts routine surveillance at the market level, it can only prosecute for noncompliance based on samples taken at the factory level, since the fortified commodity has left the control of the relevant manufacturer. The team noted that, on a noncompliance issue, UNBS would allow the processor to defend itself by providing its own retention samples from that particular batch, since these would have been stored under the manufacturer’s stated storage conditions.

One last point to mention here is that regulations enforced by other regulatory authorities may influence procurement of “fit for purpose” fortification pre-mix.

The following situations are provided as an example of how Food Control activities can be constrained by legislation outside those normally considered the domain of Food Control. These situations were only identified in Uganda, but similar ones may exist in other ECSA countries.

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9 Quote from the assessment team.
10 The team received indications that Food Control does not consider itself competent in this area and/or this area falls outside its mandate.
11 Verbal statement.
In Uganda fortification pre-mix is considered a drug due to the concentration of micronutrients. Because pre-mix thus falls under the auspices of the National Drug Authority (NDA), as well as under UNBS, the two separate regulatory authorities monitor and enforce the fortification program.

The NDA mandate requires that NDA pre-approve suppliers into Uganda, which has caused considerable debate regarding the pre-mix being used in the current GAIN activities in Uganda on at least two points.

The team reported that all imported and exported foods (including fortified foods) appear to be checked by Port Health for conformance (charges are levied), which the team believes to be beyond the capability of Food Control (South African port health authorities consider themselves fortunate if they can check 10% of imports and operate on a “risk assessment” process targeting food safety rather than quality compliance). This has caused a situation in which parts of the food control process are viewed as a revenue collection mechanism, with concomitant loss of faith in the system within industry.

During interviews with the relevant food control authorities the team noted that many of the problems and/or perceptions discussed above have been extensively aired within and between the authorities. This has caused Kenya to establish a National Food Safety Coordination Committee which, although it has no legislative mandate, provides a “harmonious forum” for industry and the various regulatory authorities to interact. Established approximately 18 months ago, the committee has not tried to prevent any particular regulator from performing a particular task, but has provided a venue for the amicable settlement of “turf” issues, achieved consensus viewpoints on specific responsibilities, and even organized a team approach to a specific regulatory issue. Also in the pipeline is a project, initially funded by the Canadian International Development Agency (CIDA) and WHO, to develop a Food Safety Policy (which would include fortified foods) geared toward a single Food Safety Authority. Stakeholder meetings are well advanced (funded by UNIDO and WHO, with a promise of funds from FAO), with two regions to complete. A national stakeholder meeting is planned for late this year or early next year.

In a similar vein, Uganda has been attempting, with some difficulty, to organize a food safety central body and to modernize the country’s food law. The Ministry of Public Services questions whether adequate human resources exist, while the Ministry of Finance questions whether adequate financial resources exist (the ministry is also not happy about establishing yet another new authority). These problems must be resolved before the issue can be submitted to the Cabinet for consideration.

While the team recognizes that significant progress has been made in Food Control—especially in the regulatory framework and capacity building of both inspection and analysis—the team feels that additional work is required, as described below.

- Food Control remains fragmented, due to different authorities being mandated to perform food control functions, although attempts are being made toward an integrated approach and should be encouraged by advocating for these changes at senior Government levels.

- Food Control wishes to be perceived as a source of support to industry, but its internal practices make it difficult for industry to believe this. These practices include:
  - The legislation follows the “guilty until proven innocent” principle.

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12 This situation is currently under review, with consideration being given to mandating the NDA to cover foodstuffs and renaming the organization the National Food and Drugs Authority (as it was formerly, until the food component was removed from their mandate as a condition of drug-related aid from Denmark). To further this objective, a “Desk Officer” has been appointed in 2009 to cover food issues.

13 Direct quote.
• The Bureaus of Standards are considerably more experienced than other standard-setting bodies in the legal aspects of standard development (although much less so in the processing component of the relevant standard), and so are seen as writing standards which are easy for them to enforce.

• The bureaus also have internal prosecutorial facilities to enforce the relevant standards.

• The bureaus are government institutions, yet they are seen to act on business principles such as achieving cost recovery, and thus are perceived as revenue generating operations.

• Copies of standards are considerably more expensive than obtaining Acts and Regulations from the government printer.

• There appear to be standards for everything, including those commodities already covered in different pieces of legislation.

• Internal policies place quotas on staff performance, i.e., so many inspections per period, so many standards per period, so many analyses per period (and running control samples, calibration checks, blanks, etc., does not constitute a sample which is chargeable—and such a policy is illegal if the laboratory is accredited under ISO 17025).

These points apply to the overall scheme of activities within the food control system and do not relate solely to the fortification program. As such, they are not outside the capabilities of ECSA to change. In addition, training of standards development officials in the fortification process could improve the perception that industry has of Food Control and speed up the roll-out of fortification in those industries.

**Food Control Conclusions**

1. Food Control falls under multiple regulations and regulators and, as a result, is fragmented and has a tendency to over-control.

2. Fortification is considered a safety risk in that Food Control perceives a risk of overdosing micronutrients to the consumer.

3. Food Control inspectors use inadequate sampling protocols unsuitable for quality assessment.

4. Food Control inspectors place undue reliance on wet chemistry when assessing compliance issues.

5. Food Control inspectors have little knowledge of the industries they monitor.

6. Industry has more than adequate documentation to demonstrate that it is fortifying in accordance with standards.

7. Food Control monitors the fortification pre-mix on a “conformance to specification” basis with no attention to “fitness for use,” that is, the ability of the pre-mix to deliver the required level of micronutrients at the point of consumption.

8. Food Control, or some other competent body, should register pre-mix suppliers.

9. Food Control and industry question one another’s competence.

10. Food Control is severely deficient in human resources.
TASK 3: LABORATORY PROFICIENCY TESTING EXERCISE

The assessment team verified that ECSA-organized LPT exercises have gradually increased, both in the number of participating laboratories and in the scope of analysis required. Beginning in May 2007 with two participants, the last completed round (Round 3) in October 2008 received 11 responses. The scope of analysis now includes Vitamin A in oil and sugar, iodine in salt, and Vitamin A and iron in wheat flour and maize meal. Additionally, participating laboratories are asked to perform qualitative testing to identify positive results, and then to perform quantitative analysis on two separate days of those samples identified as positive, i.e., containing the micronutrient of choice.

The team was advised that LPT Round 4 had just closed (during the first week of November).

However, the team was concerned that the laboratories failed to follow explicit instructions on how to conduct the ring trial. The instructions sent to each laboratory state as follows:

“This PT exercise serves a number of purposes apart from testing performance of individual laboratories. As a result, laboratories are requested to test the samples as follows:

- Conduct qualitative tests in all single samples, with the purpose of screening and identifying those samples that may NOT be fortified.

- Separate the samples that tested positive for the presence of the added fortificants into 2 sets for each type of fortified food.

- Test each set of samples on TWO different days according to the methods provided in the manual.”

Only three respondents actually analyzed each of the positive samples on two separate days. The majority of the respondents split the positive samples into two separate groups, analyzing one group on one day and one group on another. As a result, critical information on laboratory variation was not generated that would have enabled the A2Z technical support team to identify and correct laboratory errors. Another problem was that the LPT samples, which contain blind duplicate or triplicate samples, were split because of this failure to follow experimental protocol.

The team was told that some laboratories do not follow the instruction “to use the methods provided in the manual” because they lack the necessary equipment, which was relayed to the LPT team. However, the assessment team is also aware that some participants are also using different methods and not mentioning this to the LPT team, which then wrongly assumes it is gathering data on specific methodology, and draws false conclusions. The team is aware that one of the participating laboratories has changed its methodology for Vitamin A determination at least three times in last three years. However, it is not methodology that is the limiting factor here, but rather a lack of communication with the ECSA organizer.

The assessment team recognizes that this activity is in its infancy, and while the team had hoped to study the raw data in depth, there was insufficient time to perform anything more than a rudimentary assessment.

The team knows that significant progress in the area of laboratory competency has been achieved in the past through exposure to laboratories, speaking to laboratory staff, and discussing how their internal procedures have changed in the past two years. However, upon reading ECSA internal reports, the reader gains the impression that the situation is actually worsening, if one only looks at the base statistical numbers such as CV. Perhaps the analysis should be performed on a laboratory-by-laboratory basis.
There are several points to consider. First, the number of laboratories is increasing; second, the laboratory data are being averaged at a point too early in the analysis in the team’s opinion (which also contributes to the loss of performance data within a laboratory\(^\text{14}\)); and third, outlier analysis is not being used, unless it is being used only to detect a single outlier at either end of the scale, whereas multiple outlier detection may be required. Further discussion of the analysis conducted by the team on the LPT data appears in Appendices F and G.

The team suggests that a pre-mix sample be included in the next LPT, since it has been the team’s experience (discussed under Food Control) that laboratories can obtain a very high degree of consensus when working with concentrated samples, but that consensus disappears with decreasing levels of micronutrient to analyze for.

As the project increases in competency the team would also propose the inclusion of samples that “just pass” in terms of minimum and maximum values placed in the standard—possibly even the inclusion of a flour/meal sample with a low moisture that would fail if tested “as/is,” but pass on a normal basis (i.e., 12% to 14% moisture).

The area of LPT is critical to the food fortification program, and program managers must be ruthless in exploiting available resources and information. Allowing Food Control (and government) to prevaricate about expansion plans, for the reason that industry has not proved it is capable, is absurd, especially when regulators have no evidence of value to demonstrate that industry is wrong. The results of the LPTs, and a layperson’s interpretation of them, should be circulated to everyone in Food Control and government.

**Laboratory Proficiency Testing Exercise Conclusions**

1. LPT participants have increased from 2 to 11 in Round 3.
2. Testing covers both qualitative and quantitative techniques.
3. Parameters covered include Vitamin A in sugar and oil, iodine in salt, and Vitamin A and iron in wheat flour and maize meal.
4. Many laboratories are not following explicit instructions on how to conduct the trial.
5. There are visible signs of increased capacity and capability.
6. LPTs should include some pre-mix and borderline samples.
7. LPT results are not disseminated widely enough.

**TASK 4: PLANS TO ESTIMATE POTENTIAL IMPACT OF THE FOOD FORTIFICATION PROGRAMS**

In discussions with UNICEF, WFP, and other institutions, it was accepted that policies existed to procure food locally where possible (provided that this did not disrupt the market economy, i.e., no procurement leading up to and during harvest) and to fortify processed foods if possible. It became clear, however, that guidelines from the Head Office providing clarification on these issues have not been forthcoming.

Nevertheless, locally sourced fortified foods are being actively investigated, although implementing partners have had problems with good manufacturing practice (GMP), the ability

\(^{14}\) The average will remain the same regardless of the number of observations included; however, the standard deviation will vary depending on how repeatable each laboratory was within itself and the value of the coefficient of variation.
of local industry to supply the quantities required in the necessary timeframe, and the results obtained from local laboratories (KEBS, UNBS, etc.) on fortification levels.

To be fair to industry, the implementing partners are difficult business partners to have because orders are placed on an as-needs basis (making quantities hard to project for emergencies), which requires the manufacturer to assume the risk that it may be left with fortification products and operations, and no buyers. One mill in Uganda went into liquidation because it expanded operations to meet NGO activities, and then the activities ceased.

The team found that ECSA is in the process of assisting member states in collecting data to determine national availability, accessibility, and consumption of staple foods.

There is little information to estimate intake of fortified foods in Kenya but the team was advised that consumption of fortified wheat flour and maize meal is below 10% of the population, and even if fortification were made mandatory, this number would only rise to 20%.

The team disagrees with the 10% figure because team members could find no fortified wheat flour on supermarket shelves. Each mill produces according to market demand, and the team was aware that UNGA only produces fortified maize meal approximately twice a week, Capwell only two hours per week, and Kabansora none at all. The 20% figure also requires validation, although the above-mentioned mills would use 250,000 metric tons (MT) (approximately) per annum against a FAOSTAT 2003 consumption datum of 2.8 million MT—equivalent to 88 Kg per person per annum (240g per day).

The team found that there is very little to go by in Kenya in estimating the level of demand for fortified foods. The only tool available which could be used, if expanded, to estimate demand is the Household Income and Expenditure Survey (HIES) module.

In Uganda it is generally accepted that there is modest demand. A consumption survey (using a seven-day and 24-hour recall model) was performed in 2008 by Makerere University in selected areas. At the Uganda Bureau of Statistics (UBOS), the current HIES includes a nutrition and food consumption module for 54 food items that constitute the Uganda food basket, but it does not specifically target fortified foods. There is also a seven-day and 24-hour recall module. The food consumption module in poverty monitoring surveys collates food and nutrition data, but not the specifics of consumption of fortified foods. Although Uganda has one of the most robust food consumption modules in the ECSA region, more data analysts are needed.

The team recognizes that fortified foods must exist in sufficient supply and accessibility before demand for them can be created through targeted advocacy, strategic mobilization of consumers, and social marketing.

Through baseline surveys on food and nutrition, Kenya and Uganda are working to develop in-country and regional databases that will track access to and consumption of food vehicles that could be fortified. ECSA is modifying data collection tools to include questions that will provide data for all aspects of fortification, including estimating demand. UBOS has proposed that a module be introduced that will provide data on access to and consumption of fortified foods, based on questions relating to commercial brands consumed in Uganda. The team was informed in both Kenya and Uganda that an important strategy being proposed is the establishment of operational linkages among government institutions, donor-funded programs, and stakeholders, which could lead to scaling up demand for and intake of fortified foods and thereby contribute to data needed to estimate demand.

Regarding HIES, it was suggested that ECSA work in conjunction with, or sponsor, country-level Bureaus of Statistics to:
• provide training on the use of data obtained from regular household surveys for estimating consumption of food vehicles identified for fortification, and possibly identify others (ECSA provided such training in Uganda in April 2009).

• estimate expenditure patterns relating to fortified foods.

• determine rural and urban distribution of fortified foods.

• establish the prevalence rates of specific fortified foods.

• help program managers define interventions and gaps.

The team could not find consolidated national or segregated data to estimate the level of micronutrient intake in Kenya and Uganda. The current offer of food fortification programs in East Africa is low. Although commercially fortified foods (specifically, salt and oil) may be reaching remote rural areas, consumers in those areas remain unaware of the benefits of these foods and that the purpose of consuming them is not to change their dietary habits.

In Uganda 90% of oil consumed is fortified, according to the Uganda Food Consumption Survey (September 2009), which focused on the use, at household level, of salt, oil, sugar, wheat, and maize flour, the selected vehicles of the food fortification program. A high proportion of the 949 households interviewed reported using edible oil, with more households in urban areas using oil than those in rural areas. The high cost of the oil was the main obstacle to consumption, although the assessment team observed that fortification has not increased the cost of oil. The study found that there was high use of oil in rural areas of northern Uganda, which could be due to easy access to food aid sent to IDP camps. Since most households found oil to be expensive, they bought it in small quantities—a typical procurement pattern in low-income communities. Similarly, most people found refined sugar to be expensive, so it was also purchased in small quantities. This procurement strategy has a significant consequence for micronutrient delivery to these vulnerable groups. The actual amount of the foodstuff being delivered should be assessed, with samples taken at the household level.

The survey also reported that the majority of households did not use wheat flour products.

In the section on micronutrient intake among children, the Uganda Demographic and Health Survey (UDHS) 2006 noted that “Children can receive micronutrients from food fortification.”

The 2006 UDHS showed that 62% of children aged 6–35 months living with their mothers consumed foods rich in Vitamin A in the 24-hour period before the survey. Further analysis revealed that consumption of foods rich in Vitamin A increased from 41% among children aged 6–8 months to 68% among children aged 18–23 months. Urban children were found to be more likely than rural children to consume foods rich in Vitamin A. The UDHS results show that 96% of children aged 6–59 months live in households using iodized salt.

The team was advised that in Kenya and Uganda social marketing and advocacy would be effective strategies for stimulating demand and accelerating both demand for, and intake of, fortified foods in the two countries.

ECSA reports state that Kenya has a draft Communication Strategy that is awaiting finalization and dissemination. In Uganda the MoH and ECSA/A2Z are making efforts to stimulate demand and consumption of fortified foods. The MoH is employing social marketing specialists to advise the NFA. However, the assessment team could not establish the presence of specific social marketing programs. In fact, throughout its field work the team constantly heard complaints of inadequate social marketing, which was considered the major constraint to the uptake of fortification and consumption of fortified foods.
Efforts in the advocacy or consensus-building component were also mentioned as constraints to fortification in Kenya and Uganda.

**Conclusions on Estimating the Impact of the Food Fortification Programs**

1. The lack of a database is a significant obstacle to estimating demand for and consumption levels of fortified foods in Kenya and Uganda.

2. If expanded, the Household Income and Expenditure Survey (HIES) modules in Kenya and Uganda can provide the necessary data to estimate consumption and intake of fortified foods.

3. It is unfortunate that the knowledge and technical expertise at the ECSA regional universities are not being fully tapped to help develop databases on food fortification programs. University participation will provide more depth than ECSA inputs because universities have greater skills, and technical and institutional capabilities than ECSA. This is an opportunity which needs to be maximized to add value to both past and current ECSA efforts.

4. USAID should be commended for creating a project at the ECSA secretariat through A2Z to assist ECSA member states in collecting data to determine national availability of, accessibility to, and consumption of fortified staple foods. Based on the team’s findings, this project is critical to expanding knowledge, practice, and benefits of addressing micronutrient deficiency in the region.

5. Important as it is, social marketing as a strategy for stimulating demand is not fully understood and has been under-developed and inappropriately implemented in Uganda. Currently, food fortification is being implemented more as an information and education (IEC) intervention rather than a behavior change component. Consumers need to adapt to eating foods rich in micronutrients, which will increase the quality of their health, instead of just being made aware of available options for their dietary intake. Professionally directed social marketing will help consumers to understand the need to incorporate fortified foods in their diet.

6. Food consumers in rural areas still find manufactured foods to be expensive and out of their reach, which leads to low consumption of fortified foods.

7. Consumers may not necessarily be aware that the foods they consume are fortified.

8. There is little consumer education on fortified foods and their value, or on micronutrient deficiency. People remain generally unaware of the causes of blindness, stunted growth, low intelligence, and disabilities.
III. RECOMMENDATIONS

POLICY, STANDARDS, AND REGULATIONS

- ECSA should assist member states through systematic and structured dialogue with relevant government institutions, food manufacturers, and other key stakeholders to identify challenges and gaps in policies affecting food fortification, with the aim of establishing strategies and processes for implementing policy guidelines and adherence to country and regional standards and regulations.

- ECSA should work closely with the Council of Ministers for Health and Trade to explore further ways of handling proposals for mandatory fortification and harmonization of standards, and how these would affect trade relations in the region.

INVolVEMENT OF PRIVATE SECTOR IN POLICY DEVELOPMENT

Given that this assessment found that fortification of foods has been perceived as a health, manufacturing, and micronutrient deficiency concern, rather than a policy concern, current efforts to create in-country and regional public-private sector partnerships should continue. Continued facilitation of industry will also be of great benefit.

STATUS OF THE FOOD FORTIFICATION PROGRAMS AND IMPLEMENTATION PROCESS

- Investment in capacity development at all levels should take center stage in strengthening program implementation and fortification processes. This calls for intensive capacity-building interventions, which should involve an exchange of experiences at regular intervals so that countries with more successful programs can see their successes replicated. Institution-based, on-the-job, and in-house training at key levels can go a long way in imparting fortification skills and technological updates. Regular contacts and engagement between industry and regulatory government bodies through National Fortification Alliance exchange sessions and consultative meetings can greatly improve government-industry relationships.

- USAID and other donors should help the ECSA secretariat more adequately provide technical assistance to its member countries in scaling up fortification programs. It is in USAID’s and other donors’ interests to increase their presence at ECSA by supporting staff strength through increased project funding to their cooperating agencies and partners.

- USAID should support ECSA activities aimed at creating strong operational linkages at the regional level that will help develop robust databases which can inform decision-making on implementation and fortification processes. This should involve working closely with country Bureaus of Statistics, universities, and research institutions.

- ECSA should identify, document, and disseminate best practices in food fortification programs in the region, with a view to having them replicated.

- Operations of the National Fortification Alliances should be strategically constituted and strengthened to enable them more effectively to coordinate and advise fortification programs.

ESTIMATING THE IMPACT OF THE FOOD FORTIFICATION PROGRAMS

- The task of estimating demands and intakes should be left to the Bureaus of Statistics, which should consider adapting the available tools or incorporating the necessary consumption of fortified foods and intake of micronutrients into their HIES modules. USAID should initially fund training of bureau staff to adapt or modify tools to capture the required data. Thereafter,
USAID can assume responsibility for supporting the new components during actual data collection, analysis, and dissemination.

- Universities, in close collaboration with country Bureaus of Statistics, should be tasked with conducting access, consumption, and impact surveys.

**ACCESS TO FORTIFIED FOODS BY VULNERABLE GROUPS**

There is little consumer education on fortified foods and their value, or on micronutrient deficiency. People remain generally unaware of the causes of blindness, goiter, stunted growth, low intelligence, and disabilities. Current social marketing strategies in Uganda must be recreated and broadened to incorporate the necessary approaches and consumer education components needed to create access to, and stimulate demand for, fortified foods. The Uganda model can be developed for replication elsewhere in the ECSA region.

The respective National Fortification Alliances, working in consultation with the Ministries of Health, should be responsible for driving the social marketing agenda.

**MONITORING AND ENFORCEMENT**

The implementation of discretionary fortification of maize meal (discretionary because access to posho mills is difficult) and mandatory wheat flour fortification can be immediately simplified if attitudes can be changed in the respective Bureaus of Standards, so that inspectors are not comfortable with merely relying on sample analysis. This change can be achieved by using the following tactics with senior management of the respective regulatory bodies:

- Reminding them that an alternative monitoring strategy—the paper trail—not only exists, but is written into their respective mandates.
- Making them aware of the limitations of laboratory analysis.
- Making them understand that fortification is not a safety risk to the public.

It will also be necessary to persuade the respective Bureaus either to underwrite the pre-mix available to industry, or to relax, even informally, their requirement that each fortified product must be true to its label right up to the point it is consumed, regardless of distribution chain conditions. Manufacturers do not have the capability to determine if a pre-mix available in the marketplace, and found compliant by the respective Bureau of Standards, is actually capable of delivering the required micronutrient content at its point of consumption, because the pre-mix has traveled through a distribution chain over which the manufacturer has no control and possibly has been subjected to temperatures and humidity levels having a detrimental effect on efficacy.

To support this activity, it would be necessary to train inspectors in the following areas:

- food processing and the related fortification methodology
- QC/QA protocols that manufacturers routinely carry out during fortification
- sampling of fortified products
- laboratory limitations when analyzing fortified products
- interpreting laboratory data
- following the paper trail.
Since neither industry nor the Bureau of Standards consider themselves capable of prescribing a pre-mix formulation designed to meet the relevant standard for wheat flour and maize meal, ECSA/A2Z should help them to address this subject.

ECSA/A2Z should provide guidelines on registering pre-mix suppliers, which should include parameters such as demonstrated stability of Vitamin A in a powder food vehicle under tropical conditions and the identification of other potential “markers” if quantitative testing is required. If, however, the paper trail is used as a monitoring technique, this will enable more frequent inspections of production facilities, if required, and so decrease the need for quantitative testing, which can be expensive.

As some quantitative testing will still be required, the LPT exercises should also include pre-mix within the ring trial and, when staff have become sufficiently competent, the inclusion of borderline samples to establish whether laboratories are capable of making compliance issue decisions (for prosecution) or not. Furthermore, the reasons for finding large variations in some results (e.g., Vitamin A in sugar) should be investigated.

The issue of legislated micronutrient contents should be addressed at the next regional workshop as compliance criteria of quality.

Since different regional standards exist because of varying views on the nutritional needs of each country, ECSA should engage the respective Ministries of Trade to forestall any negative trade issues—possibly by agreeing on a range of micronutrient requirements rather than trying to establish identical requirements.
IV. FUTURE DESIGN FOCUS AREAS

1. Development of robust databases (HIES, food consumption surveys, etc.) to inform decisions:
   - Member countries should expand or modify their current HIES and university-based food consumption survey tools to capture data on food consumption trends.
   - Regular surveys on food consumption should be conducted.
   - The number of data analysts at the Bureaus of Statistics should be increased.
   - Food consumption data should be disseminated regularly.

2. Establishment of a strong technical presence at ECSA (management and technical assistant backups):
   - ECSA should be assisted in making food fortification activity an integral part of its food and nutrition program, and should allocate significant staff time to learning comprehensive technical skills from A2Z.
   - USAID and AED/A2Z should consider placing additional technical staff at ECSA to help ECSA implement the food fortification activity.

3. Implementation of focused and structured human resources and institutional capacity development for laboratory staff, inspectors, statisticians, and nutritionists at the Bureaus of Standards:
   - ECSA should support and facilitate regular update training for laboratory staff, inspectors, and factory production staff.
   - ECSA should identify, or develop and supply, relevant reference materials to the Ministries of Health, the Bureaus of Standards, and food factories.
   - Laboratories and food manufacturers should be urged to invest in state-of-the-art equipment.

4. Advocacy and social marketing strategies:
   - Social marketing strategies that reflect income and expenditure disparities of potential and actual consumers of fortified foods should be developed.
   - Advocacy and social marketing materials for promoting consumption of fortified foods should be designed and produced.

5. Structured consumer awareness and education on the benefits of micronutrient intake:
   - Awareness and education materials to promote the benefits of micronutrient intake should be designed and produced.
   - Sustained awareness and education activities through radio, print media, and television spots should be launched.

6. Document and disseminate materials on good and best program experiences for possible adoption and replication.

7. Develop strategies for facilitating industries:
− Regular National Food Alliance meetings should be held at which information is shared and common approaches for addressing fortification challenges are developed.

− A consultative forum for manufacturers to review technical food production issues and processes should be supported.

− National Fortification Alliances should prepare strategic and business plans.

− Critical areas for establishing well-functioning public-private partnership interventions should be identified.

− The appropriate government institutions should be urged to remove unnecessary hurdles for food manufacturers, particularly lengthy bureaucratic processes, which can cause importation costs to escalate.
APPENDIX A. SCOPE OF WORK

GLOBAL HEALTH TECHNICAL ASSISTANCE PROJECT
GH TECH

EXTRACT—SCOPE OF WORK
(Revised 9-8-09)

I. TITLE
Activity: ARF/EA—REVIEW OF ECSA-HC Food FORTIFICATION ACTIVITY

II. PURPOSE
The purpose of this review is to provide the United States Agency for International Development (USAID/EA) with an independent assessment of progress, achievements and plans of the food fortification activity being implemented by East, Central and Southern Africa (ECSA-HC) Health Community with USAID funding.

III. OBJECTIVES
In conducting the assessment, the selected team will:

1. Technically assess the progress of the food fortification activity to date and its contribution towards achieving the stated results
2. Highlight achievements and also provide recommendations for improvements needed to achieve results
3. Review current plans and propose strategies to estimate the demand, utilization, consumption and potential benefit of the food fortification program as a public health intervention. The assessment team will synthesize data on current consumption patterns, conduct field interviews to estimate demand and potential benefit, and will make recommendations for the future design of the ECSA food fortification program.

IV. SCOPE OF WORK
The assessment team will review the food fortification program’s strengths and weaknesses against the objective and expected results. Based on the review findings, the team will present results achieved to date, document lessons learned, establish baseline data/potential for nutritionally vulnerable groups to access fortified foods, and make recommendations regarding new or modified approaches required to achieve the intended goals.

The assessment team will cover the following areas:

Illustrative questions to assist in the assessment are provided below. The assessment team is expected to refine this list of illustrative questions during an in-country Team Planning Meeting (TPM). The assessment questions will be shared and finalized with the USAID/EA/RHH and ECSA-HC team at the start of the assessment.

TASK 1: Policy and Standards: The aim is to determine the extent to which the food fortification project has influenced changes in government food fortification policies within East African countries and throughout the ECSA-HC region.

1. Are member countries adopting standards and regulations that will promote food fortification within countries and across borders in the East African region?
2. In the past these countries did not have food fortification policies but still some manufacturing companies claim to fortify some foods. The assessment should determine whether or not governments (in enacting policies) have involved the private sector (manufacturing companies) in the process.

3. What is the status of the food fortification programs, policy development and implementation process in each country and across borders?

4. What were the key policy enablers and/or constraints to implementing food fortification programs in the ECSA-HC region?

5. To what extent has the ECSA-HC regional activity on food fortification influenced the introduction or scaling up of fortification programs within countries and across borders?

**TASK 2: Food Control:** Identify and determine the extent to which governmental authorities in the region have adopted and implemented food fortification guidelines and standards on food control.

1. Are food inspectors trained on food control procedures at factories, importation sites and retail stores?

2. Have the food inspection actions been strengthened by this project?

3. Have reports about food control been published and disseminated?

4. To what extent do manufacturers strategically communicate information on their fortified foods?

5. Are the basic detectable nutrients in fortified products meeting the minimum fortification standards?

**TASK 3: Laboratory Proficiency Testing Exercise:** The aim is to examine if the analytical capabilities of the food control laboratories involved in the food fortification programs have been improved.

1. Have the participating laboratories in the proficiency network acquired new analytical skills that are useful for the control of fortified foods?

2. Have the laboratory personnel improved in their knowledge and skills as compared with those before the introduction of this project?

3. Is the reliability of the laboratory results better now than before?

**TASK 4: Estimating the Impact of the Food Fortification Programs:** The objective of this component is to examine and provide specific recommendations to improve data collection to estimate the demand, utilization, consumption and potential benefit of the food fortification programs in vulnerable groups of the population.

1. To what extent are fortified foods reaching vulnerable groups (children under the age of five years and women of reproductive age)

2. What are the tools in place to estimate demand?

3. What is the level of demand for fortified foods in the region, and what are the proposed strategies and methodologies for estimating demand?

4. Does information exist to begin the process of estimating intake? How can the project use Household Income Expenditure Surveys?
5. What is the nutritional impact of the estimated additional micronutrient intakes?

6. Do any/all children under the age of five and women of reproductive age have access to any commercially fortified foods in the selected countries?

V. METHODOLOGY

The review team is expected, in its response to the solicitation, to address the tasks and related questions above. The response should include a description of how the methodology responds to the above tasks and questions; from whom (and what), and how, data will be collected; and how the data will be analyzed. The methodology should be collaborative and participatory, including partners and key stakeholders (including USAID/EA) as much as possible in planning and conducting the assessment.

The following essential elements should be included in the methodology as well as the additional methods proposed by the team

- **Document Review**: ECSA-HC will provide the assessment team with a package of briefing materials related to the implemented food fortification activities. The team is also expected to collect and annotate additional documents and materials, which it will make available to ECSA-HC for future use. The team will review all available materials prior to conducting key informant interviews and as necessary throughout the course of the assessment. In particular the team will rely mostly on a desk review for policy information in all the countries in the region that are covered by the ECSA-HC food fortification program.

- **Team Planning Meeting**: The full team will have a two-day team planning meeting upon arrival in Kenya. The team planning meeting is an essential step in organizing the team’s efforts. During this meeting, the team will produce a work plan, timeline, interview instruments, and preliminary draft outline of the report. Roles and responsibilities will be agreed upon, and the team will have an initial briefing from USAID. This meeting will allow USAID (and the partners) to present the team with the purpose, expectations, and agenda of the assignment. In addition, the team will:
  - clarify team members’ roles and responsibilities,
  - review and develop final assessment questions,
  - review and finalize the assignment timeline and share with USAID,
  - develop data collection methods, instruments, tools, guidelines and analysis,
  - review and clarify any logistical and administrative procedures for the assignment,
  - establish a team atmosphere, share individual working styles, and agree on procedures for resolving differences of opinion,
  - develop a preliminary draft outline of the team’s report, and
  - assign drafting responsibilities for the final report.

- **USAID/EA/RHH and ECSA-HC Teams Briefing**: The assessment team will hold a preliminary meeting with the USAID/EA/RHH and ECSA-HC teams in Nairobi, Kenya, agree on the key research questions, selected countries and finalize the schedule.
  - **Key Informant Interviews**: The assessment team will meet with key stakeholders and partners and conduct qualitative, in-depth interviews using a combination of structured and semi-
structured open ended questionnaires. The team shall conduct face-to-face interviews with selected key informants in Kenya and in Uganda.

- **Industry assessment:** The team will identify manufacturing outlets for interviews, observation and collection of samples for lab testing. The focus will be on private sector adoption/participation in and/or knowledge of national/regional standards. This industry assessment will cover Kenya and Uganda.

**VI. TEAM COMPOSITION, SKILLS AND LEVEL OF EFFORT**

At the minimum a two-person external team working jointly with ECSA-HC, A2Z and USAID is required to carry out this assessment. The external team will be comprised of individuals with research skills in medical or social anthropology/epidemiology, food technology and control, and/or nutrition and; policy/management. This team will lead and work with ECSA-HC, A2Z, USAID/EA and relevant government ministries. Areas of collective work with ECSA-HC, A2Z and USAID/EA will include development of assessment tools; selection of countries; field interviews and review of drafts. Country representatives will also be invited to participate.

**External team:**

- **Team leader** — Nutrition and food fortification specialist with experience in program monitoring and evaluation. Experience is in policy management, especially in East Africa, would be an advantage.

- **Second Team member** — Public Health or Social science specialist or Nutritionist. Alternatively a Food Science and Technology/ Food Control specialist. In addition the person should have programming expertise/experience and a bias in nutrition.

**Other Team membership (Non-GH Tech consultants)**

- A senior government representative staff in Kenya and Uganda will accompany the team to assist access to both government offices and to private companies for interviews

- ECSA-HC representative - The ECSA Nutrition Advisor will participate to re-enforce collaboration and to achieve buy-in for regional fortification efforts.

- A2Z representative- The A2Z local representative will accompany the team in particular to assist with work on sampling and lab assessments;

- USAID/EA representative- The USAID/EA MCH advisor will be an integral member of the team with a role specified through the team planning meeting.

- USAID/W representative- The USAID/W A2Z AOTR will be a member of the team with a role specified through team planning meeting.

Every team member will report to the Team Leader

**VII. LOGISTICS**

ECSA/A2Z will identify and select the logistics person per country ECSA can provide overall logistics e.g. hotel bookings, air ticketing, appointment to senior government offices and manufacturing companies, car hire etc.
VIII. DELIVERABLES

Debriefing Meetings:
The assessment team will debrief with ECSA-HC at the end of each country visit and with USAID/EA and ECSA-HC on completion of field work (Nairobi). The team will hold a third meeting with ECSA-HC and USAID/EA to present the key findings and a draft report by task. Succinct appropriate briefing materials (by task) will be prepared and distributed during the briefings. USAID/EA and ECSA-HC will review the draft reports and provide feedback to the assessment team within six (6) working days and the final report within five (5) working days.

Draft Assessment Report:
A synthesized draft report will include, at a minimum, the following: scope and methodology used; important findings (empirical facts collected by evaluators); conclusions (evaluators’ interpretations and judgments based on the findings); recommendations (proposed actions for management based on the conclusions); and lessons learned (implications for future designs and for others to incorporate into similar programs).

The assessment team will provide ECSA-HC and USAID/EA/RHH teams with a draft report that includes all the components of the final assessment report. USAID/EA/RHH will receive at least two copies of the report (hard copy and one electronic copy in Word Format). USAID/EA/RHH and ECSA-HC will provide comments on the second draft report to the assessment team leader within 5 working days of receiving the report.

Final Assessment:
The final report must address the comments provided by USAID/EA and ECSA-HC regarding the draft within 10 working days after receiving the feedback on the draft report.

GH Tech will provide the edited and formatted final document approximately 30 days after USAID provides final approval of the content

Proposed OUTLINE for Assessment REPORT

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           Annotated List of Documents Collected and Reviewed
           Persons Contacted
APPENDIX B. PERSONS CONTACTED

REGIONAL

USAID East Africa
Victor Masbayi, Nutrition and Child Health Specialist, USAID/EA/Regional Health and HIV Programs
Moses Mukuna, Health Care Financing and Planning Specialist, USAID/EA/Regional Health and HIV Programs
Wairimu Gakuo, Strategic Information Specialist, Regional Health and HIV/AIDS Office

East, Central and Southern African Health Community (ECSA)
Mofota Shomari, Manager, Food and Nutrition Security Program
Carol Tom, Regional Food Fortification Advisor, A2Z Project/ECSA

KENYA

BIDCO Oil Refineries Ltd.
Manish Patel, Team Leader, QA/QC

Kenya Bureau of Standards
Evah Oduor, Director, Standards Development and International Trade
Peter Mutua, Chief Standards Officer

Kenya Medical Research Institute (KEMRI)
Dr. Yeri Kombe, Director, Centre for Public Health Research
Philip Ndemwa, Senior Research Officer

Kenya National Bureau of Statistics (KNBS)
Mary Wanyonyi, Senior Manager, Food Monitoring Environment Statistics

Ministry of Public Health & Sanitation
Dr. Josephine Kibaru, Head, Department of Family Health
Terrie Wefwafwa, Head, Nutrition Division
Gladys Mugambi, Coordinator Micronutrients, Nutrition Division
Kilinda Kilei, Head, Food Control Services

National Public Health Laboratory Services
Nancy Njine, Biochemist
UGANDA

A2Z
Dr. Alfred Mashandich Boyo, Resident Advisor
Ronald Afidra, Food Fortification Officer

Food and Agriculture Organization of the United Nations
Stella Sengendo, National Food Security Analyst

Makerere University
Professor William Kyamuhangire, Department of Food Science and Technology
Sarah Kisakye, Project Assistant, Monitoring and Evaluation, Ministry of Health Food Fortification Program

Mukwano Industries
Paul Mubiru, Oil Fortification Quality Assurance Manager

Ministry of Health
Dr. Elizabeth Madraa, Head, Food and Nutrition
Joan Kyotkutamba, Program Assistant, Social Marketing & Communication, Food Fortification Program

National Drug Authority (NDA)
Dr. Elizabeth Okello, Senior Inspector of Drugs (Vet)

National Agricultural Research Laboratories (NARO)
Dr. William Ssali, Head, Food Biosciences Research Centre (FBRC)

United Nations World Food Program
Martin Ahimbisibwe, Senior Program Assistant and Nutritionist

Uganda Bureau of Statistics (UBOS)
Juliana Kalibaala, Senior Statistician

Uganda Industrial Research Institute (UIRI)
Professor Charles Kwegisa, Executive Director
Eng. Dr. Dick Kamugasha, Director, Technology Development Centre (TDC)
Vincent Makhoha, Head of Laboratory

Uganda National Bureau of Standards (UNBS)
David Eboku, Senior Standards Officer

United Nations International Children’s Emergency Fund (UNICEF)
Brenda Kaijuka Muwuga, Nutrition Specialist

World Health Organisation
Dr. Geoffrey Bisoborwa, Nutritionist
APPENDIX C. TECHNICAL REGULATIONS AND STANDARDS

Reference to WTO TBT Annex 1 provides the following definitions:

A “Technical regulation” is a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

A “Standard” is a document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

The following “Explanatory note” is provided in the text:

The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardisation community are based on consensus. This Agreement covers also documents that are not based on consensus.

The point being that a law (internal) that requires a food vehicle to contain a minimum quantity of micronutrient(s)—as in the case of mandatory fortification—is a technical regulation, whereas discretionary (or voluntary) fortification and labeling (which would include the logo) is a standard under the WTO Agreement. This nuance may have implications for the stated aim of harmonization across the region—a point of which only two of those present at various interviews/meetings were aware. From KEBS the team was informed that it was a “simple” matter of informing EAC Secretariat and COMESA. The team was further advised the EAC will direct the Standards Committee for Harmonisation (Technical Committee 1 Working Group) to look at fortification standards through that sub-committee and then report back to the tripartite group of EAC/COMESA/SADC for consideration. That was not the team’s interpretation of the WTO TBT Agreement—seeking clarification on this issue is advised as it may have hidden implications for future activities. Head of Food Control–Kenya, who has a legal background, was similarly cautious.

On having harmonized standards, the views expressed covered the whole ambit. Some believed it would be workable, others believed that it would not, due to differing health constraints. Others expressed the view that they could see difficulties if some countries had mandatory fortification whereas others had discretionary fortification.
APPENDIX D. FORTIFIED AND ENRICHED

Within the standards for maize meal (KS 168) and wheat flour (KS 169), the statement “Fortified with vitamins and minerals” is a requirement, and the use of the logo is not mentioned. Similarly for vegetable fats and oils (KS 326:2), the statement\(^\text{15}\) “FORTIFIED OR ENRICHED WITH VITAMIN A” or the fortification logo is required, while for sugar (brown KS 1702 and plantation KS 38) the requirement subtly changes to “FORTIFIED OR ENRICHED WITH VITAMIN A” or the fortification logo, or both.

Within the Uganda standards, the labeling is standardized as a basic “fortified x” where “x” is the food vehicle. However, no mention is made of logo use, which only appears to be mentioned in Statutory Instruments No 2, The Food and Drugs (Food Fortification) Regulations, 2005, and is not referred to in the standards.

The team recognizes that the Guidelines on Food Fortification with Micronutrients published by WHO and FAO use the following definitions, listed in the glossary:

- **Enrichment** is synonymous with fortification and refers to the addition of micronutrients to a food irrespective of whether the nutrients were originally in the food before processing or not.

- **Fortification** is the practice of deliberately increasing the content of an essential micronutrient, i.e., vitamins and minerals (including trace elements) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health.

It is interesting to note that the terms “enrich,” “enriched,” or “enrichment” appear only 13 times in the Guidelines (usually in the reference to U.S. enrichment of wheat flour with folic acid), whereas “fortify,” fortified,” “fortification,” and “fortificant (s)” appear several hundred times.

It appears that Codex is the original source of this position because the General Principles for the Addition of Essential Nutrients to Foods GAC/GL 09 (1991 amendment) states:

2.5 **Fortification or enrichment** means the addition of one or more essential nutrients to a food whether or not it is normally contained in the food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

The team has discussed this issue with colleagues involved in the fortification process in Africa and has become aware that this definition is somewhat contentious. The team would argue that the “old” use of the term “enrichment” should remain in place, i.e., when the addition of micronutrients takes the level of micronutrients to a higher content than was there originally in the food.

While the team accepts that the use of one or other of the terms should be an internal decision of the country, it should be an issue that has ECSA consensus. The team agrees that the use of both in a conjoined manner should be discouraged.

Policy documents and regulations state that the fortification logo is “owned” by the Ministry of Health, but the team points out that the addition of micronutrients to foods has been common practice for decades—a short time in any supermarket will demonstrate how widespread the practice has become. If the term “enriched” becomes linked with the logo within any one of the standards, then it is likely that:

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\(^{15}\) The change to uppercase lettering within the relevant standard is presumed, by the team, to be deliberate.
• the consumer will become confused about the difference between a foodstuff that is “enriched” with the logo, versus “enriched” without the logo.

• all manufacturers—worldwide—will have to change their packaging to comply with standards.
## APPENDIX E. CURRENT STATE OF STANDARDS

The following illustrates the relative position of the ECSA recommendation and what Kenya and Uganda have in their respective standards.

<table>
<thead>
<tr>
<th></th>
<th>ECSA Factory/Average Addition mg/Kg</th>
<th>&quot;Legislated&quot; MINIMUM mg/Kg</th>
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<td><strong>Salt</strong></td>
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<tr>
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<td>20</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>30</td>
</tr>
</tbody>
</table>

Source of ECSA data: "ECSA Fortification Levels for Staples 070507; Factory Level."
Source of Kenya data: Relevant standards for factory average.
Source of Uganda data: Relevant standards for factory average.
At first glance the standards seem compatible and within the limits of laboratory detection would probably not cause too many problems. Closer inspection, however, indicates that while the Kenyan standard is very close to the ECSA recommendation (the main difference being the folic acid, which has been halved\textsuperscript{16}), when the formulator calculates the required pre-mix formulation, it becomes evident that the pre-mix formulation for Uganda is considerably different. This in itself may not be much of an issue because if Kenya should run out of pre-mix and need to borrow from its neighbor, Kenya would simply have to increase the dosage to achieve comparable results as indicated above. However, this may mean that economies of scale—one pre-mix for the region—may be lost.

<table>
<thead>
<tr>
<th></th>
<th>ECSA</th>
<th>Kenya</th>
<th>Uganda</th>
<th>ECSA</th>
<th>Kenya</th>
<th>Uganda</th>
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<td>Wheat</td>
<td></td>
<td>Maize</td>
<td>Wheat</td>
<td></td>
</tr>
<tr>
<td>Fortificant g/Kg Pre-Mix</td>
<td>Fortificant g/Kg Pre-Mix</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>33.3</td>
<td>26.6</td>
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<td>177.8</td>
<td>100.0</td>
</tr>
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<td>Thiamin</td>
<td>12.3</td>
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<td>46.1</td>
<td>45.3</td>
<td>26.2</td>
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<td>26.7</td>
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<td>70.6</td>
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<td>0.0</td>
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<td>6.9</td>
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<td>10.0</td>
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<td>100.0</td>
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<tr>
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<td></td>
<td></td>
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<td>250.0</td>
<td>289.1</td>
</tr>
<tr>
<td>NaFeEDTA</td>
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<td>384.6</td>
<td>598.8</td>
<td></td>
<td></td>
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<tr>
<td>Zinc oxide</td>
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<td>125.0</td>
<td>77.3</td>
<td>83.3</td>
<td>83.3</td>
<td>62.5</td>
</tr>
<tr>
<td>Filling material (at least 25%)</td>
<td>299.0</td>
<td>299.0</td>
<td>201.5</td>
<td>273.2</td>
<td>284.4</td>
<td>388.6</td>
</tr>
<tr>
<td>Make up to</td>
<td>1,000</td>
<td>1,000</td>
<td>1,000</td>
<td>1,000</td>
<td>1,000</td>
<td>1,000</td>
</tr>
</tbody>
</table>

Of greater concern is the disparity between what the formulator indicates the pre-mix formulation should be for Uganda, and what the relevant standard indicates should be the formulation—as shown below:

\textsuperscript{16} The formulator indicates this decision is correct because it will avoid increasing serum folate levels in women aged 19–50 to too high a level.
<table>
<thead>
<tr>
<th></th>
<th>Uganda Maize Calculated from Formulator</th>
<th>Indication from US 509:2006 Standard</th>
<th>Uganda Wheat Calculated from Formulator</th>
<th>Indication from US 561:2006 Standard</th>
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<tbody>
<tr>
<td>Vitamin A</td>
<td>26.6</td>
<td>53.3</td>
<td>100.0</td>
<td>83.3</td>
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<tr>
<td>Thiamin</td>
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<td>9.9</td>
<td>26.2</td>
<td>27.8</td>
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<tr>
<td>Riboflavin</td>
<td>6.0</td>
<td>10.0</td>
<td>12.5</td>
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<tr>
<td>Niacinamide</td>
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<td>101.0</td>
<td>65.7</td>
<td>126.3</td>
</tr>
<tr>
<td>Pyridoxine</td>
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<td>18.3</td>
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<td>Folic Acid</td>
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<td>4.4</td>
<td>6.9</td>
<td>6.9</td>
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<tr>
<td>Vit. B-12</td>
<td>10.0</td>
<td>20.0</td>
<td>37.5</td>
<td>37.5</td>
</tr>
<tr>
<td>Ferrous fumarate</td>
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<td></td>
<td>289.1</td>
<td>312.5</td>
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<td>NaFeEDTA</td>
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<td>461.5</td>
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<td>Zinc oxide</td>
<td>77.3</td>
<td>55.3</td>
<td>62.5</td>
<td>93.8</td>
</tr>
<tr>
<td>Filling material (at least 25%)</td>
<td>201.5</td>
<td>284.6</td>
<td>388.6</td>
<td>281.1</td>
</tr>
<tr>
<td>Make up to</td>
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<td>1,000</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Dose (g/MT)</td>
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<td>250</td>
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</tbody>
</table>
## APPENDIX F. LPT CORRELATIONS

One other parameter to be considered is the use of correlation analysis as indicated below:

<table>
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<tr>
<th>Mean</th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<td>41.16</td>
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<td>105.97</td>
<td>47.17</td>
<td>0.027</td>
<td>34.37</td>
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<tr>
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<td>58.89</td>
<td>2.03</td>
<td>28.37</td>
<td>93.63</td>
<td>44.32</td>
<td>48.58</td>
<td>114.4</td>
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<td>0.55</td>
<td>1.00</td>
<td>0.65</td>
<td>0.85</td>
<td>0.17</td>
<td>0.68</td>
</tr>
</tbody>
</table>

From the above data it would appear that columns (Laboratories) 2 and 9, and possibly 7, are having major problems, but if we perform correlation (abbreviated corr) analysis (below), we see that Laboratory 2 is highly correlated, with the mean (the value we expect), and we probably have a systematic error which should be easy to resolve.

<table>
<thead>
<tr>
<th>Mean</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<th>6</th>
<th>7</th>
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<tbody>
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<td>2.43</td>
<td>41.16</td>
<td>81.08</td>
<td>38.67</td>
<td>67.67</td>
<td>105.97</td>
<td>47.17</td>
<td>0.027</td>
<td>34.37</td>
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<tr>
<td>26.5</td>
<td>58.89</td>
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<td>93.63</td>
<td>44.32</td>
<td>48.58</td>
<td>114.4</td>
<td>39.94</td>
<td>0.053</td>
<td>23.22</td>
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<td>19.3</td>
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<td>22.6</td>
<td>38.5</td>
<td>20.34</td>
<td>37.25</td>
<td>45.4</td>
<td>12.32</td>
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<tr>
<td>Corr</td>
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<td>0.92</td>
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<td>0.56</td>
<td>0.55</td>
<td>1.00</td>
<td>0.65</td>
<td>0.85</td>
<td>0.17</td>
<td>0.68</td>
</tr>
</tbody>
</table>

The team was only able to visit a small (but representative) number of laboratories and found them to be staffed by (generally) enthusiastic staff working with equipment that has seen better days.

While little can be done about the latter, the team noted several improvements that could be made to laboratory practices. One is proper labeling of solutions, i.e., name of solution, concentration, dated, prepared, use by, the person who made the solution. Another improvement would be to counter the tendency for solutions to be “perfect,” so that if, for example, a 0.1N solution is required, that is what is made up, although the team would question if it was not slightly off the mark. The use of control charts, temperature measurement (climate control would be a utopia), and control samples should be implemented, particularly as the laboratories participating in these LPT exercises do not perform such analyses on a routine basis. The team would also question the validity of many of the moisture measurements made in these laboratories—an analysis so often taken for granted but probably one of the most difficult to get correct.
APPENDIX G. LPT ANALYSIS

The team looked at the sample preparation data (homogeneity) for LPT 3 with a view to identifying the source and extent of analytical error\(^\text{17}\) to ascertain if the regulatory limits were practical. Unfortunately, the data were only available for one laboratory.

For sugar, UNBS requires 20 ± 10 mg/Kg Vitamin A, whereas KEBS requires 10 ± 5 mg/Kg Vitamin A; both of them permit an error of 50% relative around the mean.

In the sample preparation, five samples were analyzed in triplicate, and a result of 14.5 ± 6.8 mg/Kg was attained, i.e., the error was 47% relative. Looking at sample variability, the same extract was measured on the spectrophotometer in triplicate; the range of the triplicate values was 11.2 to 20.4 mg/Kg and the average error was ± 1.7, or 12% relative, indicating that this was the error from purely sample reading, i.e., neither sampling nor extraction errors are included. Repeating the exercise for other sugar LPT samples, the team noted relative errors of 52% on a 3.3 mg/Kg sample, 61% on a 14.5 mg/Kg sample, and 59% on a 7.6 mg/Kg sample, with spectroscopic errors of 30%, 9%, and 7% respectively.

As these are the data from a single laboratory well versed in the technique it must, therefore, be questioned if the legal minima and maxima are within the technical capabilities of the various laboratories in the region. It appears that compliance agreement between laboratories is more a matter of luck than technical capability.

For salt, UNBS requires 60 ± 20 mg/Kg iodine, whereas KEBS requires 45 ± 15 mg/Kg iodine; both permit an error of approximately 30% relative around the mean.

In the sample preparation, 10 samples were analyzed in duplicate, and a result of 57.3 ± 7.9 mg/Kg was attained, i.e., the error was 14% relative. Looking at sample variability, i.e., part of the same sample dissolved and titrated, the range of the duplicate values was 55.0 to 63.1 mg/Kg and the average error was ± 5.0, or 9% relative, indicating that this was the error from purely sample reading. Repeating the exercise for other salt LPT samples, the team noted relative errors of 5% on a 50.6 mg/Kg sample, 4% on a 32.7 mg/Kg sample, and 14% on a 17.2 mg/Kg sample, with sample errors of 2%, 2%, and 9% respectively.

Despite the fact that these data are from a single laboratory well versed in the technique, it would appear that the legal minima and maxima are within the technical capabilities of the various laboratories within the region.

For maize meal, UNBS requires 50 ± 10 mg/Kg total iron, whereas KEBS requires 22.5 ± 7.4 mg/Kg total iron,\(^\text{18}\) giving a permitted relative error of 20% and approximately 30% respectively around the mean.

In the sample preparation, 10 samples were analyzed in duplicate, and a result of 42.6 ± 7.6 mg/Kg was attained, i.e., the error was 18% relative. Looking at sample variability, i.e., part of the same sample extracted and measured using the spectrophotometer, the range of the duplicate values was 36.6 to 48.7 mg/Kg and the average error was ± 3.6, or 8% relative, indicating that this was the error from purely sample reading. Repeating the exercise for other maize meal LPT samples, the team noted relative errors of 18% on a 29.2 mg/Kg sample, and 10% on a 18.6 mg/Kg sample, with sample errors of 9% and 6% respectively.

\(^{17}\) Analytical error is defined at the 95% confidence level, i.e., 1.96 x standard deviation. Relative error is the analytical error’s percentage of the mean value.

\(^{18}\) The team would question the validity of this number.
Despite the fact that these data are from a single laboratory well versed in the technique, it would appear that the legal minima and maxima are within the technical capabilities of the various laboratories within the region.

For wheat flour, UNBS requires $80 \pm 20$ mg/Kg total iron, whereas KEBS requires $50 \pm 10$ mg/Kg total iron, giving a permitted relative error of 25% and 20% respectively around the mean.

In the sample preparation, 10 samples were analyzed in duplicate, and a result of $43.7 \pm 3.1$ mg/Kg was attained, i.e., the error was 7% relative. Looking at sample variability, i.e., part of the same sample extracted and measured using the spectrophotometer, the range of the duplicate values was 41.0 to 45.0 mg/Kg and the average error was $\pm 1.7$, or 4% relative, indicating that this was the error from purely sample reading. Repeating the exercise for other wheat flour LPT samples, the team noted relative errors of 13% on a 26.5 mg/Kg sample and 15% on a 19.3 mg/Kg sample, with sample errors of 10% and 9% respectively.

Despite the fact that these data are from a single laboratory well versed in the technique it would appear that the legal minima and maxima are within the technical capabilities of the various laboratories within the region.
APPENDIX H. REFERENCES

ECSA

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KENYA


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**REGIONAL (OR WIDER)**

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AOAC–Laboratory methods.


**CODEX ALIMENTARIUS**—Relevant Standards and Guidelines for Foods, Labelling, Nutritional Claims and Sampling.


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IUPAC—Laboratory Proficiency.

JECFA–Laboratory Methodology.

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The Link Volume 1 Issue 3, USAID and COMPETE September/October 2009.
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OTHER
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