Assessment of the milling industry for the purpose of wheat flour fortification – Albania

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Prepared on behalf of UNICEF Albania; November 2010

ACRONYMS

CoA	Certificate of Analysis – often called Certificate of Compliance
FAO	United Nations Food and Agriculture Organisation
FIFO	First In, First Out
FOB	Free or Freight on Board
g	Gram
GDP	Gross Domestic Product
IDA	Iron Deficiency Anaemia
IDD	Iodine Deficiency Disorders
INSTAT	Institute of Statistics
KASH	Këshilli I Agrobiznesit Shqiptar (Albanian Agrobusiness Council)
Kg	Kilogram
Km	Kilometre
MT	Metric Ton
QA	Quality Assurance
QC	Quality Control
SPS	Sanitary and Phytosanitary
TBT	Technical Barrier to Trade
UNICEF	United Nations Children's Emergency Fund
WHO	World Health Organisation
WTO	World Trade Organisation

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Fabrika E Miellit NELA – Owner

Miell Tirana – Roland Hysa; President

KASH – Robert Pavaci; Executive Director

KASH – Enver Ferizaj; President

Atlas Sh A - Çobo Kreshnik; Mill Manager

ONIR – Pullumb Rrasa; Owner

UNICEF – Mariana Bukli; Health and Nutrition Officer

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Additionally the following provided valuable insights during the meeting below held to debrief stakeholders at the completion of the field visits

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EXECUTIVE SUMMARY

An assessment of the wheat flour milling industry has been carried out. Previous data from the milling industry showed that flour consumption in Albania was 360 g/day/person; average flour consumption 460,000Mt/yr consisting of total flour milled 432,000Mt/yr and flour imports of 27,000 Mt/yr. Out of 194 mills only 20 of them have a capacity greater than 20 Mt/day and 60% of national consumption comes from 4 mills.

During the assessment and through the use of a questionnaire the data indicated that the mills surveyed (6 large and 7 smaller) accounted for slightly less than 400,000 MT per annum of imported grain (consistent with adjusted INSTAT data) which is equivalent to 280,000 MT of flour or 60% of the total estimated market. All of the mills operated in a range of 50% to 85% utilisation of capacity (the larger mills having a higher utilisation ratio). In total multiple flour types are produced by all the mills namely - Type 00, Type 40, Type 45, Type 50, Type 60, Type 70, and Bran

Any one mill produced at least 4 of the above flour types. Prices ranged from 60 to 65 Lek/Kg for type 00 flour to 53 to 60 for the higher extraction flours (types 45 to type 60). Bran price was relatively consistent at 28 to 30 Lek/Kg Whilst the smaller mills offered only 50 Kg bags of flour the larger mills provided multiple pack sizes.

The cost of fortification was estimated at <US$ 2/MT of flour (fortifying with NaFEeDTA; Folic acid and Vitamin B_{12} which is equivalent to US$ 0.2 per person per annum with a coverage of at least 60% of the population.

SUMMARY

NO OF MILLS	MILL MAXIMUM CAPACITY MT/DAY
3	200-300
3	100-200
3	50-100
4	20-50

These mills working at a 95% utilisation (allows for normal maintenance) could mill approximately 540,000 MT of wheat equivalent to approximately 380,000 MT of flour. Given that imported wheat is estimated at approximately the same level (see Impact Assessment) later then the utilisation data quoted by the mills of approximately 60 to 70% is validated. This means that the above mills could produce a minimum of 270,000 Mt of fortified flour per annum (at the 70% utilisation) with a possible extra 40,000 MT coming from the missing 13 smaller millers (20 to 50 MT per day).

Assuming a population of 3.17 million this equates to 0.23 Kg of flour per person per day or 0.39 Kg or 0.33 Kg of wheat per person per day – which given the element of rounding in these calculations is very close to the estimated (see Impact Assessment later) 0.36Kg/person/day.

Note the argued local production of wheat at >300,000 MT at an average yield of 0.4 MT per Hectare is unsustainable and, it could be

argued, would not provide bread on the table for a period longer than a few months.

The coverage estimate from Skjope of 60% is probably, therefore, an underestimate.

The cost of fortification is very low at 0.2 Lek/Kg which compares very favourably with the cost of low grade flours at approximately 55 Lek/Kg and high grade flours at 65 Lek/Kg

As the level of awareness of this fortification initiative is relatively low a National Meeting of all stakeholders – at senior decision making level – has been recommended. This meeting should take place as early as possible in 2001 and with an aim to have implemented fortification by December 2011 in commercial mills producing in excess of 20MT per day.

It has been further recommended that trading partners be advised of Albania's intention to institute mandatory fortification so that those trading partners can institute their own activities in order that they be compliant with Albanian law.

BACKROUND

INFORMATION PROVIDED BY UNICEF

Children in Albania face many challenges that affect their chances for a better start in life and reduce their potential to lead productive lives as adults. In spite of relatively low U5 mortality rates (22 per 1,000 - still high compared to other countries in the region) and good exclusive breastfeeding rates in the first months of life, Albanian children face multiple nutrition problems including high rates of stunting and overweight, disparities in health and nutrition status and micronutrient deficiencies (IDD and IDA).

Albania remains one of the poorer countries in Europe where 24.7 per cent of children live in poverty (WB2005). Poverty is concentrated in the northeast, rural and peri-urban areas of Tirana and among Roma and Evgjit ethnic minorities and is strongly associated with the increased prevalence of chronic malnutrition among children under five.

The nutritional status of children has improved over the last 5 years. However, 19 percent of children under age five were stunted. Stunting was present even among children under six months of age. Stunting indicates chronic malnutrition and is more common in the mountain region (28 percent) than in Urban Tirana and central region; Children in lowest wealth quintile are two times more likely to be stunted (27 percent) than those in highest quintiles (13 percent). Wasting (too thin for height) which is a sign of acute malnutrition is 9 percent. 5 percent of children under age five were underweight for their age. Twenty two percent of children under five were overweight.

Micronutrients are essential vitamins and minerals required for good health. Micronutrient malnutrition has been identified as a public health problem in Albania. ADHS 2008-9 indicates that 17 percent of children 6-59 months in Albania have some level of anaemia. Anaemia is considerable higher in rural areas than in urban areas, for children of women with no education and for lowest wealth quintile. Nineteen percent of women whose haemoglobin level was tested were found to be anaemic.

It is considered that iron deficiency anemia counts for most of anemia cases. Increasing of the consumption of iron and other micronutrients through sustainable flour fortification of widely consumed foods has great potential for improving health and nutrition status of children and women. Copenhagen consensus report (2008) revealed that the benefit – cost ratio globally for fortification (Iron, Iodine) is 9,5:1.

Data from the milling industry show that flours consumption in Albania is 360 g/day/person; average flour consumption 460,000Mt/yr; Total four milled 432,000Mt/yr; Flour imports 27,000 Mt/yr. Out of 194 mills only 20 of them have a capacity greater than 20 Mt/day and 60% of national consumption comes from 4 mills.

Taking into consideration current nutrition situation of women and children in Albania, a new Joint programme on Nutrition, funded by the MDGF-Spanish Government, was developed jointly with WHO, FAO and the Albanian Government and will help place nutrition and food security higher on the government agenda and design interventions focusing directly to the most vulnerable population groups.

MILLING INDUSTRY

Over a period of 2 weeks (see Appendix 1 for Scope of Work) the consultant visited 6 [six] of the largest mills in Tirana and the immediate vicinity, met one small miller coincidently and through a mill questionnaire (see Appendix 2), developed by the consultant, (contacted by phone by Robert Pavaci using a shortened version of the questionnaire – see Appendix 3) as a guideline, information was gathered on:

- Ownership – public or private
- Capacity rate, utilized capacity
- Wheat prices
- Flour prices
- Flour types and prices
- Extraction rates
- QA/QC capability
- Pack sizes
- Technical capacity at the individual mill

Whilst the consultant was provided with high level access to the milling industry it must be recognised that the type of information sought was, in some areas, highly sensitive. This resulted in some information requests being politely declined, some over estimated and some underestimated. None of this was malicious – in fact the overall response from industry was positive – but in the current economic climate industry had other things on their mind; specifically the high input costs, "illegal" imports of flour (especially from Serbia) and under utilisation of mill capacity.

All of the mills visited (or discussed with owners) were privately owned. Five of the six mills could easily be classified as world standard and the 6th still of high standard.

Milling capacity ranged from 150 MT to 400 MT per 24 hours with the mills running at, or close to, maximum capacity but for a restricted period of time depending on market conditions. The smaller mills claimed an utilisation level of 40 to 60% with the larger mills operating at a claimed utilisation of 60 to 80%. Analysis of quantities of wheat procured broadly vindicated these values (in one case the utilisation claimed was significantly overstated) but this observation must be tempered by the fact that only half the mills indicated actual procurement values for wheat preferring to stick with approximations of utilisations.

Obtaining mill gate delivered grain prices proved even harder – however the FOB price[1] of Russian wheat was (date and price range) 25/11/09 @ US$ 186/192; 30/10/09 @ US$ 158/183; 08/10/09 @ US$ 145/167; 28/08/09 @ US$ 112/117 and 13/08/09 @ US$ 150/175 – with cost of delivery (difference between FOB and mill gate price) either being unrealistic (in the consultants opinion) or not given.

Obtaining flour type, price, packaging and supply information proved easier.

All millers produce a range of white flours plus an average of approximately 10% of production being whole wheat or brown flour. White flours were variously described by function

1 Sourced via US Wheat Associates November 2010

i.e. pie, pastry, pizza bun, bread etc and/or by a number system i.e. 00, 040, 045, 050, 055, 070, 080, 090 which is generally considered to be an indication of ash values (the lower the number the less the ash content ergo the more refined the flour).

Type 00 flours are the most refined and account for between 5 and 10% of many miller's production and are sold at retail level in small pack sizes i.e. 1 Kg selling at 60 to 65 LEK per Kg

By far the most popular flours were the 040, 045 and 050 (with 050 predominating) which accounted for >60% of the production and sold, at mill gate, at between 55 and 60 LEK per Kg.

Similarly the 50 Kg pack size predominates the market at 70 to 80% for most millers and the 1 Kg retail pack accounting for approximately 10%. There was an exception to this as one miller has a heavy business focus at retail level – about 30% of production in 1 Kg packs – and a reduced 50 Kg market at 45% of production.

One of the tasks set in this assignment was to attempt to differentiate between the different markets i.e. commercial and home baking. Unfortunately this proved to be impossible as almost all the millers sold between 80 and 100% of their production to wholesalers who collected directly from the mill i.e. the mill did not distribute to the wholesalers so the mill had little if any information about the final destination or use of their flour.

A small proportion, about 10% was sold direct to bakeries. As stated above there is an exception amongst the millers whose market focus is at the retailers – about 60% of production with the balance into the markets and bakeries i.e. almost no dealings with wholesalers.

Extraction rate was frequently quoted at 70% but this failed to take into account that approximately 5% (sometimes more) second grade flour was also obtained from the bran cleaner (one mill did not use this technique) which could be blended into the 070, 080 and 090 flours.

The main millers had laboratory facilities that (those seen) were of an exceptional standard – though it was noticed that the operational techniques had some significant defects.

Subsequent information obtained from 7 smaller millers operating in the range of 16 to 120 MT/day increased the total wheat consumption to slightly less than 400,000 MT/annum - equivalent to 280,000 MT of flour (70% extraction) of similar type to that produced by the larger millers. Again 0.45 to 0.50 type predominating. All of the smaller millers however sold their flour in 50 Kg bags.

SUMMARY

No of Mills	Mill Maximum Capacity MT/Day
3	200-300
3	100-200
3	50-100
4	20-50

These mills working at a 95% utilisation (allows for normal maintenance) could mill approximately 540,000 MT of wheat equivalent to approximately 380,000 MT of flour. Given that imported wheat is estimated at approximately the same level (see Impact

Assessment) later then the utilisation data quoted by the mills of approximately 60 to 70% is validated. This means that the above mills could produce a minimum of 270,000 Mt of fortified flour per annum (at the 70% utilisation) with a possible extra 40,000 MT coming from the missing 13 smaller millers (20 to 50 MT per day).

Assuming a population of 3.17 million this equates to 0.23 Kg of flour per person per day or 0.39 Kg or 0.33 Kg of wheat per person per day – which given the element of rounding in these calculations is very close to the estimated (see Impact Assessment later) 0.36Kg/person/day.

Note the argued local production of wheat at >300,000 MT at an average yield of 0.4 MT per Hectare is unsustainable and, it could be argued, would not provide bread on the table for a period longer than a few months.

The coverage estimate from Skjope of 60% is probably, therefore, an underestimate.

As will be argued later the pricing of flour is relatively consistent across the range of mills – surprisingly consistent suggesting the smaller mills are paying considerably more for their wheat. The cost of fortification is very low at 0.2 Lek/Kg which compares very favourably with the cost of low grade flours at approximately 55 Lek/Kg and high grade flours at 65 Lek/Kg

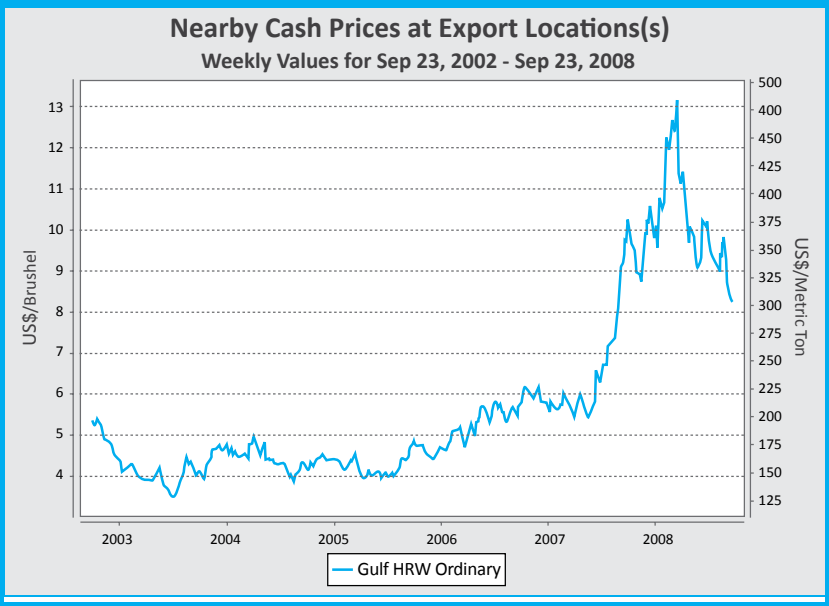
BAKING ASSESSMENT

According to the Bakery Association there are approximately 2,000 bakeries of which about 500 are in the Tirana area. Most bakeries (defined as those that physically make bread as opposed to retail outlets that sell bread as part of their stock portfolio – this is estimated by the Association to account for > 40% of total bread sales) are very small and situated on major thoroughfares i.e. main streets utilising in the order of 300 to 500 Kg per day; larger bakeries are typically utilising in the order of 700 Kg per day. Most, if not all, operate 7 days per week (excluding specific days of cultural significance) giving a total uptake of flour of approximately 200,000 MT to 350,000MT.

Based on an extraction rate of 73%, which is in line with both observations made at the mills (between 70 and 75%, the former claimed the latter observed) and with the 1999 Food Aid Convention http://www.foodaidconvention.org/en/index/faconvention.aspx that uses a conversion factor of 0.73, the wheat required to produce the above flour would be approximately 275,000 MT to 480,000 MT

On the same basis the information used to prepare for the Skjope Workshop indicated import data of flour imports of 27,000 MT which would have been converted by FAO using a factor of 0.73 (by definition) which equates to approximately 37,000 MT of wheat.

Since the embargo on wheat exports from Russia (the primary source of wheat for Albania) the flour price has risen from around 42 LEK per Kg to around 61 LEK per Kg whilst the bakeries increased the bread price by



Weekly Price of ordinary hard winter wheat,2003 to 2008

Source: U.S. Wheat Associates

around 10 LEK (assuming all other prices stayed constant and given a water absorption of 50% the actual increase should have been around 13 LEK). The Association commented that even this reduced increase was unpopular with the consumer and that they came under pressure from Government to minimise this increase even further.

The consultant was unable to determine what happened in the market place after the major price increase in 2007/08 which caused food riots in several parts of the world nor was the consultant able to determine why after Prime Minister Putin placed the embargo on Russian wheat to protect the local market from price increase that some form of intervention was not initiated in Albania to similarly protect against the above, significant, price increase of bread.

The graph below indicates the extent to the price fluctuation during 2007/08 – the current price of the same wheat being approximately US$ 220; again increased due to the Russian drought and subsequent embargo.

The market is very price sensitive and in a move designed to protect the consumer the Association pushed for bread pricing to be more transparent and it is now law that bakeries indicate the price of bread per unit mass (1 Kg) as well as indicating the selling price per unit i.e. per loaf. Consumers, and this is not unique to Albania, believe they are buying bread on weight which they, mistakenly, equate with volume. The price of the large family loaf varies from 70 to 80 LEK though on a mass basis the price difference is not significant and appears more related to the bakery site, overheads and ability to cross subsidise via speciality breads.

Through the use of bakery improvers, which

are added at the mill and, possibly, even at the bakery it is possible to produce a loaf with the desired volume but significantly lower mass. The consultant has, on this assignment, seen bread with evidence of significant volume boosting (air) which further evidences the price sensitivity of bread.

In partial defence of the milling and baking industry a significant portion of the blame for this can be placed directly at the door of the primary input cost for both sectors of the industry – the price of wheat. The recent upheaval in market forces due to wheat crop problems in Australia, and more recently – and of greater significance to Albania – the embargo on wheat sales from Russia which have had an unusually heavy (many analysts believe an overreaction) knock on effect on world wheat prices that will, in all likelihood, take some considerable time to reverse (if they ever do).

The milling industry is, therefore, capable of absorbing significant swings in the grain price, without Government subsidy, whilst at the same time adding bakery improvers that cost more than the cost of the proposed fortification. As a result the consultant does not envisage any price increase that can be put down to fortification – though several of those interviewed commented on potential "speculation" (meaning fortification would be used to increase prices); such activities should be strongly resisted.

IMPACT ASSESSMENT
CALCULATIONS & ASSUMPTIONS

FAOSTAT data indicates a total wheat food consumption of 428,000 MT in 2007 http://faostat.fao.org/site/368/default.aspx#ancor [Accessed November 2010 – last update 2nd June 2010] with 406,000 MT of that being imports. Whilst it is easy to assume that all the imports moved into the local food chain whilst the local production of 250,000 MT went to "Other utilisation" this is dangerous as whilst FAO defines "other utilisation" as non-food usage it, in order not to distort national food consumption data, FAO includes consumption by tourists in this area as well. The later, tourists, would be eating from import production products (hotels, cafes etc) whilst the local low income subsistence type farmers would be consuming the local production.

The level of consumption of the tourist sector is unknown but, according to INSTAT (consultants interpretation of "Economic Indicators/Tourism" – accessed November 2010) the tourist industry is approximately 25% foreign and 75% Albanian; but some broad assumptions can be made. From the same data source it can be interpreted that 56,000 foreign tourists spent an average of 2.3 nights in Albania so the foreigner impact on consumption data can be taken as minimal.

Local wheat consumption would likely be highest in the wheat production areas i.e. Korçë whilst flour imports from Serbia, whilst having an impact on urban consumption (based on discussions with local millers and evidenced by the low mill utilisation) would likely predominate in areas close to the border i.e. Kukës, Lezhë and Shkodër and based on the information obtained on distribution costs (0.5 to 1 LEK per MT per Km).

The Skjope preparation information indicated the major mills accounted for 60% of the national populations consumption – given as 360g/person/day - and none of the numbers above discount that estimation. It should also be noted that whilst FAOSTAT data is usually at least 2 years out of date the data is managed by professional statisticians using internationally accepted models and should, therefore, be considered a reasonably reliant indicator. Given the increase in local wheat production it may actually be a slight underestimate. Consideration must, however, be given to the distribution of that consumption and the socio economic groups in that distribution.

http://www.dogana.gov.al/doc/BuletiniTregJashtmeJanarDhjetor2009.htm
[Accessed November 2010]

INSTAT 2009 data page 19 gives data on Chapter 10 (all cereals) imports 418,000 MT in good agreement with FAOSTAT same period of 406,000 MT for wheat but poor agreement with the "all cereals" value of 554,000 MT which includes maize, rice and barley.

Chapter 11 (products of the milling industry), however, indicates imports of 47,000 MT

http://www.dogana.gov.al/doc/Buletini%20%20Treg%20Jashtme%20Janar-Gusht%202010%20publ.htm
[Accessed November 2010]

INSTAT 2010 data page 19 gives data for Chapter 10 (all cereals) of imports of 259,000 MT for the period January to August 2010. Using a pro-rata basis (consultant discussed this with Zef Gjeta and we considered this

to be a valid assumption) this would give an import wheat data of 388,000 MT

Chapter 11, again adjusted, indicates imports of 52,000 MT

Provisional data for Albania 2009 - http://faostat.fao.org/site/567/default.aspx#ancor – [Accessed November 2010 – last update 2nd September 20101] indicates an increased wheat production of 333,000 MT compared to the 250,000 MT in 2007 (the 250,000 MT is in good agreement with FOASTAT 2007 data above though several interviewees have questioned if the claimed 333,000 MT of local wheat is realistic)

The decrease in wheat imports is broadly in line with increased local production, but still below the levels of 1998 (INSTAT "Economic Indicators/Agriculture/Field Crop Production") – but as the local production is not used by the larger millers it begs the question "Are the smaller millers taking increased market share?"

Whilst the consultant accepts there may have been a slight increase in market share it must be recognised that local wheat prices will have raised in accordance with import prices as Albania has a completely free market system.

The suspicion is that subsistence level farming of wheat may have increased and that the smaller mills are "toll milling" – there has been a significant increase in the number of farmers described as "Crop without livestock" in the INSTAT indicators quoted above – up from 37,500 to 57,500 – whilst the other categories of farms have generally seen a decrease.

This has some significance as fortifying subsistence level production is fraught with difficulties – it is not impossible, just difficult. If the wheat is being toll milled then the miller does not own the grain and is simply providing a service. As such the miller would not fall under any national regulation for fortification which may be developed. The caveat to this is that it is unlikely subsistence level wheat production would provide 100% of those producers' annual requirements – as the average yields of wheat at >0.4 MT per hectare is poor. In theory one hectare could provide wheat for about 3 people (400 Kg / (0.36 Kg per day x 365 days)) for a year.

Given that INSTAT estimate about 360,000 farmers and 697,000 hectares (or about 2 hectare per farm) of agricultural land it is doubtful subsistence level farming would be on anything larger than 0.5 hectare for all agricultural outputs.

IMPACT CONCLUSION

From the above it would appear that approximately 60% of the population of 3.17 million (INSTAT January 1st 2008) or nearly 2 million people would be consuming fortified bread on a regular basis whilst the balance of population would consume at least some fortified bread once their own wheat stocks had been depleted.

Imports are comparatively insignificant at a quoted 27,000 MT – though the milling industry would argue this is an under estimate.

The INSTAT data above for Chapter 11 goods (products of the milling industry) is 52,000 MT and even if this was all wheat flour (highly unlikely but can be checked by Excise under HS Code 11.01) this needs to be compared to the

283,000 MT (imports of 388,000 MT wheat x 0.73) of locally milled and fortified flour. Note: 388,000 MT equates to a consumption level of 0.34 Kg per person per day; whilst slightly down on the Skjope data the number indicates that the recent price increase has not had that significant effect on consumption.

In fact if food prices continue to rise then the consumers will eat less of the "luxury" foods and move increasingly back to the Albanian staple – bread. The change in dietary pattern and reduction of dietary diversification makes it even more important that wheat flour be fortified to mitigate the potentially reduced micronutrient intake.

Additionally the Albanian Government would be fully entitled to require that all imported flour into Albania be fortified to meet National standards – they can do this once they have implemented fortification themselves and informed trading partners of their intentions; this is not a Technical Barrier to Trade (TBT) as the two WTO agreements (the Results of the Uruguay Round of Multilateral Trade Negotiations – in the legal texts. Geneva, World Trade Organization, 1995 www.wto.org/english/docs_e/legal_e/legal_e.htm accessed November 2010) which are considered of greatest relevance to fortified food are the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), and the Agreement on Technical Barriers to Trade (the TBT Agreement). Under these agreements, countries may adopt provisions that limit trade for legitimate reasons; the legitimate reasons include "inter alia, national security requirements, the prevention of deceptive practices, the protection of human health or safety, animal or plant life or health, or the environment". Fortification measures usually fall under the protection of human health category but it must be remembered that such measures should not unnecessarily restrict trade i.e. the protection of health must be justified – which it clearly is in the Demographic and Health Survey 2008 -09

In this regard the consultant would advise that Serbia, whilst not fortifying itself at this point in time (November 2010) it is believed to have both the capability to do so and the willingness to do so should importation requirements of a trading partner require it. The consultant is also aware of some fortification initiatives in other neighbouring and trading partner countries.

IMPACT - COST IMPLICATIONS

At the UNICEF organized Regional Technical Flour Fortification Workshop, June 2009, moderated by the consultant Jack Bagriansky, an attempt was made to develop a cost benefit model. This model has subsequently been reworked by Jack using further data extracted from the Demographic Health Survey 2008-09 to which the consultant has modified the GDP as per the latest information from INSTAT.

The cost of all malnutrition indicators to Albania is estimated at a current US$ 107 million per annum of which 65% can be assigned to "Lost Future Potential" [60% being due to stunting] and 20% to "Lost Current Productivity". From INSTAT GDP 2008 Semi-Final data it is estimated that the Albanian GDP is US$ 10,881,000,000.

All malnutrition, therefore, equates to a GDP loss of approximately 1%

The lost future potential is highly significant as this is a year on year increasing (as the population increases) drain on the Albanian economy.

Cost of micronutrient pre-mix will depend on discussions yet to be held in Albania but are currently estimated at a maximum of US$2 per MT of flour (approximately 0.2 LEK per Kg – 0.07 LEK per person per day) assuming a pre-mix consisting of Ferrous Sulphate or Sodium Iron EDTA, Folic acid and Vitamin B_{12}. Additional costs to take into account are mill start up costs (once off procurement of micro feeders and packaging changes) and mill operational costs (QA/QC etc). Government costs would relate to the monitoring of fortified flour and to the social marketing of fortification.

FORTIFICATION REQUIREMENTS
INDUSTRY

All of the mills visited already have micro feeders adding bakery improvers and so may prefer to deal with their regular suppliers. Their mill supplier is almost certainly able to procure the micro feeders required and most of the bakery additive suppliers' source pre-mix as a service to their clients when required. Nevertheless contact details of some of the myriad of suppliers are provided below.

EQUIPMENT SOURCES

The following single web site links to 67 suppliers of micro feeders.

http://sosland.gcnpublishing.com/gmabg/index.cgi?final_cat1=7&final_cat2=145&cat1_2=7&cat2_2=145&search_type=&search=search

Millers should be urged to source a good quality micro feeder – some of the ones seen by the consultant are surprisingly poor quality compared to the rest of the mill. Appendix 4 deals with some specific issues that need to be considered when procuring a micro feeder.

PRE-MIX SOURCES

The following web site links to a certified system of procuring pre-mix from a selection of reputable suppliers who are constantly independently monitored in terms of quality. GAIN facilitates a tendering process for the required pre-mix so ensuring competitive pricing of guaranteed pre-mix. There is also the possibility of accessing some preferential financing facility.

http://www.gainhealth.org/programs/gain-premix-facility

This is important as a study[2] carried out by the consultant indicated that the original source of micronutrients (which any reasonable buyer of pre-mix would not be aware of) is of significance in ensuring that the pre-mix is "fit for purpose". This has implications for both the miller and Food Control as it goes a considerable way to satisfying Food Control that the miller is exercising due diligence.

The "Home Pages" of three reputable pre-mix manufacturers (as opposed to suppliers) are provided below.

http://www.dsm.com/en_US/html/dnp/products.htm

http://www.food-fortification.com/Home.aspx

http://www.fortitech.com/default.aspx?&TabID=40

QA/QC PLANS

A more detailed description of typical QA/QC protocols is provided in Appendix 5

The objectives of any system is to:

- Provide information on what needs to be done to ensure that regulatory and consumer requirements are met.
- Improve knowledge regarding record-keeping and monitoring procedures that have to be instituted to be compliant with the quality assurance scheme.
- Improve understanding of different elements of the inspection procedure to be followed.

2 Investigation into Various Technical Aspects of the South African Food Fortification Programme; P. Randall December 2005. Compliance and Proficiency Testing – UNICEF Agreement No SSA/SAFB/2005/00000465-0

CONTROL AND MONITORING SYSTEMS

Quality assurance / quality control is the total of the organised arrangements made with the objective of ensuring that food products are of the quality required for their intended use at consumer level. It is important to ensure quality control processes comply with food fortification regulations.

QA PROTOCOL

It is important that the micro feeder performance be checked on a regular basis. Adding too little fortification mix is against the regulations and will not deliver the expected nutritional improvement to the customer. Adding excessive amounts of fortification mix will be detrimental financially. Over dosing of fortification mix is unlikely to pose any dangers to the consumer. This is because the bread flour products i.e. bread, will have a strange taste that the consumer will object to. This occurs at dosage levels well below those likely to cause toxicity. Whereas the consumer will not be harmed they will, however, be unhappy and unhappy consumers do not, usually, become repeat customers – as a result business suffers. Mills also need to note the importance of sampling which is discussed under Food Control both when taking samples for themselves and when food inspectors take samples. Note that in food law the mill should accompany the inspector during the inspection, ensure a legal sample is taken, and ensure that they themselves are given a portion of that sample for possible verification at an accredited laboratory.

TRAINING

The QA/QC plans in Appendix 5 are generic and require tweaking for particular mill situations – of particular importance is identifying where in the mill a representative sample may be obtained.

FOOD CONTROL

The Food Control Authority had only been established in Albania in mid 2010 through a funding and consultation agreement with the Economic Union. At the time of the consultants visit the relevant authorities were in Europe undergoing training and the remaining staff where still moving into the recent built facilities. As a result the consultant was unable to speak to the Food Control Authority so much of the following is based upon assumptions and previous experiences with food control bodies.

REGULATIONS AND MONITORING

Whether a voluntary or regulatory programme is established it will be necessary to establish a regulatory framework for industry to work within. In a voluntary programme this is necessary to give industry permission to fortify and establish the limits it must work within. In a mandatory programme the regulations will prescribe the specific characteristics of the fortification programme.

Regulations also prescribe the mandate under which the Food Control Authority works – typically a Food Act – and details the powers and duties of the inspector and the analyst, possibly even prescribing how those duties

and analyses are to be performed.

First it must be established if fortification is actually legal – in South Africa it was necessary to repeal a law which prescribed that "wheat flour shall be made from wheat and wheat alone".

Once that has been established it is then necessary to undergo an extensive consultancy process with the stakeholders to establish the scope of the regulatory framework and its format. For example some countries have a specific regulation for fortification whilst others have national standards that have to be complied with under the mandate in another piece of legislation. It is important to recognise that fortification itself is not a safety risk as any overdosing to levels remotely approaching the upper level of safety would be inedible.

Whilst fortification may be mentioned in an Act of Parliament it should be remembered that altering an Act is a very time consuming and lengthy process as several countries have found to their chagrin. Having a readily altered standard or a regulation in which the specific details of the pre-mix formulation is in an Appendix (altering an appendix is easier than altering a regulation) should be considered.

Typically a Food Act empowers the inspector to access records i.e.

- "*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;*" cited from Laws of Kenya, The Standards Act Chapter 496 Revised Edition 1981 section 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.*" cited from The Uganda Gazette No 2 Volume XCVIII dated 14th January, 2005. The Food and Drugs (Food Fortification) Regulations, 2005.

The above clearly demonstrates that monitoring and enforcement could be effectively carried out using an alternative strategy to wet chemistry – namely following a paper trail – that could very quickly control the fortified wheat flour entering into the market place.

Almost every piece of fortification regulation or standard states not only the prescribed compounds that may be added but also states minimum and maximum levels for those compounds. Prescribing minimum levels is logical and is typically calculated as a specific percentage tolerance below the prescribed legal level; but prescribing the maximum as the equivalent tolerance above the legal level is, in the consultants' opinion, illogical.

Firstly the intrinsic level of the specific micronutrients is known to vary significantly

– considerably more than the amount most fortification pre-mixes are adding. The fact that what we are adding is more bio available to the consumer than the intrinsic content is irrelevant here.

Secondly the regulations or standards rarely take into account the sampling and analytical errors that are inherent in compliance testing at the ppm levels used in food fortification programmes.

To support the above argument the consultant would refer to a study[3] carried out in South Africa in which it was demonstrated that internationally accredited (for vitamin and mineral analysis) laboratories and various other laboratories from pre-mix manufacturers etc could reach a high level of consensus (typical coefficients of variation (CV) between laboratories of 10-12%, the CV within any laboratory was lower) on the composition of fortification various pre-mixes in original and adulterated form) but those same laboratories could not reach consensus (typical CV's between laboratories of 40%, within any laboratory CV's were lower but higher than that achieved on the pre-mix) on laboratory prepared, homogeneous, finished products both original and adulterated form. The implications for disputes both within and between countries on the analysis of fortified products are obvious.

Thirdly laboratories rarely measure the actual compound added but rather the total content of that micro nutrient. Iron, for example, is often measured as total iron using atomic absorption on an ashed sample rather than measuring the specific compound (and that is not possible for some compounds); total folate is measured not folic acid (only recently has a method has been developed to specifically measure added folic acid).

This lack of precision combined with a variable intrinsic content – which would be an unknown for any particular sample – makes criminalisation of the innocent a very real possibility. Typically in food law you are guilty till proven innocent which would be very difficult to accomplish based on analytical chemistry.

Setting of the maximum as the equivalent maximum tolerance around the prescribed level is also based on no known scientific basis – it is simply a neat arbitrary decision which has no place in a legal document. Maximum levels do need to be set but they should be set on scientific grounds such as the maximum safe intake as indicated by WHO etc

The regulations or standards also need to specify sampling protocols that the inspector must follow when taking samples for compliance testing.

Almost all regulations and standards make extensive use of Codex Alimentarius, in fact they are normally "Codex or better" documents. Despite this heavy reliance on Codex the Guidelines on Sampling (CAC/GL 50:2004) issued by Codex are frequently totally ignored by the authorities as they prescribe sampling from the square root of the number of packages in a consignment. Whilst the consultant would freely admit this can be impractical in a high volume situation such as in a flour mill, it is not scientifically valid to take a single package as being representative

3 Investigation into Various Technical Aspects of the South African Food Fortification Programme; P. Randall December 2005. Compliance and Proficiency Testing – UNICEF Agreement No SSA/SAFB/2005/00000465-0

of the whole. The regulatory authorities and the industry need to arrive as a consensus view of what constitutes a legal sample.

The authorities also have to be aware of the possibility the test they are using may actually be an abuse of the method. The classic example of this is the titration method used to analyse Potassium iodate in salt; this test was actually originally developed to test the purity of the Potassium iodate itself not to measure ppm levels of iodine in salt.

One short cut the inspectors could take would be to obtain a sample from the mills own monitoring programme as described in Appendix 5

LABORATORY ANALYSIS EQUIPMENT AND PERSONNEL

UNKNOWN but the laboratory is housed in a purpose built facility financed by the EU and to EU standards so it is believed to be adequately equipped and staffed.

NATIONAL SAMPLING PLAN

In any fortification programme national sampling runs are integral part of sustainability. Firstly they indicate the level of compliance of the industry – complementing the specific mill inspections.

Secondly they indicate the level of coverage the fortification programme is achieving

TRAINING

Specific training in what happens in a mill, the sources of variability etc and sampling may be required.

SMALL(ER) MILLERS

One area that will need addressing is the issue of small(er) millers. Do they, can they, should they fall under fortification regulations or standards?

Fortification at small mill level is technically possible but an administrative nightmare plus it is often difficult to get the pre-mix to them.

Many of the mills actually do not own the wheat they mill – so called toll millers – but simply provide a milling service to the local community at a fee. Many will operate on an irregular basis.

Monitoring and enforcement of these mills may not be cost effective unless the national sampling runs indicate that a specific area has no coverage and a Demographic Health Survey indicates a public health risk in that same area. In which case then targeted fortification intervention and support (both technical and financial) would be indicated.

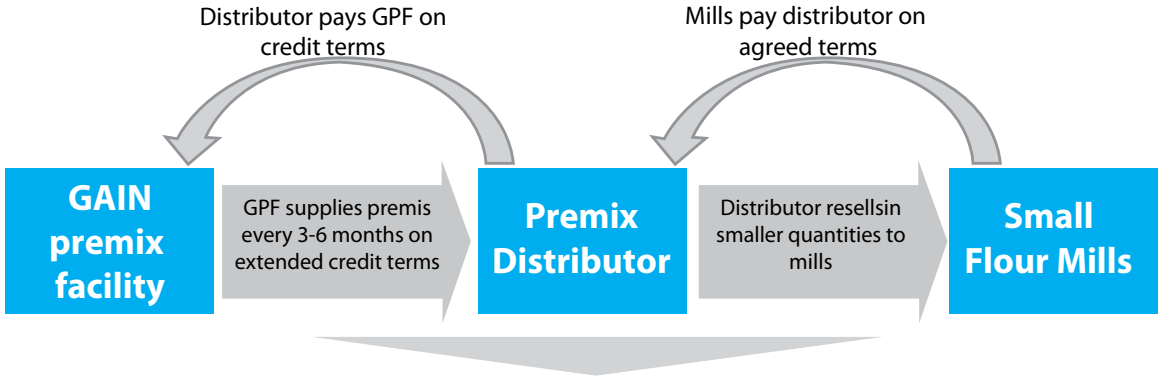
If the social marketing of fortification achieves its goal then the small millers will be asked by their community why they are not fortifying and the millers will come to the authorities seeking assistance.

Malawi and Morocco have had a measure of success in promoting small scale fortification, but it has taken significant donor and Government support to achieve this.

Case Study: Morocco Distributor Model

www.gainhealth.org

The GPF is working with premix distributors in Morocco to reach the hundreds of small flour millers with certified, affordable premix



Key Benefits of this Approach:

- The Distributor pay a key role in getting premix to teh small mills which the GPF can't service directly.
- Costomers leverage the overall volume by tendering for a consolidated order

MILLER – REGULATOR INTERACTION ON FORTIFICATION

In most countries, and the consultant expects Albania is the same, this is a problem – an "us and them" attitude. The consultant has been both a food inspector and a miller so would like to offer the following commentary:

The problem arises out of the fact that neither side understands the others position. The miller sees the inspector as a policeman (in many cases they are justified) who is out to make their lives difficult, who they can't go to for advice or technical support if they have problems because the inspector is perceived as looking for reasons to prosecute. The inspector has a set of rules that have to be complied with – sometimes rules that are not warranted or out dated or copied over from the pharmaceutical industry – and has little knowledge of the food production process. The inspector usually has too many duties and is under pressure (internal management) to meet unrealistic deadlines. Any food related incident that hits the media without it going through food control first reflects badly on the authority and specifically the inspector.

The inspectors are, or should be, fully conversant with both what the regulations

and standards state and why they are stated. Further the inspector should be capable of advising industry on how to comply with the relevant regulation or standard. The inspector then takes on the role of both monitoring and enforcing that regulation or standard.

Unfortunately, all too often, the inspector is viewed with suspicion and only as the enforcer who has no idea about the food process they are monitoring. This situation has arisen because the inspector has not had the time to learn about the industry they are monitoring – the inspector is dealing with all sectors of the food industry and such diversity takes years to understand. Specialisation of food inspectors is, generally, not an option as this tends to limit promotion prospects. Further the inspector is trained, or at least psychologically brainwashed, in protecting the consumer from food safety issues rather than specification compliance (except in the area of metrology).

Safety such as microbiological or toxicity issues are paramount and as such can be assessed with relative ease. If one package is problematic then it is highly likely all packages will have the same problem – there is also a limited need to understand the particular food process, though the inspector should be able to provide industry with some guidance as to where to start looking for the source of the problem.

Compliance with nutritional content is considerably more complex to assess.

Firstly industry and the inspectorate must both understand the inherent variability of the foods nutritional content, the inherent variability of the process (a flour mill is always in a state of flux which the miller tries very hard to minimise) and the difficulty the miller will experience in homogeneously mixing in very small quantities of micronutrients. The mill could, in theory, mix to pharmaceutical standards of homogeneity, but the cost factor would be unacceptable – especially in a staple food.

Secondly the inspector must realise that such variability is neither a safety risk to the consumer nor of any significance. The consumer will be consuming large portions of the food (±350 g of flour in this case - which will undergo further mixing in the bread making process) whereas the analyst who the inspector sends the sample to will use maybe only 0.5 g of the food. A bit more or less of the micronutrient in any portion is irrelevant. The analyst can only report on the analysis of the sample as received not on its representativeness of the total food produced - that is up to the inspector (hence the argument about CAC/GL 50 above). The analyst is also aware (or should be) of the analytical error in the analysis but rarely declares that error to the inspector who, almost certainly, would not be aware of it.

The inspector, however, has a regulation or standard to uphold and by training and past experience views analytical reports in a pass or fail mode. The “rule book” does not permit value judgement.

It is essential, therefore, that industry and regulator both be involved in the regulatory process and, especially for flour fortification, the inspector should have at least a passing knowledge of the milling process and the stringent QA/QC processes that the mill is (should be) implementing. Industry will comply

with any sensible fortification requirement as the cost of fortification is so low whereas the cost to brand image of non-compliance can be crippling.

A short workshop on the fortification process followed by a practical in a mill usually goes a long way to minimising the barriers between the two stakeholders.

"SOCIAL MARKETING"

The term social marketing is in " " as it is being used rather loosely. What is required is probably a mix of social marketing, health communication and health education with social mobilisation and community advocacy also possibly being required.

The millers, bakers and the consumer association are already saying they are on board with the fortification initiative but all stakeholders are also aware that consumer awareness is very poor and that a significant amount of effort will be required in raising this awareness – specifically on fortification.

This will actually be a function of Government – possibly a cross Ministry function – that will need to focus on the health benefits and the fact that fortification alone will not influence the bread price.

The actual messages, and means of getting them across, needs to be established through wide consultation. Consultants' research, discussions with stakeholders and members of the public have indicated television as effective means of communication to a wide sector of the population.

SOME POTENTIAL MEDIA ISSUES WITHIN FLOUR FORTIFICATION PROGRAMMES

(extracted and adapted from a document created by Peter Ranum)

In any programme care should be taken to be aware of and be able to react to negative publicity on the fortification programme – having pre developed answers should be considered; or at the very least have a small group of people who have the necessary knowledge and authorisation to speak to the media. Examples (not all of these are valid arguments or will be applicable in Albania but have been included to give an idea of the type of problems that have arisen – *some comments have been added in italics*) these are:

1. It will not help everybody. Population groups most susceptible to micronutrient deficiency – the poorest of the poor, pregnant women and young children - are too often not reached because they consume little in the way of flour-based foods and the amount of fortifying agent added to flour is likely to be too small to meet their needs. *It will not help everybody is certainly going to be true initially and the poorest of the poor may not be reached initially. The food consumption is not applicable in Albania*
2. There is no agreement on fortification levels for young children that are both effective and safe. *Incorrect – WHO and CDC have established effective and safe levels*

3. A large portion of the world's population does not consume flour or maize meal as a staple food. *Not true for Albania*
4. Surveillance systems have not been adequate to insure compliance and safety in some countries, and the cost of starting and maintaining such a system is usually not considered. Many cash-strapped developing countries have neither the personnel, facilities nor other resources required to establish such systems
5. Convincing evidence is still lacking on the effectiveness of flour fortification with iron. *Incorrect – WHO and CDC have accumulated evidence; the problem arises that some countries are using electrolytic iron which is not generally well absorbed, consumer habits such as drinking tea with their meal inhibits iron absorption and other health issues such as malaria*
6. Iron fortification alone is ineffective in correcting iron deficiency unless the contributing factors are simultaneously addressed. *Agree – it is not a silver bullet – but in Albania the other factors are being addressed*
7. There are increasing concerns about the possible adverse effects on some population groups of folic acid fortification. *This one has arisen in Albania already at Institute of Public Healthsee*http://www.sph.emory.edu/wheatflour/folicacidpresentations.php *for plenty of answers to this*
8. Accurate information on the magnitude of folic acid deficiency is lacking, and there is no evidence that genetic defects are evenly distributed throughout the world. *Increasing evidence is emerging but Albania has no visible data*
9. The public health rationale for large-scale flour fortification with zinc and B vitamins remains to be demonstrated. *Zinc is coming under increasing public health interest and B vitamins are justified as they are all contributors to health (that was why they were originally erroneous called "vital amines" and if you are deficient in one micronutrient you are probably deficient in several others. They also act synergistically*
10. An emphasis on flour fortification could divert attention from using other effective food vehicles - at least where iron is concerned - such as fish sauce, soy sauce or curry powder. *Not applicable in Albania*
11. Flour fortification could change dietary, and therefore trade, patterns in cultures where flour is not a staple food. *Not applicable in Albania*
12. The decision to fortify flour should be left to the national public health authorities based on the specific mix of local needs. They should consider and include other intervention methods. *It has been and other interventions are not only considered but ongoing*
13. There is strong tradition in some countries that certain traditional foods, such as flour and bread, should

be "pure" and kept free of chemical adulterants. *Certain this one will arise but you are not adding chemical adulterants but micronutrients that are/were already in the diet*

14. Fortification standards will restrict the free trade of these foods between countries. *Certain this will arise as well – fortification is not a TBT but you must follow WTO rules*
15. Millers and bakers will use fortification as an excuse to raise the price of their products in excess of what it costs them to do it. *Already an issue – the message about how minimal the cost of fortification is must be clearly spelled out.*
16. Mass fortification will be viewed as an attempt to control population growth. *Common one this – adding contraceptives – social marketing, health communication etc must clearly say why this is being done*
17. There is no good agreement on the types and levels of micronutrients to be added to wheat flour and maize meal. *There are clear guidelines issued by WHO etc that allow for choice of micronutrients according to food vehicle and need*

DRAFT IMPLEMENTATION PLAN

At this point in time (November 2010) the number of people who have any awareness of the flour fortification initiative is extremely limited – wider consultation is required.

ACTIVITY 1

Whilst a provisional pre-mix formulation has been developed it is necessary that before Activity 2 begins the relevant stakeholders (Ministry of health in consultation with professional associations has to agree on premix formulation) and establish positions on possible additions to the formulation i.e. Vitamin B complex and Zinc etc. Any additions should be justifiable on the basis of identified or perceived need, costed and be ready for debate in Activity 3.

Time line is as soon as possible and must have been completed by the start of Activity 3

ACTIVITY 2

Establish a complete list of potential stakeholders and facilitators and their availability.

Draft an agenda for Activity 3

Establish any cost implications of Activity 3 and source the relevant funding.

Formalise and disseminate the information regarding time, place and duration of Activity 3

Time line is as soon as possible and must have been completed by the start of Activity 3

ACTIVITY 3

A national meeting facilitated by experts in the various aspects of flour fortification is needed, and has in fact been requested during this feasibility study.

This meeting should take note of the following identified success factors in other fortification programmes and act accordingly:

- ✓ Generate knowledge and awareness
- ✓ Timely action before a perfect plan
- ✓ Consider other experiences applicable
- ✓ Abandon "Tunnel Vision Nutrition"
- ✓ Create an effective communication climate
- ✓ Generate concrete plans and the adequate legal framework
- ✓ Participation of all players in developing a solution, not only implementing it
- ✓ Develop "catalyst" or "interface" agents
- ✓ Regulation framework established by consensus
- ✓ Industry self regulation
- ✓ Health authorities in a more enabling than controlling role

The meeting should involve all stakeholders from Government to consumer and the stakeholders should be decision makers who can not only authorise certain activities but be capable of getting them done. One word from a Minister or Deputy Minister can launch the full might of a Government Department. Similarly one word from a Managing Director of a flour mill can instigate implementation of fortification as soon as the necessary tools (equipment, pre-mix etc) are in place.

The national meeting should conclude with concrete agreements to facilitate fortification and an agreed upon action plan with time lines. This national meeting then needs to

establish a "National Fortification Alliance" (NFA) that can oversee the process, facilitate removal of any obstacles encountered and co-ordinate activities.

AGENDA

Sufficient information has been already gathered to conclusively demonstrate that a public health problem exists, that fortification as part of a national strategy can alleviate the problem, that the chosen food vehicle is viable and that the cost implication is minimal. This information needs to be disseminated to the wider audience of stakeholders so that they can provide their inputs in a free debate in which instant decisions can be made.

Once a decision is reached on the points below it should be clearly minuted who is responsible for that task (preferably a name as well as their institution) with a "plan B" for unforeseen circumstances. Many programmes have undergone delays due to promotions or reassignment of individuals (completion of a successful programme is largely due to specific individuals rather than institutions). The meeting should also be aware that sometimes these changes introduce individuals who do not agree with a specific approach and come to a consensus view on how that should be addressed if it happens.

The formulation of the pre-mix needs to be consensually agreed with inputs from nutrition, public health, academia bearing in mind inputs on possible technical constraints on industry (must not change the product in anyway), cost implications and safety. The suggested starting point is:

Ferrous Sulphate or NaFeEDTA at 20ppm or 15ppm respectively

Folic acid at 1ppm

Vitamin B_{12} at 0.008ppm

All of the above is in accordance with WHO Interim Consensus Statement http://www.who.int/nutrition/publications/micronutrients/wheat_maize_fortification/en/index.html

Activity 1 may have concluded that some additions to the above are required and these should now be presented at this forum for initial debate. The outcome of this debate should be a consensus agreement on 2 or 3 possible formulations (bearing in mind experiences of other countries) which can then be tested by industry for compatibility (See Activity 4).

It should also be discussed that if, at some future point in time, another micronutrient needs to be added to address a public health problem what should be the protocol for implementing this change – it is not practical to have activity 3 level meetings for such issues so a short, sharp process needs to be agreed upon.

Industry needs to establish if they are going to procure the necessary micro feeders through their own network or whether they are going to collectively place an order with a supplier (usually has cost savings through bulk ordering) or a combination of both. If any collective approach is going to be used consensus must be agreed upon as to who is the focal point for this.

Customs and Excise need to clarify if HS Code 84.37 is their interpretation of the requisite importation procedure and what the import tariff implications are, if any. Should the import

tariff be anything but zero then this meeting should press Ministry of Finance for either a zero rating (which 83.37 has) or for exemption on this consignment. An immediate decision on this needs to be made.

Similarly industry needs to establish the process of procurement of the pre-mix. This needs to be decided at this point in time as the procurement process has implications on the regulatory framework.

Again Customs and Excise need to clarify if HS Code 30.03 is their interpretation of the requisite importation procedure and what the import tariff implications are, if any. Should the import tariff be anything but zero then this meeting should press Ministry of Finance for either a zero rating (which 30.03 has) or for exemption on all and any future imports of pre-mix. Pre-mix is an ongoing cost in the fortification programme and, as such, Governments have zero rated pre-mix in other fortification programmes if they had any previous tariff in place. An immediate decision on this needs to be made. In essence tax exemptions should be advocated for – if necessary as industry should not have to bear the full cost of addressing a public health issue. The Government should also take ownership of this and lessen the burden on the industry and make it more feasible i.e. Government in an "enabling" role rather than a "controlling" role.

The next agenda item needs to be a discussion on whether the fortification programme is to be a voluntary or mandatory one. All of the indicators point towards a mandatory programme but this must be agreed upon at this meeting and all parties aware of each other's position on this issue. Should it not be possible to reach a consensus view on this matter then Government must fiat on the issue immediately. This is not a matter that can be held over as it significantly impacts on regulatory activities.

Having established the programme to be mandatory an open discussion on the legal framework is required. The options are a specific regulation or a technical standard.

Whilst the actual formulation will not be known at this point the general outline can be drafted i.e. what factors need to be included, implications of existing regulations etc, who has the mandate to monitor compliance and how that monitoring will be carried out (see below).

The monitoring system needs to be discussed and agreed upon. Chemical analysis of fortified flour is not as easy as many think due to the low levels of analyte being tested for. Nevertheless it forms the cornerstone of many regulatory activities. The option of monitoring through a "paper trail" needs to be considered as an alternative or complementary method. The meeting should debate the relative merits of monitoring through certification of the pre-mix from suppliers who have been authorised by the regulatory authority or some other body that the regulatory authority accepts i.e. the GAIN programme uses independent accredited laboratories to monitor the pre-mix used through its pre-mix facility and, essentially, underwrites that pre-mix to the buyer. Either way it should be agreed that it is Governments role to establish that the pre-mix is fit for purpose (the miller has neither the equipment nor the competency to perform

this task) and take into account that the industry will require that they are not stuck with a sole supplier issue i.e. you can buy from who you want provided they are pre approved by the regulator.

Sampling protocols also need to be discussed and agreed upon – noting that some existing legislation in this regard may already exist. If some does exist it will be necessary to discuss if the existing protocol is valid for the purpose of fortification compliance.

The cost implications, and who pays, for compliance monitoring has to be agreed upon and such discussions will obviously impact the monitoring structure debate. National sample runs are not an issue as that is a Government cost factor. The dissemination of the results of those sample runs need to be defined – what information is disseminated, in what form and to whom.

Staff level capacity and competency issues may arise and it is important they are openly discussed and how any shortcomings can be addressed and over what time frame.

Agreement will have to be reached on the type of labelling that will be required and it clearly established what nutritional claims can and cannot be made. A standard nutrient content label format should be agreed upon with the actual numbers being filled in at a later stage. It should be all millers should use the same label to avoid confusion/misrepresentation in the market place. This label derivation must recognise that the intrinsic content of the wheat flour is a variable so it must be agreed upon what typical values should be used for the intrinsic content, thereby permitting the calculation of final content to be derived. This has often unforeseen consequences in that challenges to nutrient content being true to label declaration from either an individual, an organisation or a country need to be considered. Using the values published in an accepted nutrient database i.e. USDA National Nutrient Database is usually acceptable in international law.

Additionally it will be necessary to establish exactly who will be covered by the regulation or standard – this has significant implications on the small(er) millers – and will need to be guided by legal opinion as to the constitutionality of legal framework as well as the practicality of monitoring and enforcement and other flour importers of the pending fortification activities. One argument is that regulation has to cover all. One provision can be made where fortification can be implemented in phases (similar to what they did in Morocco). You start with the large mills which cover the largest market share, create awareness and educate population, demand will increase, then move on to the smaller mills). The counter to this philosophy is that not all mills actually own the grain they mill i.e. they are “toll” millers who provide a grinding service to their clients – it is unclear if they fall under any typical fortification regulations.

Legal opinion will also be required on WTO implications (should not be a TBT issue) and agreement reached on who will notify neighbouring countries.

The debate on the strategy relating to communication and raising consumer awareness and should focus on iron deficiency anaemia and its consequences and fortification as an intervention as a means to address a

public health nutrition. It is essential that the consumer understands why this is being done so they will not reject the product.

Important issues are consensus views on what is in the messages that are going to be disseminated and agreement that all stakeholders are going to pass on the same message through their individual channels and/or forums. This discussion will be largely generic and will be fine tuned by a smaller group as a separate activity.

The possible inclusion of nutrition education and the importance of micronutrients into the school curriculum should also be discussed – specifically what should be included and when it could be included.

The meeting, having discussed all of the above, should now be in a position to take a clear position on when all of the above can be completed. This time frame should be realistic as industry will have a time limiting factor on packaging which they typically order large quantities at a time – knowing there is going to be a label change will impact on their procurement process; legal will have a time limiting factor of obtaining comments on the proposed legal framework and developing a communications plan is usually a relative long and laborious process. Depending on the starting date for Activity 3 – which if that is early in 2011 – a launch of fortification with much media coverage and comment from Government should be possible in November 2011

It should also be noted that funding for many of the activities may need to sourced and it should be agreed upon how much and who will be funding it.

Having reached consensus on all of the above issues decisions can then be made on the composition of the NFA – which should be as small as possible but also as representative as possible. This group should be capable of meeting at least every 3 months and issuing progress reports to all stakeholders.

The meeting should conclude with a written Memorandum of Understanding which clearly states who needs to do what and have indicative timeframes. It should also have a statement of commitment to the process. This MOU should then be signed by all stakeholders.

The time line for this is as soon as possible in 2011.

ACTIVITY 4

The milling industry will, understandably, require proof that the suggested formulations do not have a significant impact on their product. As such they will require testing the formulations themselves.

It is suggested that GAIN be approached for a donation of the relevant formulations by UNICEF which can then be distributed to the various mills.

Once the trials have been completed – which should not take more than 2 months including storage tests – the millers can provide inputs to NFA for appropriate action and into Activity 6

The time line for this should be about 1 month after the activity 3 to allow for sourcing the different pre-mixes and should be completed within 3 months of activity 3. Activities run by the millers.

ACTIVITY 5

Promulgation of the legal frame work drafted

in activity 3 and circulation to all stakeholders for comment. The addition of information from Activity 6 can be included later.

The time line of this should aim at getting out the draft within 2 months of activity 3 to allow 3 months for comments. As activity 6 data becomes available this can be issued as an addendum. Activities run by the relevant legal department.

ACTIVITY 6

Once a consensus view from industry on the impact, if any, of the pre-mix on their flour and bread has been achieved then the pre-mix formulation will be fed in by the NFA.

This activity will then design the necessary nutritional label and pass the information on to both the millers and the monitoring authority.

The time line for this will be from about 3 months after activity 3 and should be completed within 1 month. Activity run by the nutritionists of the relevant stakeholders.

ACTIVITY 7

A communication strategy will have been discussed in Activity 3 so the group will have a framework to work within. This framework will need fleshing out and a definite plan for dissemination complied with a budget.

The time line for this will be immediately after activity 3 and will last at least until the fortification launch. Consideration should also be given to if reinforcement of the fortification message will be required after the launch. Activities run by the Ministry of Health communications team with technical support from UNICEF, WHO etc

ACTIVITY 8

This activity will be the oversight operations of NFA who should meet on a regular basis and have a constant thumb on all activities. They do not need to necessarily participate in these activities themselves but they must be aware of who is doing what and when. They should be proactive in communicating with the other activities checking for potential stumbling blocks and facilitating their removal. The time line for this will be immediately after activity 3 and will continue until the launch of fortification. Activities run by the elected stakeholders.

APPENDICIES

Appendix 1

Major tasks to be accomplished in this assignment

- Conduct milling industry visits using the attached template questionnaire to assess the production of fortifiable flour in the current state of the milling industry. (Fortifiable flour is defined as flour produced in flour mills with rated capacities above 30 MT per day). Number of mills assessed to be agreed with focus on large ones.
- Data should be collected from individual milling company visits and should include information on ownership (private versus public), rated capacity versus utilization, quality control systems used, process control systems, flour types, extraction rates, flour market information, flour prices.
- Data should be collected on the flour milling industry at the industry level, covering industry of food association, milling industry ownership, wheat procurement (imported or local) Wheat prices, flour prices, Imported flour levels, export flour levels, food subsidies, flour markets bakeries versus home baking.
- Data to be collected on fortification equipment needs fortification QC needs and premix requirements. Total fortification costing possible based on other consultancy.
- Mill visits should be used as an opportunity to advocate for flour fortification at the mill and national industry level.
- Visit to food control authorities to assess and determine additional equipment, personnel and training requirements to monitor flour fortification.
- Facilitate and present at relevant meetings, seminars and roundtable discussions with national stakeholders;
- Work closely with UNICEF Health officer and national counterparts to conduct the assessment.

End product

Assessment report

Deliverables:

- Preparation of Summary report listing number of mills, range of operating capacities and utilization rates, main flour types and percentage of demand for flour each type
- Summary on potential impact of flour imports and exports on market share and reach of fortified flour.
- Develop a list of feeders and fortification equipment, premix requirements, QC tools and equipment for national implementation of fortification
- Develop a draft implementation plan and budget for flour fortification at the milling industry national level.

Appendix 2

1. Name of mill – identify if mill is a single entity or part of a milling group within Albania
2. Location
3. Contact details
4. Public or Private ownership
5. Mill Information

Annual Purchases (MT)	Import or Local (%age)	Source	Mill Rated Capacity(MT/24 hours)	Mill Utilisation (%age)	Actual Milling (MT/24 hours)	Time spent milling per day per week
Comments on Data by Consultant						

7. Extraction Rate
8. Procurement Information – Grain

Grain Source	Procure self or via Trader	Cost FOB	Cost Mill Gate	Cost Distribution Shipping	Cost Distribution
Comments on Data by Consultant					

10. Product Information

Flour Types	Proportion of Production (%age)		Pack Size (Kg)	Proportion of Production (%age)	Cost (Lek)
00			50		
040			25		
045			12.5		
050			10		
055			5		
070			1		
080					
090					
Bran					

12. Capacity and Capability to Fortify

Add Improvers	Use Micro Feeders	Dilute prior to Addition	Testing Capability	Improver Ingredients and/or Brand Names
Comments on Data by Consultant				

14. Open Discussion – Concerns of Miller

Appendix 3

NOTE: A shortened version of the questionnaire was used with the smaller millers for several reasons.
Firstly they would be asked for these answers by e-mail/fax and telephone.
Secondly they would be asked these questions by someone who may possible be seen to have a vested interest (KASH) rather than by the consultant.
Thirdly it had already been established that obtaining some of the information was extremely difficult and the list below was considered to be a minimum requirement.

1. Name of Mill
2. Location
3. Maximum Capacity of Mill
4. Quantity of wheat milled per year
5. Percentage Local Wheat
6. Level of Utilisation
7. Wheat Price Mill Gate per MT
8. Flour types produced
9. Flour Price Range at Mill gate
10. Flour Pack Sizes

Appendix 4

The following is extracted from a Small Millers Training Manual prepared and edited by the consultant, funded, published and circulated by the South African Department of Health, GAIN, Micronutrient Initiative and UNICEF

Micro feeders – Questions to ask yourself and the suppliers

How accurate is the micro feeder?

Feeder accuracy, in itself, is not a single determinant. It is a function of repeatability, linearity and stability. Repeatability is consistency of feed at a given setting; linearity is how accurately the feeder discharges across the operating range and stability is performance drift over time.

- **Repeatability**

Commonly termed precision this factor is the most familiar to users and is a measure of the short term consistency of the discharge rate. It is important to quality assurance because it measures the variability of the discharge feed[4] and hence of the final product.

Repeatability is measured by taking a series of timed samples from the discharge stream, weighing them, calculating the standard deviation and expressing that deviation as a percentage of the mean value of the samples taken (coefficient of variation). Given a coefficient of variation of 0.2% a variation of 1 deviation (±) means that in 68.4% of cases the variation from the mean will be ± 0.2%; for 2 deviations 95.5% will be mean ± 0.4%. Traditionally 2 deviations (sigma) are considered acceptable.

A definition of repeatability should include both the variability and the method used to determine that variability assessment i.e. ± 0.5% of average @ 2 sigma based on 20 samples of 1 minute.

- **Linearity**

The repeatability above measures only the variability of the discharge – it does not provide information about whether the feeder is delivering, on average, the targeted rate. To perform linearity several groups of samples need to be taken across the stated operating range[5], and these values then averaged to produce a single value. Again average values and deviations are calculated. A linearity statement would, therefore, look something like ± 0.2% based on 5 samples of 1 minute over a range of 5% to 100%

- **Stability**

This is perhaps the most important criteria, and the one most overlooked. Many factors contribute to drift – some are the characteristics of the fortification mix the rest are feeder related. Drift

4 Note this does not include the variation in the flow rate of the mill product i.e. the maize meal or bread flour.

5 Note this will typically be 5 to 100% but millers should be wary of using a feeder that is operating so close to the limits of its capability.

is checked by calibration checks – the more often and severe the drift the more checks, and adjustments, are required. This is a hidden on-going cost to the miller and out of specification product (which carries its own economic consequences).
You should ask the supplier about the above factors. Remember however, the tighter the variation the higher the cost is likely to be.
One of the best ways to establish if really minimal variation is necessary is to look at the cost in terms of fortification mix. Yes the variability will be both positive and negative but it tends to shift towards the negative (give higher overages) as the fortification mix becomes compacted. The more QA checks that are put in place the more frequently the overage is reset to zero but costs can rapidly spiral out of control. Obviously the higher the volume the greater the potential losses but even with the cheapest volumetric feeder on the market and a low overage with single shift and a five day week the loss is potentially 7.5% of the initial capital outlay per year.

Volumetric or Gravimetric?
By definition gravimetric feeders measure the weight and adjust output to maintain the desired discharge; volumetric feeders do not weigh the discharge they deliver a set volume of material per unit time (based on the constraints mentioned above) which is translated to an inferred weight based on the manual calibration.
Volumetric are simple and cheaper but cannot detect or adjust to variations in the fortification mix. For materials that do not vary significantly in density this is not an issue. Fortification mixes do vary. Variation in density between individual suppliers can be accounted for in the calibration. Variation in density over time requires that the feeder minimise the effect. The mill is constantly vibrating causing compaction of the fortification mix and, therefore, an increased weight per unit volume discharge. Conditioning augers and various other techniques are crucial to the minimisation of this density effect.
Volumetric feeders are the most common in the food industry but such density variation must be addressed. This density variation will be clearly seen in the stability tests.

What type of screw feeder?
Volumetric feeders deliver a set volume per unit time. Altering the flow rate is accomplished by altering the screw speed. A range of screw designs, sizes and geometries plus agitation systems are used (or not in some cheaper systems) to optimise discharge characteristics.
Three main factors influence screw feeder accuracy. The consistency of the delivered volume per screw revolution, the accuracy of screw speed control and the material density variation.
Free flowing materials fill the screw consistently – as fortification mix is slightly hygroscopic- this flow ability must be protected by the miller taking suitable care of the fortification mix. Materials can also be too free flowing – termed floodable – and flow uncontrollably through the screw. Back stream blockages are likely to remain undetected for considerable time unless suitable protocols are instituted i.e. visual check of discharge.

The supplier is in the best position to advise the best configuration for the fortification mix – the technology behind single or double spiral, single or double auger, fixed or variable pitch etc has been developed for a reason; they each work best in specific circumstances. Suppliers should be in a position to offer alternatives and always insist on a demonstration.

What are the main trouble shooting and maintenance issue?

- **Training**

Assuming the feeder was properly selected and engineered then most problems arise from improper installation, inadequate maintenance, lack of operator and maintenance training and changes in the fortification mix or operating conditions.
Many micro feeders look "plug and play" and suppliers usually offer installation as a "costed extra". Many problems can be avoided both at the outset and in the future by ensuring staff receive adequate training and problem solving skills and supplier installation should be viewed as insurance for the future.

- **Fortification Mix**

If a feeder was selected, engineered and configured to handle a particular fortification mix changes to the fortification mix or operational requirements can cause unanticipated problems. As changing the fortification mix may alter flow characteristics outside the anticipated range you may find that changing back to the original fortification mix supplier may be the most viable option. Increasing the capacity of the mill may take the discharge rate outside the feeders capabilities – many feeders have the capability to be re-ranged, something to consider if expansion is on the horizon. Variation in ambient temperature and/or vibration can also lead to problems – the supplier is often the best source of advice.

- **Speed Control**

With volumetric feeders the most common cause of problems is the integrity of the speed control and a change in the volume per revolution relationship.
If the speed sensor does not perform accurately then control is impossible. Depending on the specifics of the mechanism then cleaning or replacing is usually required. It is always best to first check if it's not a loose connection (see the importance of supplier installation and training).
If the screw speed control is not the problem then the most likely cause is the volume per revolution relationship. The most likely reason is a build up preventing consistent flow. The short term solution is to strip and clean the screw and/or discharge tube. The more permanent solution may require a change in screw design, bin design, or agitation or even something else. Such modifications are usually more expensive than procuring the correct feeder in the first place. Check that adequate training is offered and confirm with staff that the training has been absorbed.

Some things to look for –

- Interchangeable screws, hoppers etc
- Easy cleaning through quick disassembly
- Minimal moving parts with durable seals
- Material handling mechanisms to minimise compaction and maximize screw fill
- Accuracy
- Low operating cost
- Easy maintenance.

Much of the above, and recommended further reading, came from:
Feeder Accuracy and Performance Timescales; Feeding Technology for Plastics Processing

Appendix 5

The following has been sourced from the same reference as Appendix 4
The objectives:

- Provide information on what needs to be done to ensure that regulatory and consumer requirements are met.
- Improve knowledge regarding record-keeping and monitoring procedures that have to be instituted to be compliant with the quality assurance scheme.
- Improve understanding of different elements of the inspection procedure to be followed.

Control and Monitoring Systems

Quality assurance / quality control is the total of the organised arrangements made with the objective of ensuring that food products are of the quality required for their intended use at consumer level. It is important to ensure quality control processes comply with food fortification regulations.

Mill Quality Assurance and Quality Control

An effective quality assurance / control system is vital to maintain the quality of fortified food stuffs as they are released in the market place. The standard procedures for mills to ensure bread flour is properly fortified include:

- The use of quality and appropriate equipment and weighing units.
- Keeping correct fortification mix inventory records.
- Proper handling and storage of fortification mix.
- Keeping correct production records.
- Conducting regular equipment inspection, once every 8 hour shift.
- Conducting regular analytical tests of samples to verify that they have been properly fortified.
- Proper labeling and packaging.

Implementation of quality assurance and quality control systems requires full cooperation of millers and government monitoring units

The following steps must be taken by the manufacturers of fortified bread flour to ensure quality control of the fortification process:

- Purchase blending equipment and / or feeder(s), weighing scales, and learn how to use the equipment properly.
- Purchase fortification mix from suppliers that have been registered with the Regulatory Authorities.
- Store fortification mix in air-tight containers well protected from exposure to light or under

the conditions laid down by the manufacturer. It is ideal to keep fortification mixes in their original containers. Once opened, exposure to the light and air should be minimized to prevent product degradation.

- Obtain and keep on record a certificate of compliance (CoA) for every batch of fortification mix.
- Employ, and adhere to, strict stock rotation procedures to prevent old stock losing potency and to comply with the shelf life expiry date. It is recommended they employ and implement the first in, first out (FIFO) system for this purpose.
- Keep records of grain procurement;
- Keep records of fortification mix inventory and usage;
- Keep production records of the amount of fortified bread flour produced;
- Keep monthly records of the amount of fortification mixes used every month. These records shall correspond with the monthly production records;
- Ensure that all critical stages of the manufacturing process are monitored to ensure the correct dosage levels are maintained through the following measures:
- Checking of fortification mix feeders at least once a shift (less frequently if reliable micro feeders are procured) to ensure they are delivering the correct dosage levels. This can be done by measuring the weight of fortification mix discharged over a specific time (1 or 2 minutes) and comparing the measurements with the target weight of fortification mix.
- Performing visual checks at least twice per shift to ensure fortification mixes are being used and that no blockages have occurred, and keeping a record of this.
- Performing iron spot tests on the bread flour at the start and end of each production run to ensure the product has been dosed correctly.
- Make all of these records available for inspection by the monitoring authorities who are responsible for monitoring the fortification program and in implementing inspection or monitoring systems for all fortified food products.

Some guidelines on the type of paperwork expected and the iron spot test are provided below:

Quality Assurance Forms

The forms that follow are examples of tools that can be used to establish a quality assurance protocol that will indicate to an inspector that the mill is doing its best to comply with regulations. These can be used as they are or can be modified to suit the miller's particular needs.

Fortification mix procurement and receival

- Keep a track of all aspects of your fortification mix procurement.
- Who you procured from, when and what.

EXAMPLE OF A FORTIFICATION MIX RECEIVAL RECORD

Supplier				
Batch Number				
Certificate of Analysis				
Quantity				
Delivery Date				
Order Number				
Invoice Number				
Invoice Amount				
Issue Date				
Voucher Number				
Signature				

Instructions mix receival record

Completion of the form: A duly authorised person in administration should complete this form.

Supplier: The onus is on you, the buyer, to ascertain that the supplier is actually registered.

Batch number and certificate of analysis: Registered suppliers usually retain adequate records to prove compliance with the specifications laid down for each fortification mix. Retaining the copies issued with each delivery reduces the administrative liability placed on the buyer.

Copies of "Certificate of Analysis", batch numbers and invoice tracking should be kept for 6 months.

Voucher number: It is strongly recommended that a requisition system be utilised to monitor the fortification mix. As a concentrate, the product has a limited shelf life.

Order number, invoice number and amount: Such records facilitate audit control

Example of an On-line process control sheet

Date:

Time	Operator	Low	Target	High	Comments

Instructions:

Use one sheet per shift rotation period i.e. 24 hours.

Indicate spot test result, compared to photographs, with an 'X' – typical photographs are illustrated in the section on the spot test itself for convenience.

Use comment section for any action taken i.e. "feeder adjusted"

Many millers like to take a sample of their production over an extended period of time so that they can submit some to a laboratory for confirmatory wet chemical analysis. Should you wish to follow that example then the steps below are the ones commonly used.

- Retain one teaspoon of product from each hour's production
- Blend above samples to produce a 24 hour composite sample
- Blend 7 daily samples to produce a weekly composite sample and retain +/- 500 grams of this weekly sample. Discard remainder of the weekly composite sample
- Blend 4 weekly samples to produce a monthly composite sample and retain +/- 500g of this monthly sample. Discard the remainder of the monthly composite sample.

Certificate of fortification mix compliance (CoA)

The actual appearance of the CoA differs from one fortification mix supplier to another but all the essential information is still provided.

The CoA is a very important document as it forms the first line of quality assurance and of the monitoring and enforcement programme. This document recognises that millers have neither the time nor the necessary skills to test the fortification mix to ensue it meets specification. As such Government have placed the onus on the supplier to guarantee that the fortification mix the miller has procured will meet the necessary standards until such time as the package is opened (the mix could now be tampered with) or until the expiry/use before date on the package.

Suppliers have to provide independent verification that they are complying with the legislation. Should the contents of the fortification mix not meet the stated specification then the supplier, not the miller, will be deemed to be at fault. The millers' only requirement is to procure from registered suppliers, or their agents, with the onus on the miller to ensure they are registered. Having demonstrated that the correct fortification mix has been procured from a registered supplier or their agent it is now only necessary to demonstrate that the fortification mix is being added as required by the regulations.

Bagging and stock control

Many mills have complex bagging and stock control systems. Inventory control forms a crucial part of establishing "due diligence" and, therefore, compliance with the regulations governing fortification. It also proves vital in financial control and establishing whether stricter stock control measures are necessary.

Example of an inventory control record

Period Start Date _____ Time _____

Period End Date _____ Time _____ Concentrate Type _____

Opening Concentrate Stock in Kilograms Physical stock as at Period Start – being the number of sealed boxes multiplied by 25kg plus the total actual weight of opened boxes.	A			
Concentrate Stock Received in Kilograms Total stock received between Period Start and Period End – being the number of boxes received multiplied by 25kg	B		TOTAL 1 A + B	
Closing Concentrate Stock in Kilograms Physical stock as at Period End - being the number of sealed boxes multiplied by 25kg plus the total actual weight of opened boxes.	C			
Concentrate Stock Loss in Kilograms Total stock loss between Period Start and Period End due to returns, damage etc.	D		TOTAL 2 C + D	
E. TOTAL WEIGHT OF CONCENTRATE USED FOR PERIOD **TOTAL 1 – TOTAL 2**				

Bag Ticket Number	**Row 1**	**Row 2**	**Row 3**	**Row 4**	**Row 5**
Finish The last bag number used during period					
Start The first bag number used during period					
Total Bags per Row Finish bag number minus Start bag number plus one					
Bag Size I.e. 65kg/ 50kg/ 15kg/ 125kg/ 10kg etc					
F Total Row Production Total Bags per Row for the period multiplied by Bag Size	F1	F2	F3	F4	F5
G. TOTAL WEIGHT OF PRODUCTION FOR PERIOD **F1 + F2 + F3 + F4 + F5**					

Total Theoretical Concentrate Usage Total Production for Period divided by the optimum concentrate dosage per kilogram G ÷ dosage	H	
Total Actual Concentrate Usage As calculated for total E	I	
DIFFERENCE BETWEEN THEORETICAL CONCENTRATE USAGE AND ACTUAL CONCENTRATE USAGE **H – I**		

The methodology for the spot test is:

IRON-QUALITATIVE METHOD AACC Method 40:40

Scope - Applicable to iron fortified wheat flour and iron fortified bread crumb.

Reagents:

Dissolve 10 g KSCN in 100 ml water. Mix with equal vol 2N HCl just prior to use.

Hydrogen peroxide 3%.

Procedure :

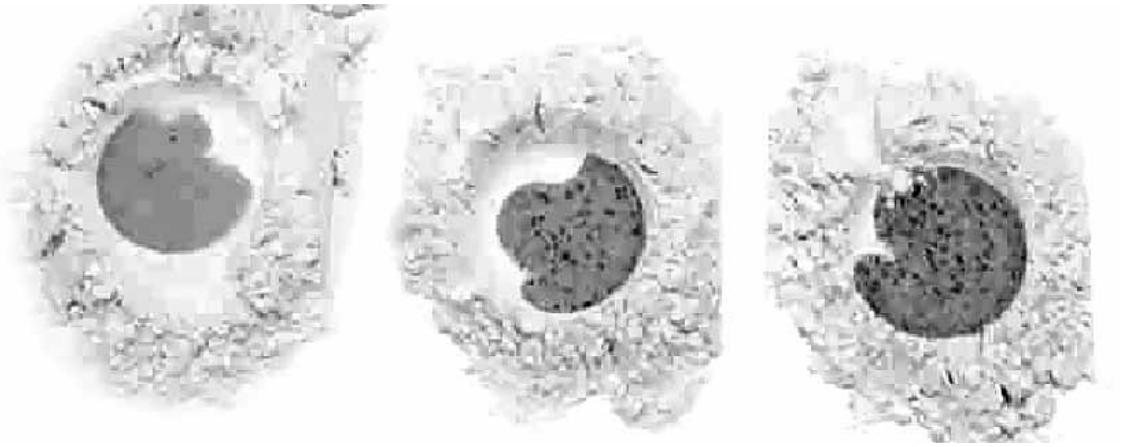
Make a flat surface of the flour or bread crumb by pressing down with a spoon. Drop a few mls of the freshly mixed HCl/thiocyanate reagent onto the surface followed by a few mls of the hydrogen peroxide sufficient to wet an area approx 1 inch in diameter.

If added iron compounds are present they will show up as red spots on the surface. Reduced iron shows up as small dots that take time to appear. Ferrous sulfate shows up as larger spots that appear more quickly. The density of the spots provides an estimate of how much iron was added, which is best done by comparison to flours having known levels of added iron.

Reference: Schlesinger, H. I., and Van Valkenburgh, H. B. 1931. The structure of ferric thiocyanate and the thiocyanate test for iron. J. Am. Chem. Soc. 53:1212.

Example of iron spot test on flour with different levels of added iron.

No added iron 30 ppm 50 ppm



MICRO FEEDER CALIBRATION AND CONTROL

INITIAL CALIBRATION

Firstly obtain an insight into the delivery capabilities of the micro feeder by carrying out the following:

- Half fill the hopper with bread flour (this has a similar density to the fortification mix).
- Turn the adjusting dial to 90% of maximum and let the machine run for 1 minute.
- Place a bowl under the outlet and collect the meal or flour coming out of the micro feeder for exactly 60 seconds.
- Weigh the flour.
- Turn the adjusting dial to 10% of maximum and let the machine run for 1 minute.
- Place a bowl under the outlet and collect the flour coming out of the micro feeder for exactly 120 seconds.
- Weigh the flour.
- Calculate the results as "quantity delivered in 1 hour" – remember that the result on setting 10 was taken over 2 minutes and not 1 minute as for setting 90

Draw a graph (put the machine settings 10 and 90 on the "x" axis (the horizontal line) and the quantity delivered on the "y" axis (the vertical line) of the results and join the two points.

The formula for calculating how much "fortification mix" an individual mill will require is:

(A / 1000) x B = quantity of fortification mix required per hour

Where A is the amount of fortification mix, in grams, required to fortify 1 MT (1000Kg) of bread flour. This amount is prescribed by the fortification mix supplier and will be clearly indicated on the container of the fortification mix.

Where B is the quantity of bread flour being produced in 1 hour.

For example a mill producing 3,200Kg of bread flour an hour and using a fortification mix requiring 250g to be added per MT the micro feeder should be set to deliver

(250 g / 1000 Kg) x 3200 Kg = 800 g

Look up 800 on the y axis and read off the corresponding value on the x axis. This is the setting the micro feeder should be set to so as to deliver 800g.

NOTE: We have taken 10 and 90 as our extreme points as there is a chance, particularly at very low settings, that the micro feeder will have higher errors – less likely if a reliable micro feeder is procured. Many manufacturers will specify the operating range and there values should be used.

Final calibration

For the final calibration it is important to use the actual fortification mix. Three settings need to be chosen and, at each setting, it is necessary to take multiple readings.

The most important setting is close to the one that the mill will be routinely using i.e. the one in the example above calculated above to deliver 800 g. Choose a setting that is easily made i.e. the target setting is 43 so choose a setting of 40 (the dial is usually calibrated in units of 10, though some have thumb wheels). Then choose 2 other settings equidistant around the above setting i.e. 10 and 70 (30 either side of 40).

The full calibration method is as follows:

1 Set the micro feeder on the lowest setting and let it equilibrate for 60 seconds.
2 Place a receptacle under the outlet and catch the delivered fortification mix for 120 seconds.
3 Weigh the delivered fortification mix and multiply that weight by 30 to get the weight delivered in 1 hour.
4 Record the result
5 Repeat 2, 3 and 4 four more times so that you have 5 results in total.
6 Check the results do not vary significantly – there should not be a variation of more than 2% between the lowest and the highest values. If there is a wide variability then repeat 2, 3 and 4 at least one more time.
7 Average the results obtained and plot on the graph "setting X quantity delivered in 1 hour Y"
8 Set the micro feeder on the highest setting and equilibrate for 60 seconds.
9 Place a receptacle under the outlet and catch the delivered fortification mix for 120 seconds.
10 Weigh the delivered fortification mix and multiply that weight by 30 to get the weight delivered in 1 hour.
11 Record the result
12 Repeat 9, 10 and 11 four more times so that you have 5 results in total.
13 Again check the results do not vary significantly – you should not have a variation of more than 2% between the lowest and the highest values. If you do have a wide variability then repeat 9, 10 and 11 at least one more time.
14 Average the results obtained and plot on the graph "setting X quantity delivered in 1 hour Y"
15 Set the micro feeder on the middle setting and equilibrate for 60 seconds.
16 Place a receptacle under the outlet and catch the delivered fortification mix for 120 seconds.
17 Weigh the delivered fortification mix and multiply that weight by 30 to get the weight delivered in 1 hour.
18 Record the result
19 Repeat 16, 17 and 18 four more times so that you have 5 results in total.
20 Again check the results do not vary significantly – you should not have a variation of more than 2% between the lowest and the highest values. If you do have a wide variability then repeat 16, 17 and 18 at least one more time.
21 Average the results obtained and plot on the graph "setting X quantity delivered in 1 hour Y"
22 It should now be possible to draw a straight line through all 3 points.
23 Clearly enter the following information on the graph:
Date
Name of person performing the calibration
Fortification mix details – Supplier and Batch Number

This now a valid calibration curve for this particular batch of fortification mix.

From experience it has been noted that batch to batch variation from the same fortification mix supplier is very small if at all. Changing suppliers does, however, usually require a

new calibration curve being generated. This is because different suppliers use different diluents (carrier) i.e. calcium carbonate, maltodextrin etc

If it is necessary to replace any part of the micro feeder then recalibration is required.

It is recommended that the calibration be routinely redeveloped at least every 6 months

Using the calibration curve

The calibration curve can now be used in conjunction with mill production data using the equation shown earlier.

Final adjustment

The above calculations have resulted in an estimate of the setting required on the micro feeder. It is very important that setting be checked and that the checking be repeated as indicated in QA Protocols.

Set the micro feeder to the setting estimated above and let the micro feeder equilibrate for 60 seconds.

Place a receptacle under the outlet and catch the delivered fortification mix for 120 seconds.

Weigh the delivered fortification mix and multiply that weight by 30 to get the weight delivered in 1 hour.

Compare the achieved result with the result actually required.

Adjust the micro feeder setting and repeat if required.

QA protocol

It is important that the micro feeder performance be checked on a regular basis. Adding too little fortification mix is against the regulations and will not delivery the expected nutritional improvement to the customer. Adding excessive amounts of fortification mix will be detrimental financially. Over dosing of fortification mix is unlikely to pose any dangers to the consumer. This is because the bread flour products i.e. bread, will have a strange taste that the consumer will object to. This occurs at dosage levels well below those likely to cause toxicity. Whereas the consumer will not be harmed they will, however, be unhappy and unhappy consumers do not, usually, become repeat customers – as a result business suffers.

Routine Checks

The following checks should be performed every two hours and the results of such checks properly and formally logged. This log will provide evidence of "due diligence" to the relevant inspectorate.

- Check the product delivery from the micro feeder by weighing the quantity delivered in 120 seconds and comparing it to the targeted delivery rate. Adjust if necessary and recheck delivery a few minutes later.
- Perform the spot test on the flour at some suitable point after the end of the meal or flour collection conveyor.