Quality Control and Quality Assurance at the Mill

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Flour Fortification Initiative
A Public-Private-Civic Investment in Each Nation

QC vs QA (extract from Wikipedia)

- **Quality control** emphasises testing of products to uncover defects, and reporting to management who make the decision to allow or deny the release.
- **Quality Assurance** attempts to improve and stabilise production, and associated processes, to avoid, or at least minimise, issues that led to the defects in the first place. To prevent mistakes from arising, several QA methodologies are used.

- QA does not necessarily eliminate the need for QC: some product parameters are so critical that testing is still necessary. QC activities are treated as an integral part of the overall QA processes.

www.diffen.com/difference/quality_assurance_vs_quality_control

- **Quality Assurance** is process orientated and focuses on defect prevention
- **Quality control** is product orientated and focuses on defect identification

Basic Principles

- Get the raw material (s) right
- Look after the critical parts of the process

- The finished product look after itself

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.

MAIN ELEMENTS

- Purchase appropriate blending equipment and / or feeder(s), weighing scales, and learn how to use the equipment properly
- Purchase fortification mix from reputable and/or registered suppliers
- Store fortification 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 minimised to prevent product degradation.

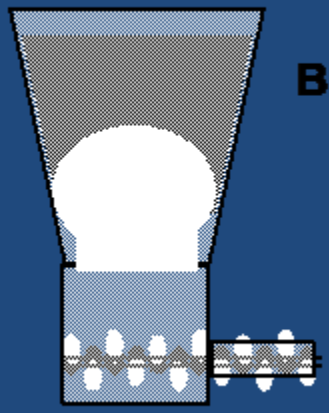
- Obtain and keep on record a certificate of compliance (CoA) for every batch of fortification mix.
- Employ, and adhere to, strict stock rotation procedures to prevent old stock losing potency and to comply with the shelf life expiry date. It is recommended you employ and implement the first in, first 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 should correspond with the monthly production records;

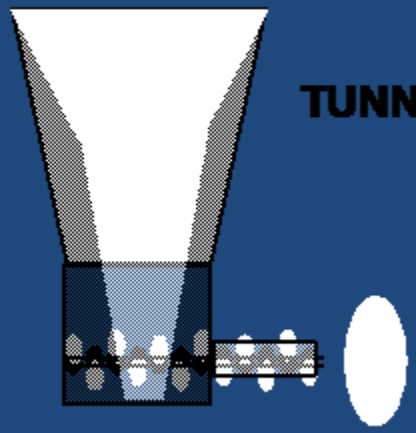
- Ensure that all critical stages of the manufacturing process are monitored to ensure the correct dosage levels are maintained through the following measures:
- Checking of fortification mix feeders to ensure they are delivering the correct dosage levels. This can be done by measuring the weight of fortification mix discharged over a specific time (1 or 2 minutes) and comparing the measurements with the target weight of fortification mix.

- Performing frequent visual checks to ensure fortification mixes are being used and that no blockages have occurred, and keeping a record of this.
- Performing regular iron spot tests on the bread flour.

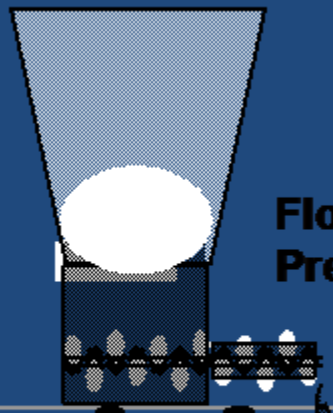
Premix Feeding Problems



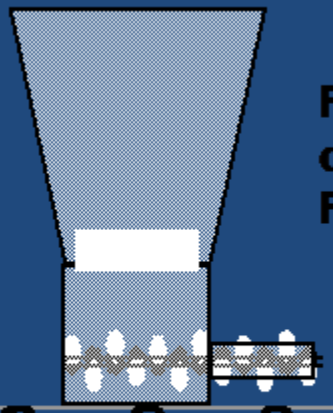
BRIDGING



TUNNELING



Flour stops
Premix keeps feeding



Feeder stops
or hopper empty.
Flour keeps flowing

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

No added iron 30 ppm 50 ppm

- If you can’t measure it you can’t control it

- Just because you can measure it doesn’t mean you have to

Making Life Easier


BÜHLER
S12
FLOUR-2

What Have We Forgotten?

Hint: Is the requirement only to add?

Left Hand Side Mixes – Right Hand Side Pushes

- Make all of these records available for inspection when required by the authorities who are responsible for monitoring the fortification programme and in implementing inspection or monitoring systems for all fortified food products.

Kenya example

- *"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.

Uganda example

- *"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.

Examples of Records

Good record keeping equates to
“due diligence”

- Make individuals not “departments” responsible for the records
- Ensure they are adequately trained – and you can prove they have been trained
- Have someone who understands the process check all the records
- Keep it SIMPLE

Example of FORTIFICATION MIX RECEIVAL RECORD

Supplier				
Type Maize/Wheat				
Batch Number				
Certificate of Analysis				
Quantity				
Delivery Date				
Order Number				
Invoice Number				
Invoice Amount				
Issue Date				
Voucher Number				
Signature				

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

No added iron 30 ppm 50 ppm

ON-LINE PROCESS CONTROL SHEET

Date:

Time	Operator	Low	Target	High	Comments

INVENTORY CONTROL

Period Start Date _____ Time _____

Concentrate Type _____

Period End Date _____ Time _____

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 in g Total Production for Period (MT) multiplied by the optimum concentrate dosage per MT G x 200g	H	
Total Actual Concentrate Usage As calculated for total E	I	

DIFFERENCE BETWEEN THEORETICAL CONCENTRATE USAGE AND ACTUAL CONCENTRATE USAGE = H – I	

Sampling for Compliance - LEGAL

- Codex CAC GL 50 recommends that the inspector samples from the square root of the number of packages i.e. If a warehouse has 60,000 bags then the inspector needs to take samples from **245** bags, combine them, mix thoroughly and sub-sample

- Taking a package from the packing line is not sampling
- Mill will have kept a small sample from each hours production and combined them – inspector has the mandate to take a sample from there

$$Total\ Error = \sqrt{Sampling\ Error^2 + Analytical\ Error^2}$$

Sampling Error

- Do something once error is 100%
- Repeat the above 4 times and halve the error
- Repeat the above 9 times and halve it again

Analytical Error

- Laboratories will thoroughly mix the sample received from the inspector
- Laboratory will then analyse the sample – possibly in duplicate and, more than likely, twice on the same extract rather than twice from the same sample

Total Error

- Laboratory error can be high - @ 95% confidence level for vitamin analysis in fortified product the result is ± 15-20%
- Distributing 200g of pre-mix in 1000Kg of flour is not easy even with a very good mixer so we could have a variation >30%

A Simple Example

- Consignment of Grain arrives at Mill.
- Mill want to test for Protein

- Variation within the truck (sampling error) is ± 0.4 %
- Analytical error on protein analysis is ± 0.2 %

$$Total\ Error = \sqrt{Sampling\ Error^2 + Analytical\ Error^2}$$

$$Total\ Error = \sqrt{(0.4)^2 + (0.2)^2} \quad = 0.45\ \%$$

$$Total\ Error = \sqrt{(0.4)^2 + (0.1)^2} \quad = 0.41\ \%$$

$$Total\ Error = \sqrt{(0.2)^2 + (0.2)^2} \quad = 0.28\ \%$$

$$Total\ Error = \sqrt{(0.2)^2 + (0.1)^2} \quad = 0.22\ \%$$

Chemical Analysis

- Is only as good as the sample itself
- Requires skilled analysts
- For fortification - requires relatively expensive to very expensive equipment and consumables
- Is time consuming and
- Most importantly its expensive

So why do it?

- Because the regulator says so
- Because we want the expensive piece of equipment
- Because “everyone” else is doing it
- Because we have to protect the public

Validity of Analysis

- Inspectors frequently take a grab sample - as they are overworked as well – so the sample is not representative but it is considered legal
- Mills are not pharmaceutical level processors and fortified foods are not like vitamin tablets (every single one the same) – we can get mills to that level of homogeneity but not economically

- The general public isn’t like an astronaut taking pills and pastes they eat bulk quantities of a food vehicle i.e. Bread which has undergone a further mixing process
- The analyst takes 0.5g of sample and tries to find the micronutrients – the consumer eats 200g of sample and lets the body find the micronutrients

So we scrap chemical assays?

- No – vital role to play in fortification programme.
- Ensure pre-mix is “fit for purpose” – note this is different to “conforms to specification” (concrete life jacket)
- Recognise the limitations of wet chemistry and use it not abuse it.

Fitness for Purpose

- Under QA we mentioned “fitness for purpose” as a prime tenant of QA
- Checking pre-mix as “fit for purpose” is a classic example.
- Vitamin A (and other vitamins) vary in price and that price difference has a hidden cost (fitness for use)

- Very few buyers ask themselves – why is this so cheap?
- Pre-mix suppliers are very price competitive so when one has a pre-mix significantly cheaper why do we think we are getting a bargain instead of being suspicious?

- We check the pre-mix and we find it "conforms to specification" so we assume everything is OK
- We said before in QA: "*Provide information on what needs to be done to ensure that regulatory and consumer requirements are met*"
- Have we checked consumer requirements?

- Consumer is expecting product to be true to label up to time of consumption (so is the regulator in many countries)
- We know we will get some losses during distribution and cooking chain but that is a factor we need to build in to our pre-mix formulation and addition rate
- Losses could be 20% depending on conditions