

Quality Control and Quality Assurance at the Mill

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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](http://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

Fitness for Purpose

- Get the raw materials right !!!
- Checking pre-mix as being “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, supplier and addition rate

- Who takes responsibility for ensuring the pre-mix is “fit for purpose”???
- Who permitted it’s importation???
- Can/Should you “assume” that because it is approved for sale it is “fit for purpose”???
- <http://www.gainhealth.org/gpf/suppliers/current-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.

RECORDS

- 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.

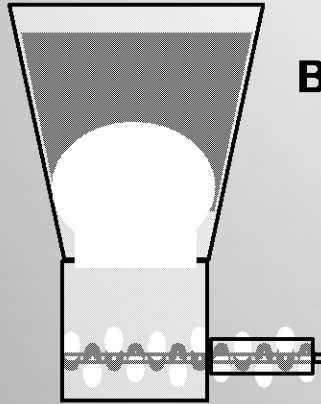
- Keep records of grain procurement;
- Keep records of fortification mix inventory and usage;
- Keep production records of the amount of fortified bread flour produced;
- Keep monthly records of the amount of fortification mixes used every month. These records should correspond with the monthly production records;

- Ensure that all critical stages of the manufacturing process are monitored to ensure the correct dosage levels are maintained through the following measures:

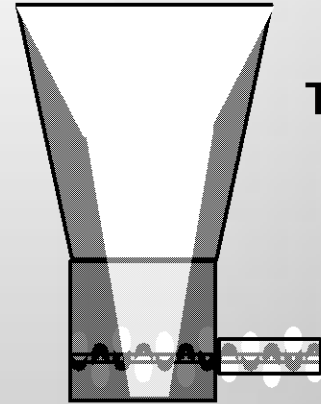
- Checking of fortification mix feeders to ensure they are delivering the correct dosage levels. This can be done by measuring the weight of fortification mix discharged over a specific time (1 or 2 minutes) and comparing the measurements with the target weight of fortification mix.

- 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.

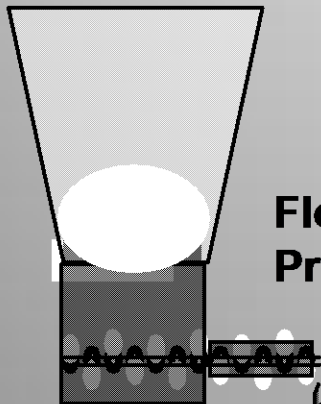
Premix Feeding Problems



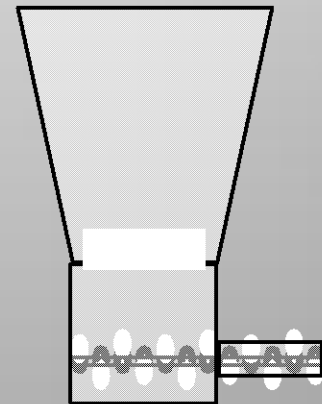
BRIDGING



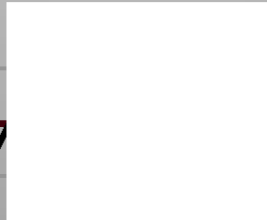
TUNNELING



**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







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.

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

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 $\pm 15-20\%$
- Distributing 200g of pre-mix in 1000Kg of flour is not easy even with a very good mixer so we could have a variation $>30\%$

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

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

A Simple Example

- Sampling error is $\pm 0.4\%$
- Analytical error is $\pm 0.2\%$

Total Error

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

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

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



Analysed 4
times

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



Sampled 4
times

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

So we scrap chemical assays?

- No – vital role to play in fortification programme.
- Recognise the limitations of wet chemistry and use it not abuse it.