Food Fortification Initiative
Enhancing Grains for Healthier Lives

AkzoNobel

Helen Keller INTERNATIONAL

IFSBH

Ministry of Foreign Affairs of the Netherlands

Maize Fortification Strategy Workshop for Africa

DSM

mc 1923
Mühlenchemie
makes good flours even better

gain
Global Alliance for Improved Nutrition

HEXAGON NUTRITION
Nutritionally Yours...

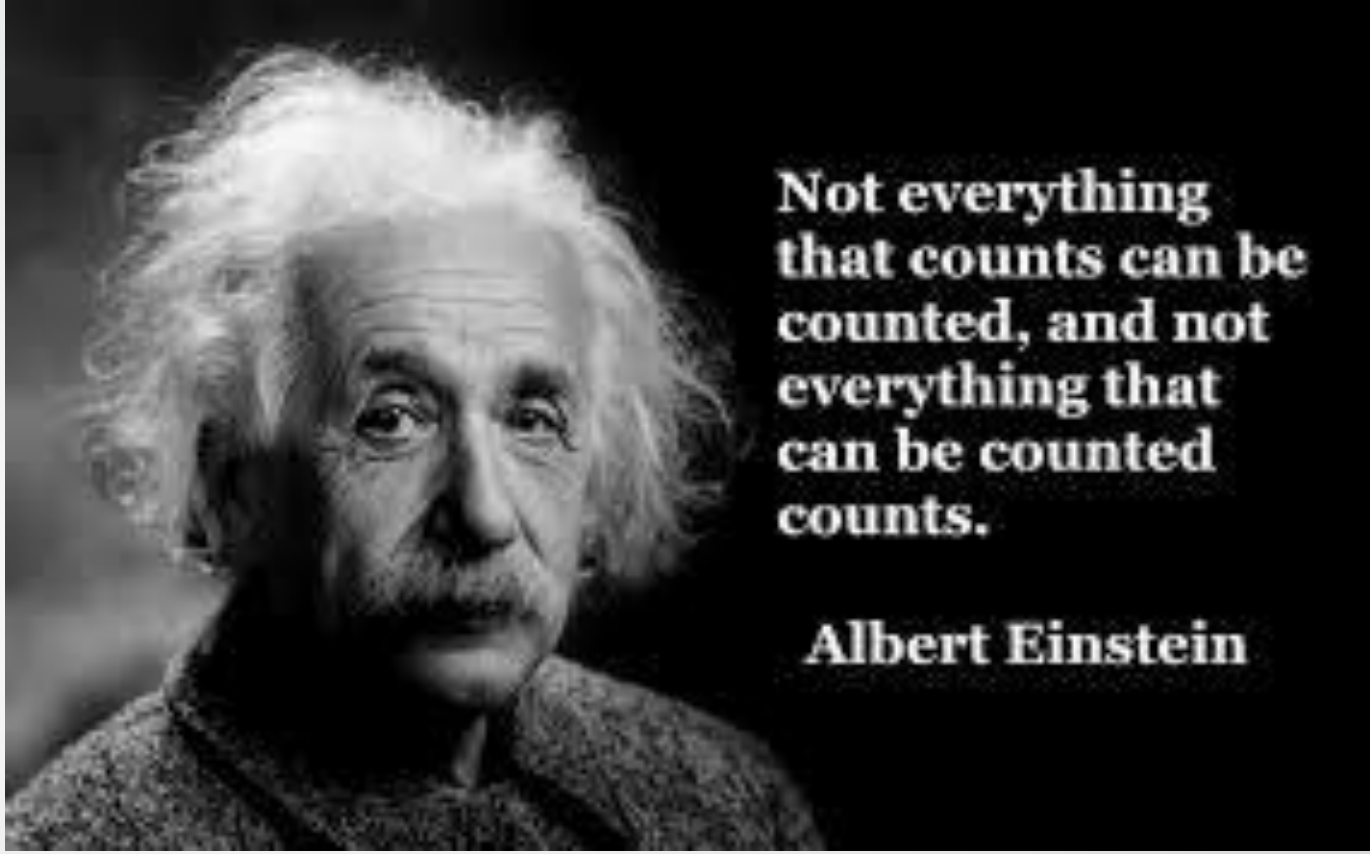
Micronutrient Initiative

BioAnalyt
measure for life

BÜHLER

Maize Fortification – QA/QC at the Mill

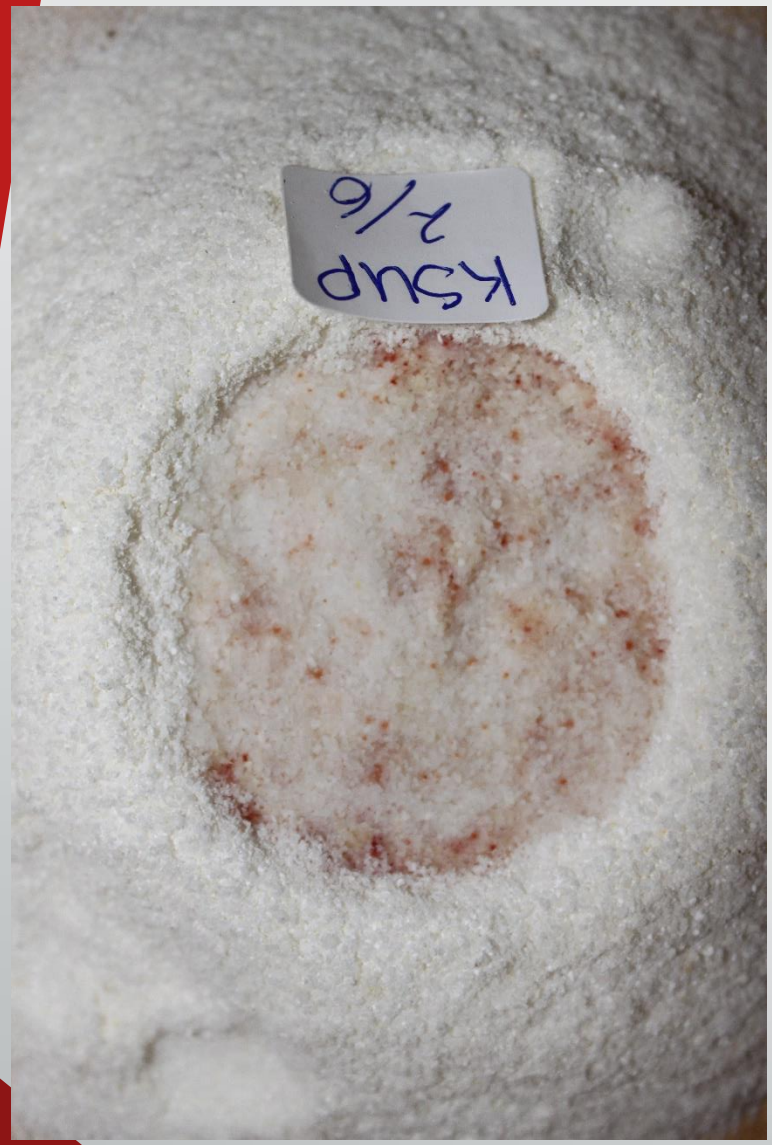
Philip Randall and Quentin Johnson



If it can not be measured it can not be controlled

MAIN ELEMENTS - Fortification

- Equipment – suitable, accessible and usable
- Quality premix
- Properly stored premix
- CoA
- FIFO
- Re-test By Date
- HACCP
- Micro-feeder control
- Rapid tests/checks
- Keep records of raw material procurement; fortification mix inventory and usage; production; premix use.
- These records should correspond with the monthly production records;



Red Spot Test

- Dissolve 10 g KSCN in 100 ml water.
- Mix with equal vol 2N HCl just prior to use.
- Add circa 5 ml of above mixture
- Add a few ml of Hydrogen peroxide 3%. – prepare daily

Traceability and Fortification

- With fortification we NEED traceability
- Traceability was originally required in case a safety issue was raised i.e. contamination, so a product could be ‘easily’ recalled
- Traceability identification also protects us against fraud and counterfeiting

Traceability and Fortification

- To comply we often add an overage
- If we do not have traceability:
- How are we going to monitor our production protocols to see if the overage is adequate or if we can reduce it slightly? [**Financial implication**]
- How are we going to demonstrate we did actually fortify that non-compliant sample? [**Reputation**]

Quantify your weak points

What are we measuring?

- The TOTAL micronutrient content of the food vehicle which:
  - May or may not already have an intrinsic micronutrient content
  - If it has an intrinsic content it is both unknown (potentially unknowable) and is
  - Highly variable due to environmental factors (totally uncontrollable) plus
  - Processing variability (impossible to predict).

Laboratory Variation

- In two trials (43 and 38 samples) in which the laboratory performed, and reported, duplicate analysis the calculated CV was 6.0 and 6.4%

- In one of the trials (12 samples) the same laboratory performed duplicate analysis without being aware of it (blind duplicates) the calculated CV was 26.2%

Control Charts

- Possibly the **most important** tool in a **laboratory** or **production** facility and the **least used**

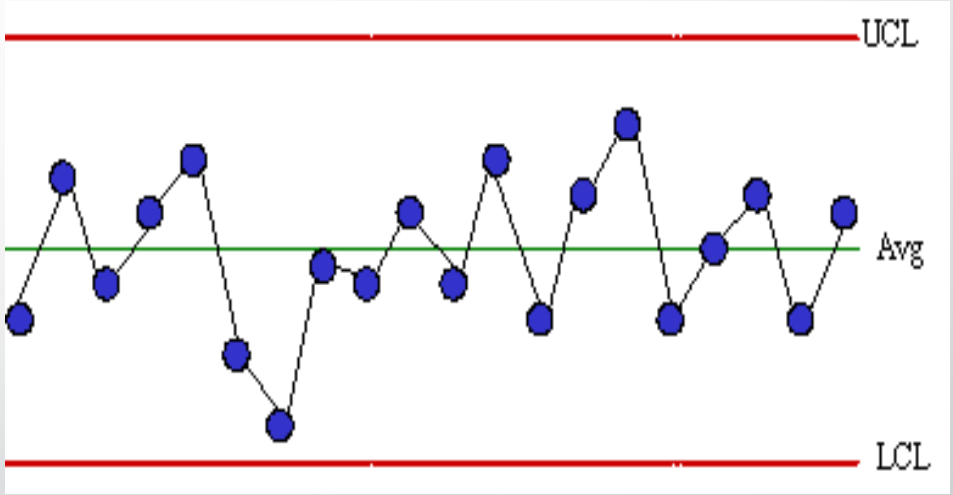
The main purpose of using a control chart is to monitor, control, and improve process performance over time by studying variation and its source.

There are several functions of a control chart:

- It centres attention on detecting and monitoring process variation over time
- It provides a tool for ongoing control of a process
- It differentiates special from common causes of variation in order to be a guide for local or management action
- It helps improve a process to perform consistently and predictably to achieve higher quality, lower cost, and higher effective capacity
- It serves as a common language for discussing process performance

Three characteristics of a process that is in control:

- Most points are near the average
- A few points are near the control limits
- No points are beyond the control limits

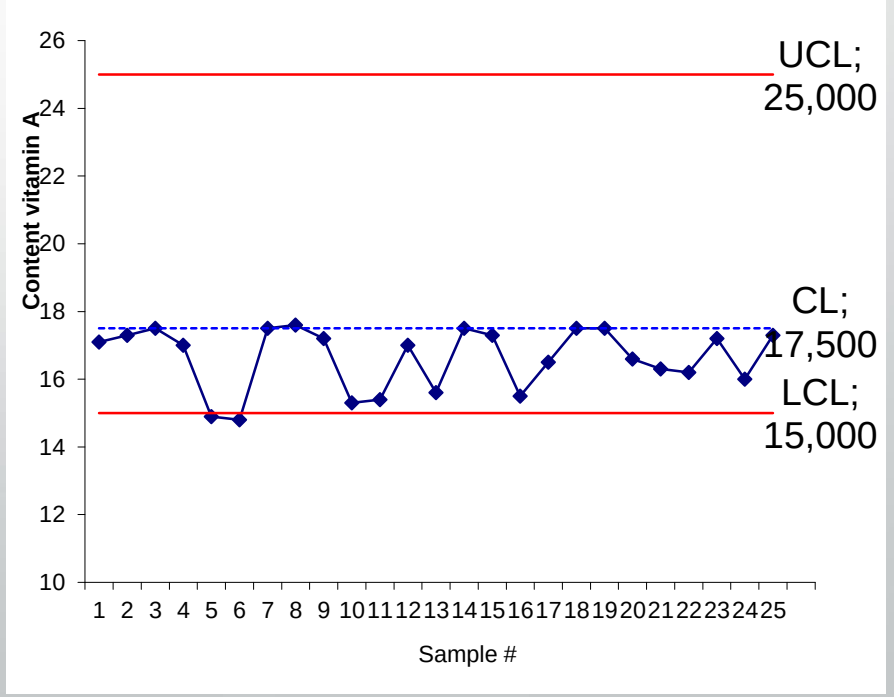


Which is easier to interpret?

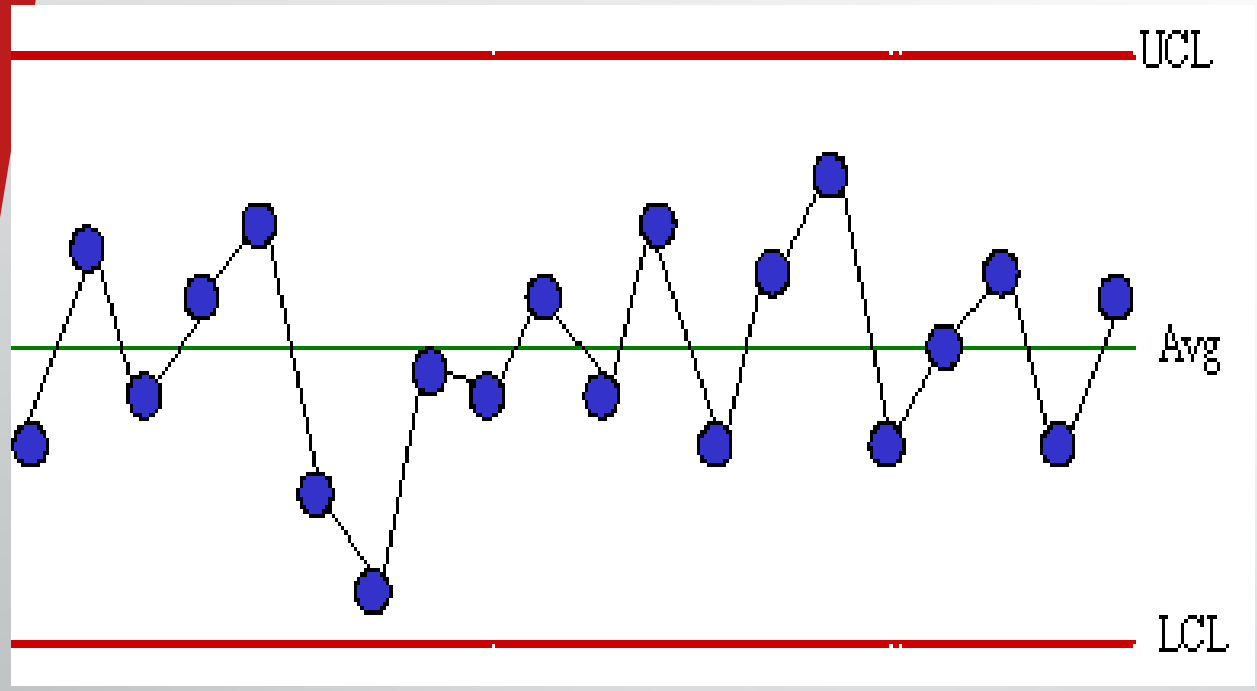
Values each hour

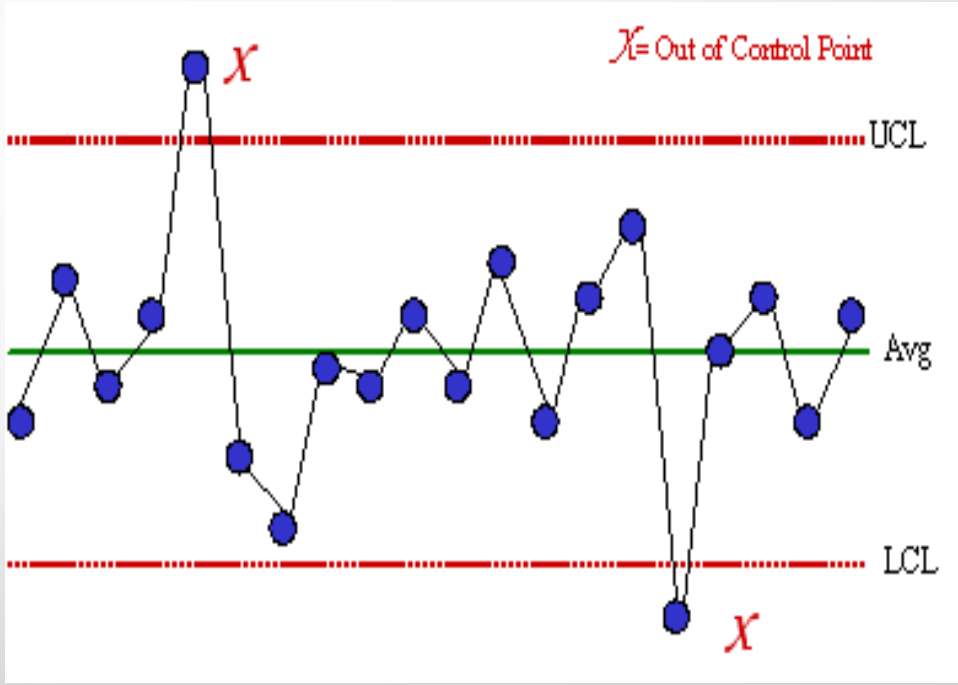
17,1	**14,8**	**15,4**	**15,5**	**16,3**
17,3	**17,5**	**17,0**	**16,5**	**16,2**
17,5	**17,6**	**15,6**	**17,5**	**17,2**
17,0	**17,2**	**17,5**	**17,5**	**16**
14,9	**15,3**	**17,3**	**16,6**	**17,3**

Time line (not a true Control Chart)



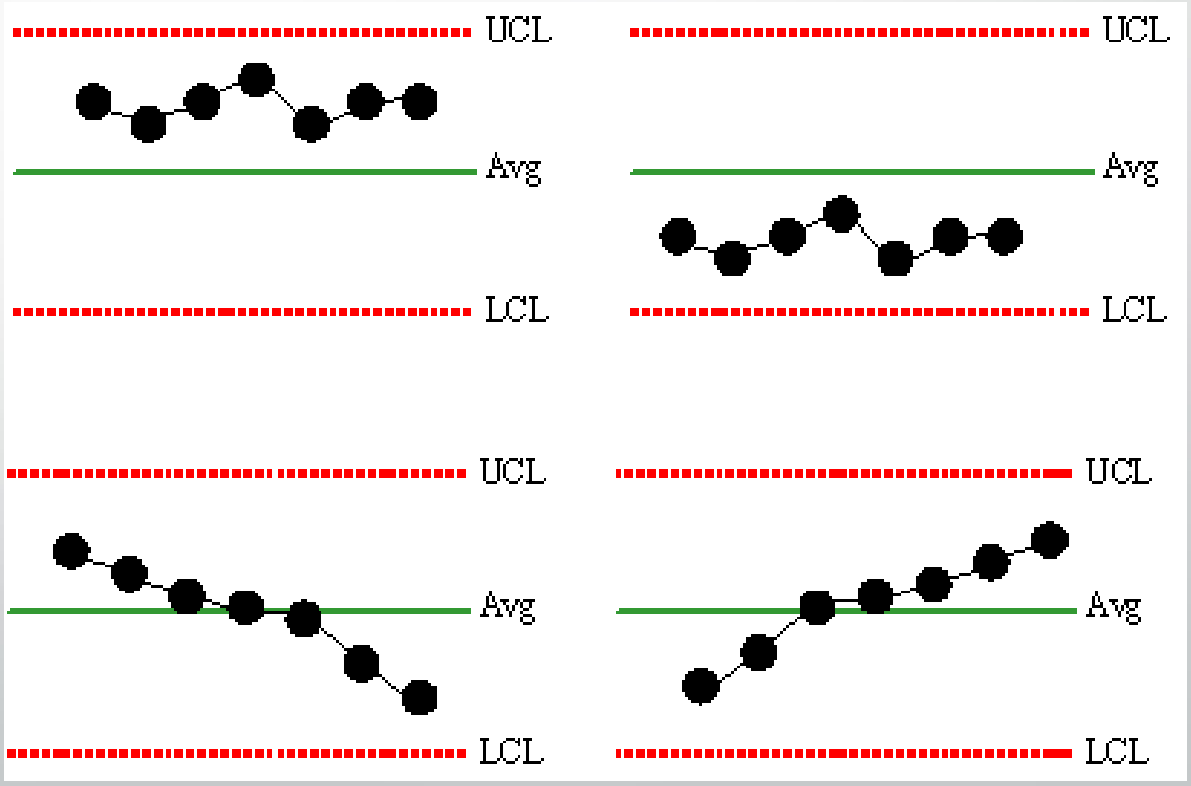
Comparison





Rule of ‘Seven’ - states that an out of control situation is present if one of the following conditions is true:

- ‘Seven’ points in a row above or below the average
- ‘Seven’ points in a row trending up or down



Extremely short variability

- A 10 Mt/hour mill to 1st Break and a 75% extraction produces circa 2,100 g per second
- A typical sample to the laboratory is 250 g

Purpose of Inspection

- The primary focus of the inspection programme must be on the process side because it will be difficult to conclusively prove that market samples have not been tampered with or stored as per the recommended requirements.


SINGIDA
Asilia
5Ltrs
Batch No:
Mfg. Date:
Exp. Date:
SINGIDA
Asilia
5Ltrs
Batch No:
Mfg. Date: 18 AUG 2016
Exp. Date: 18 AUG 2017

What to expect during an Inspection

- The factory inspection comprises of the following:
  - Reviewing of written procedures,
  - Reviewing of records,
  - Personnel interviews,
  - Observation of the fortification process and
  - Collection of samples.

What to expect during an Inspection

- An opening session should be held with the General Manager, Factory or Production Manager, Quality Assurance and Control Department Manager and Laboratory Manager to brief on the purpose and approximate duration of the visit
- A technical audit will then follow, with the aid of the inspectors checklist
- Noncompliance will be recorded during the audit .Non-compliances found during the last visit and the recommendations made will be reviewed

Checklist

Cleaning and sanitation

1. Production area
2. Packaging area
3. Grain reception and warehouse
4. Staff facilities and warehouse

- Cleaning and sanitation practices take place in all these areas in order to produce a safe product.
- Mill should take actions towards implementing these aspects
- Environmental Health Inspectors will verify the progress made since the last inspection

Personnel

1. Good hygiene practices required for personnel
2. Wearing of protective clothing
3. Trained in the tasks they perform

- Personnel are required to follow good hygiene practices such as the washing of hands ,not wearing jewellery, wearing protective clothing including beard and moustache nets

Micronutrient premix

1. Premix inventory is up to date
2. Certificate of analysis is received
3. Premix is stored under adequate conditions
4. Handling " first in ,first out " system
5. Premix is handled well in the fortification site

- Adequate quantity of premix
- Premix handled in an appropriate manner
- Premix stored in a warehouse separated from chemicals and avoid cross contamination
- Premix has a certificate of analysis and from an approved source

Feeder

1. Records of feeder performance are available
2. Premix level in feeder adequate during visit

- Feeder is checked periodically to ensure it has adequate levels of fortificant to avoid running out unnoticed.
- Operator checking that it is discharging adequate amounts of premix according to the products flow

Feeder Related

1. Records of flour/maize produced and premix used up to date
2. Samples taken for analysis in every shift
3. Corrective actions taken when the ratio of production to premix usage is incorrect

- Every relevant action to be recorded as part of QA, inspectors reference, for traceability
- Records of corrective action taken when problems are suspected should be kept

Activities

1. Records of samples analysed
2. Daily composite samples prepared
3. Labelling meets specifications
4. Fortified product is properly stored
5. First in first out (FIFO) system applied to dispatch

- Records of analysis should be kept
- Composite samples are prepared and stored as required These are stored for 1 month or shelf life
- Product meets specifications of regulations
- Verified through records

Sampling

Sampling and Fortification

- Sensitive issue – especially in the area of international trade.
- Cannot treat imports stricter than local production (need to discuss implications with local WTO contact point)

Sampling

- Fortified products are heterogeneous for micronutrients compared to being homogeneous for moisture

- Mill staff are taking samples every hour in large mills.
- Mills composite these hourly samples to ensure there own sample is representative
- Regulator can take from this composite

Precaution

- Keep a few packs of each batch in the warehouse under your recommended storage conditions
- Ensure traceability and you can now contest non-compliance in the market samples

Milling and Fortification

- Addition rates of, for example, 200g/MT require we actually know how much flour is being produced per unit time.
- Variability in mills (per unit time) can be significant as extraction varies according to mill set up (easy to control) and the maize to 1st Break itself (not so easy to control)

Sample 1 - Premix

- At the end of the audit samples for laboratory analysis MAYBE collected
- Sample 1 – Premix from current production; circa 50 g; with a duplicate **sealed** sample for the mill
- Copy of the relevant Certificate of analysis

Sample 2 - Daily composite samples

- During the inspection visit, the inspector will go to the laboratory and check that "daily composite samples" for the last 30 working days are appropriately stored.

- Sample 2 - From the composites randomly select three. Take equal amounts of each of the 3 samples and blend to produce a composite sample from production. Divide the sample into 2 and leave a **sealed** sample for the mill
- Record all relevant information relating to the random samples i.e. identification, date of production, analysis results etc.

Sample 3 - Samples from production

- In the packaging area take circa 500 g from any bag before weighing and sealing [IF SAFE TO DO SO].
- Repeat every 10 minutes until 8 samples have been collected.
- Take equal amounts of each of the 8 samples and blend to produce a composite sample from production. Divide the sample into 2 and leave a **sealed** sample for the mill.

Sample 4 - Samples from warehouse

- In the warehouse randomly select 8 bags of the same type of production – **from a different day** - and take circa 500 g from each bag.
- Take equal amounts of each of the 8 samples and blend to produce a composite sample from production. Divide the sample into 2 and leave a **sealed** sample for the mill.

$$TE = \%Bias + 1.96CV$$

$$Z = \frac{|x_1 - x|}{\sigma}$$

Allowable inaccuracy ?
Allowable imprecision ?

$$r_{10} = \frac{x_2 - x_1}{x_n - x_1}$$

Defeated when not repeated - the reproducibility problem

$$T_n = \left(\frac{x_n - \ddot{x}}{\sigma}\right)$$

$$\%CV = \frac{\sigma}{\ddot{x}} \times 100$$

$$\sigma^2 = \sum_{i-1}^{N} \left(\frac{\partial f}{\partial w_i}\right)^2 \sigma_i^2 + 2 \sum_{i-1}^{N-1} \sum_{j-i-1}^{N} \frac{\partial f}{\partial w_i} \frac{\partial f}{\partial w_j} \sigma_i \sigma_j \sigma_{ij}$$