

Atelier de Formation des Formateurs en Enrichissement de la Farine

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Flour Fortification Initiative

A Public-Private-Civic Investment in Each Nation



Helen Keller
INTERNATIONAL

NATIONAL REGULATORY MONITORING SYSTEM

Chemical Assays

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

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

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

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 $>30\%$

A Simple Example

- Consignment of Grain arrives at Mill.
- Mill want to test for Protein
- Variation within the truck (sampling error) is $\pm 0.4 \%$
- Analytical error on protein analysis is $\pm 0.2 \%$

Total Error

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

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

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

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

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

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

A Case in Point

- 2 internationally accredited (for vitamin and mineral analysis) laboratories plus 5 pre-mix supplier laboratories participate in a ring trail to assess how much reliance can the RSA Department of Health place on an external analysis for prosecution purposes.
- The 2 accredited laboratories had already been verified against the Canadian accredited reference laboratory for such analysis.

- For the purpose of the following study CV was taken at 1 standard deviation
- For compliance verification it would be expected for a laboratory to report to 1.96 (2) standard deviations i.e. at 95% confidence level

Method

- Laboratories are provided with freshly prepared pre-mixes which are then adulterated to be below the legal limit.
- Each lab receives 2 original, but different, pre-mix formulations, 2 adulterated by 10% and 2 adulterated by 20%
- Each of the above is provided to the laboratory on 2 or 3 different occasions i.e. Blind duplicate or triplicate samples

Results

- Each laboratory is requested to analyse the pre-mixes for Vitamin A, Riboflavin, Thiamine, Niacin, Pyridoxin, Folic acid, Iron and Zinc
- Each laboratory correctly identifies the 100%, 90% and 80% samples.
- The coefficient of variation (CV) within anyone laboratory was <5%
- The CV between laboratories was typically 10-12% depending on micronutrient

Conclusion

- If you fool around with fortification pre-mix any reasonably competent laboratory will catch you out.

On Fortified Product??

- Same experimental design using pre-mixes designed to be used at 200g/MT i.e. 1:5000
- Samples prepared in laboratory using the same food vehicle (wheat flour) but the 2 different pre-mixes (avoids variability in intrinsic value issues) and made thoroughly homogenous.

Results

- Each laboratory is requested to analyse the pre-mixes for Vitamin A, Riboflavin, Thiamine, Niacin, Pyridoxin, Folic acid, Iron and Zinc
- Individual laboratory CV's >10% so even within a laboratory compliance verification questionable.
- Between laboratory CV's >40%

Conclusions

- Group could definitely not distinguish even at 20% adulteration level so disputes are inevitable.
- Compliancy or not would depend on luck

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

In Context

- RSA study in 2005 found that four (4) registered suppliers of wheat flour and maize meal pre-mix into the country where compliant with “conformance to specification” on all the vitamins and minerals
- Same study subjected those pre-mixes to accelerated storage conditions of 40°C; 75% RH for 30 days using an environmental cabinet

- Pre-mix was placed in paper bags same as used for retail sale of wheat flour and maize meal
- Pre-mix was analysed by three (3) internationally accredited (for vitamin and mineral analysis) laboratories for Vitamin A at days) 0, 15 and 30

- Suppliers A and B = pre-mixes (wheat and maize) had a **RETENTION** of Vitamin A of $\approx 80\%$ after 30 days
- Supplier C = pre-mixes (wheat and maize) had a **LOSS** of Vitamin A of $\approx 90\%$ after 30 days
- Supplier D = had a retention of Vitamin A in one pre-mix of $\approx 80\%$ but had a loss in the other of $\approx 90\%$

- Both the wheat flour and maize meal pre-mixes had the same micronutrient compounds but in slightly different proportions.
- It was concluded that it was not due to micronutrient interaction
- Chance remark from one supplier indicated probable reason for this anomaly

- Supplier C sometimes bought Vitamin A from the same source as supplier D but on other occasions from a different source
- Very strong indications that original source of Vitamin A makes the difference between “conformance to specification” and “fitness for use”

IRONY

- South African millers had insisted upon “proving” fortification would not affect organoleptic properties and would survive the distribution chain.
- Conducted a 12 month trial using multiple grades of wheat flour and maize meal (with their respective pre-mixes) under a wide variety of distribution conditions and concluded that they had no problems BUT

- They had only used one source of pre-mix (Supplier A)
- Then suddenly the RSA market is open to multiple suppliers – all of whom are registered, and deemed credible, on the basis of “conformance to specification” investigations

- RSA has now made an amendment to the regulations requiring suppliers to, confidentially, inform the Department of Health who they are sourcing their micronutrients from and to advise them if they change sources.
- Food Control inspectors now check not only IF millers are fortifying but also WHOSE pre-mix they are using