Laboratory Requirements for External Monitoring

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What are we looking for?

- Compliance – often within unrealistic limits – of the micronutrient content of a fortified food vehicle

What are measuring?

- The TOTAL micronutrient content of the food vehicle which may or may not already have an intrinsic micronutrient content which if it has an intrinsic content it is both unknown (potentially unknowable) and highly variable due to environmental (totally uncontrollable) and processing variability (impossible to predict).

What is the Inspector going to do with the analysis report?

- Compare the analysis report with the regulations (Standard and/or Technical Regulation)

- If outside the prescribed limits take action – potentially implement prosecution proceedings

Sampling Report – see Stan 150

- a) type and origin of the salt;
- *b) alterations of state of the salt (e.g. presence of foreign matter);*
- *c) date of sampling;*
- *d) lot or consignment number;*
- *e) method of packing;*
- *f) total mass of lot or consignment;*
- *g) number, unit mass of packages and whether the mass is given net or gross;*
- *h) number of items sampled;*
- *i) number, nature and initial position of sampled items;*
- *j) number, composition and mass of the bulk sample(s) and the method used to obtain and* conserve it (them);
- *k) names and signature of people who have carried out the sampling.*

Instructions on CODEX Sampling Procedures CX/MAS 1 - 1987

- "In particular, the estimate of the value MAY be dependent upon the method of analysis used, but it is ALWAYS dependent on the type of sampling plan and the lot acceptance procedure used"

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

A Simple Example

- Sampling error is ± 0.4%
- Analytical error is ± 0.2%

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

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

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

= 0.41 %

Analysed 4 times

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

Sampled 4 times

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

Multiple Laboratories

- 2 accredited (ISO 17025) laboratories plus 5 pre-mix supplier laboratories participate in a ring trail to assess how much reliance can RSA place on an external analysis for prosecution purposes.

Methodology

- HPLC – Numerous methods
- Spectroscopy
- Microbiology

- Method often depends on concentration

- Two ISO 17025 accredited laboratories provide different results on the same sample – who is correct?
- Codex “Special Foods” and Margarine contain specified methods for Vitamin analysis

CODEX Standard 234 - 1999 contain method amendments adopted 2011

- Fluorometry
- Colorimetry
- Spectrophotometry
- Microbioassay
- Rat bioassay
- HPLC (added in 2001)

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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)

In Context

- RSA study found that the 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^{o}C; 75% RH for 30 days using an environmental cabinet

- 2 Suppliers had a **RETENTION** of Vitamin A of ≈80% after 30 days
- 1 Supplier C had a **LOSS** of Vitamin A of ≈90% after 30 days
- 1 Supplier D had a **retention** of Vitamin A in one pre-mix of ≈80% but had a l**oss** in the other of ≈90%

- 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

	Moisture	Protein	Ash	Iron	Zinc
Mean CV	4.6	7.6	13.6	21.8	13.0
Max	18.6	13.2	42.8	55.6	16.1
Min	9.2	4.4	4.4	11.6	9.4

	Thiamine	Riboflavin	Niacin	Pyrodoxine	Folic acid
Mean CV	55.7	36.7	39.0	35.8	44.4
Max	75.8	43.8	57.0	40.0	81.9
Min	34.8	27.0	23.6	29.4	30.2

	Vitamin A	Cyanocobalamin
Mean CV	141.0	130.0
Max	370.0	333.2
Min	62.4	43.4

Recognise the limitations of wet chemistry and use it not abuse it.