Monitoring and evaluating food fortification programmes

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Enhancing Grains for Healthier Lives

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Problem statement

- Food fortification programme initiated
  - Micronutrients from producer to the consumer
  - Hurdles:
    - Availability nation-wide
    - Purchase in local stores
    - Purchase by targeted families (price of alternatives?)
    - Sufficient intake
    - Quality decrease during distribution chain

⇒Need for analysis of the **implementation efficiency** of the fortification programme

⇒Need for monitoring and evaluation

Monitoring

- Refers to the continuous collection, review and use of information on programme implementation compliance, and informing corrective actions so as to fulfill

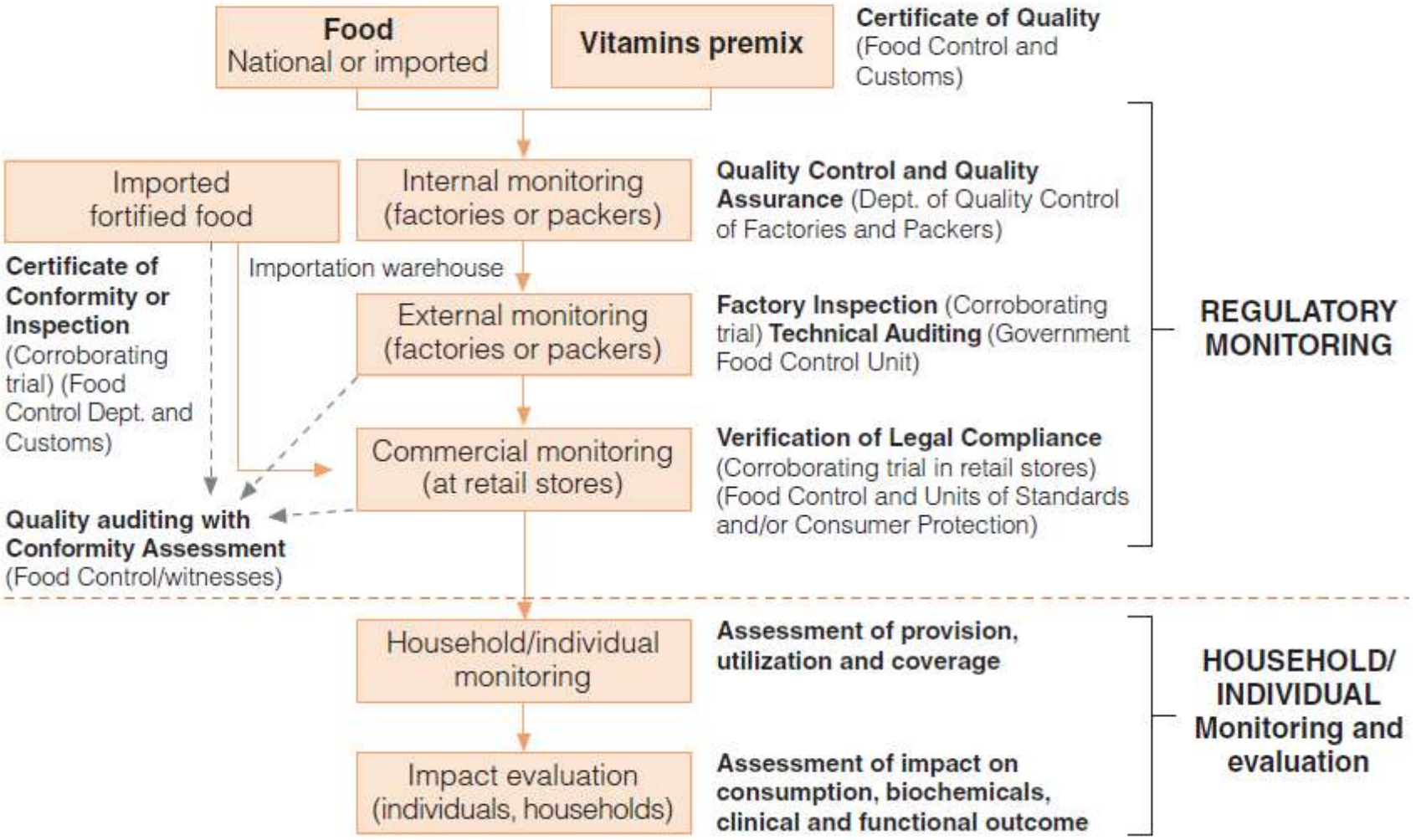
=> Ensure that the fortified product (of desired quality) is made available and is accessible to consumers in sufficient amounts

Evaluating

- Refers to the assessment of the effectiveness and the impact of a programme on the target population
- Are the nutritional goals reached?
  - Intake of fortified food or nutrients ↑
  - Nutritional status ↑
- Only after proper program implementation

-> FIRST monitor, LATER evaluate

Model monitoring and evaluation system for food fortification programmes



Regulatory monitoring

- Ensure that fortified foods meet nutrient quality and safety standards thoughout their shelf-life
- Comprises:
  - Internal monitoring
  - External monitoring
  - Commercial monitoring
- Questions:
  - Is GMP applied?
  - Is HACCP in place?
  - Are inspection and technical auditing functions at the factory and at packaging facilities implemented satisfactory?

Regulatory monitoring

	What?	Who?
Internal	QA/QC	producers, packers, importers
External	Inspection and auditing at factories and packers	government
Commercial	Compliance at the retail stores	government

How to measure success?

Suggested criteria for measuring success at various monitoring stages for food fortification programmes (expressed as a percentage of samples that must comply with minimum levels and Maximum Tolerable Levels)

Monitoring stage	Minimum levels			Maximum Tolerable Level[d]
	Household[a]	Retail[b]	Production[c]	
Internal	100	100	≥80	<20
External (inspection)	100	≥80	–	<20
Household	≥90	–	–	<10

[a] The Household Minimum Level is the amount of nutrient that must be present in the food at the household level before being used in meal preparation. This value is estimated to reach a nutritional goal after considering losses during food preparation (specific additional intake of certain nutrients).

[b] The Retail Minimum Level (or the Legal Minimum Level) is the nutrient content of the fortified food at retail locations at the moment of sale. Usually it is 20–30% larger for vitamins and iodine, and 3–5% larger for minerals, than the Household Minimum Level.

[c] The Production Minimum Level is the nutrient content of the fortified food in the factory, which considers an overage for losses occurring during production, distribution and storage. It is the decision of the manufacturer/importer which overage to use to ensure that the product retains the Retail Minimum Level during the duration of its commercial life.

[d] The Maximum Tolerable Level (MTL) is the maximum allowed content of a specific micronutrient in a fortified food to assure that none of the consumers receives an amount near to the Tolerable Upper Intake Level (UL).

Internal monitoring

- Quality assurance in food fortification consists of establishing the following procedures:

— obtain from the providers a certificate of quality[1] for any micronutrient mixes used;

— request, receive and store in a systematic, programmed and timely manner the ingredients and supplies for the preparation of a preblend[2];

— produce the preblend according to a schedule that is adjusted to the rate of food manufacturing and fortification;

— control the adequate performance of the preblend equipment;

— appropriately label and deliver the preblend;

— use the preblend in the same order of production (i.e. first in, first out);

— verify appropriate functioning of the feeder machines and the mixers in a continuous and systematic manner;

— ensure that the product is adequately packaged, labelled, stored and shipped.

Internal monitoring

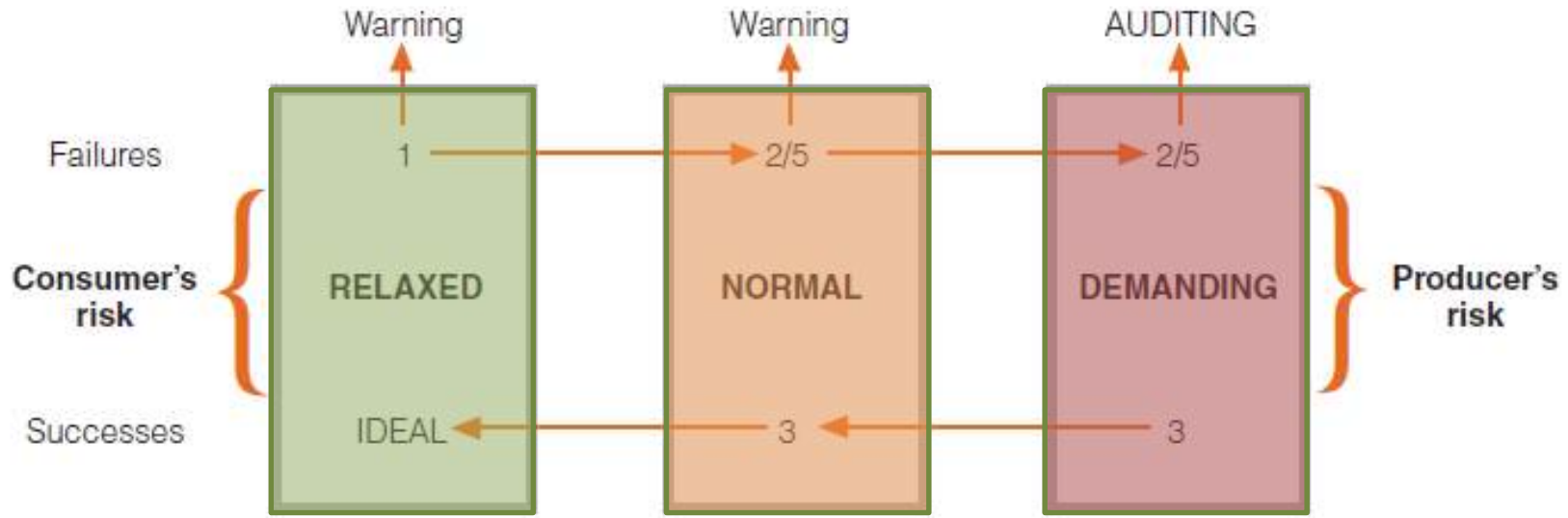
TABLE 8.3

Suggested regulatory monitoring activities for a food fortification programme

Monitoring stage	Action/indicator (success criteria)	Frequency/timing	Methodology and entity responsible for action
Internal monitoring (quality control and assurance)	GMP applied	Daily.	*Method:* Follow a GMP manual approved by company directors. *Responsible:* Factory manager.
	HACCP system in place, where applicable	Daily.	*Method:* Follow a HACCP manual approved by company directors. *Responsible:* Factory manager.
	Premixes and preblends available in sufficient amounts for at least 15 days of production	Daily.	*Method:* Continuous inventory of micronutrient premixes and preblends in existence and use. Confirm that batches of premix are used in the same order in which they were produced. *Responsible:* Factory manager.
	Dosage is in the correct proportion	At least once per shift.	*Method:* Ensure premix flows according to the production rate so that the theoretical average is as expected and the Production Minimum Level is always attained. *Responsible:* Factory quality control department.
	Corroborating tests (at least 80% of samples fulfil the Production Minimum Level and less than 20% reach the Maximum Tolerable Level)	At least every 8 hours; if success criteria are not fulfilled, frequency of sampling should be increased to every 2–4 hours.	*Method:* Take a random sample(s) from packaging line. A fast semi-quantitative assay can be used at shorter intervals, but at least one daily-composite sample should be analysed using a quantitative assay. *Responsible:* Factory quality control department.

Quality Control: sampling

Suggested frequency and intensity of sampling for monitoring compliance with standards



Sampling frequency

• Internal monitoring	8 hours	4 hours	2 hours
• External monitoring	3 months	Monthly	15 days

External monitoring

- Does the producer comply with approved technical standards
- Performed by governmental food control authorities
- Two types of action:
  - Inspection
  - Technical auditing

External monitoring

TABLE 8.3

Suggested regulatory monitoring activities for a food fortification programme (*Continued*)

Monitoring stage	Action/indicator (success criteria)	Frequency/timing	Methodology and entity responsible for action
External			
Factory (inspection and technical auditing)	Fortification centre carries out QC/QA procedures and maintains up-to-date registers	At least once every 3–6 months; frequency of visits should be increased to 1–4 times/month if problems are detected.	*Method*: Conduct auditing to verify performance of the QC/QA procedures and registry, and that fortification centres adopt GMP. *Responsible*: Food control authorities.
	Corroborating tests (at least 80% of individual samples fulfil the Legal Minimum Level and less than 20% reach the Maximum Tolerable Level)	Combine testing with visits to examine QC/QA and GMP procedures; if intentional or serious mistakes are suspected, plan a Quality Audit for Evaluation of Conformity.	*Method*: Collect 5 individual samples of packaged product and take 5 samples from the production line, and test for compliance. *Responsible*: Food control authorities.
At importation sites (applies to imported/ donated products)	Obtain Certificate of Conformity[a] of sale from country of origin	Each time a product lot enters the country.	*Method*: Examine documentation, quality and labelling of products in the customs warehouses. *Responsible*: Importation officials in collaboration with food control authorities.
	Corroborating tests (at least 80% of individual samples fulfill the Legal Minimum Level and less than 20% reach the Maximum Tolerable Level)	Combine with examination of importation papers. If intentional or serious mistakes are suspected, plan a Quality Audit for Evaluation of Conformity.	*Method*: Randomly select 5 individual samples from the lot and test for compliance with the Legal Minimum Level and the MTL. *Responsible*: Importation officials in collaboration with food control authorities.

Commercial monitoring

Whole wheat flour label, Niacaragua

Confirmation of label claims → Penalties or Recall

Importance of well established analytical procedures!

Developing countries: use commercial monitoring for identifying brands and factories who deserve closer auditing

Commercial monitoring

Commercial (inspection at retail stores)	Corroborating tests (at least 80% of samples of each brand fulfill the Legal Minimum Level and less than 20% reach the Maximum Tolerable Level)	Systematic and continuous examination of the product distributed to all regions of the country; each region should be visited at least once a year.	*Method:* Visit stores to collect samples; send samples to official laboratories for quantitative assays. At the local level, semi-quantitative assays may also be used to confirm presence of fortificant if fraud is suspected. *Responsible:* Local personnel from public institutions (e.g. representatives of ministries of health, industry, consumer protection organizations).
Quality Audit for Evaluation of Conformity	Verify production or stored batch complies with standards when analysed using statistical sampling criteria	Whenever it is necessary to take legal actions; can also be requested and financed by producers to certify production lot for exportation.	*Method:* Visit fortification centres suspected of non-compliance with regulations and standards, or when required by exporting industry. Follow technical recommendations of the Codex Alimentarius Commission (*345*) or any equivalent guidelines suitable for this activity. *Responsible*: Personnel of the public agency for food control: as visits to fortification centres are performed under suspicions of non-compliance of regulations and standards, these activities should be carried out in the presence of independent witnesses.

GMP, good manufacturing practice; HACCP, hazard analysis and critical control point; MTL, Maximum Tolerable Level; QC/QA, quality control/quality assurance.

[a] The Certificate of Conformity is a statement that the imported product complies with a set of specific standards.

Household monitoring

- Regulatory monitoring: required quality at retail level -> same assumption at household level
- Aims:
  - Are the fortified products
    - accessible (i.e. available and affordable)?
    - being purchased (and if not, why)?
    - being consumed in sufficient amounts (and if not, why)?
  - Which target groups are not being reached and why?
  - Do individual family members consume sufficient amounts?

Methodological considerations

- Gathering data concerning provision, utilization and coverage
- How?
  - Primary data collection
  - 'piggy-back' or join on to other programmes
  - Market surveys: price and availability
  - Surveys (household and community)

Impact evaluation

- Does the intervention reaches its overall goals?
- Evaluation of outcomes:
  - Intake of fortified foods ↑?
  - Intake of micronutrients ↑?
  - Nutritional status improved?
  - Prevalence of micro-nutrient deficiencies ↓?
  - Prevalence of diseases, growth faltering, child mortality ↓?
  - Differences among age/physiological groeps of population?

Impact evaluation

- Different approaches:
  - Adequacy evaluation
  - Plausibility evaluation
  - Probability evaluation

Impact evaluation

- Adequacy evaluation:

  to assess whether the prevalence of specific micronutrient deficiencies is acceptable or such that there is a public health problem

- Example:
  - Goal: prevelance of iron deficiency among children: 10% or less (pre-established cut-off point) => evaluate prevelance
- Simple and least costly

Impact evaluation

- Plausibility evaluation:

  To be able to state that it is plausible that food fortification was the cause of changes in nutritional status

- Example:
  - The reduction in prevelance of iron deficiency is related to the food fortification program <-> iron intake↑ due to animal products (confounding factor)
- Comparison between control group and intervention group or before-and-after study

Impact evaluation

- Probability evaluation:

  To determine, with a level of probability that was established before the evaluation, that observed changes in nutritional status are due to fortification

- Establish causality between food fortification program and reduction in prevalence of iron deficiency
- $p<0.05$
- Double-blind study

Impact evaluation

- Question formulation:

Examples:

  - Has the intake of a fortified food increased to expected levels following a food fortification programme? => plausability or probability evaluation
  - Is the intake of a fortified food at the expected level: is 90% of the population consuming salt fortified at the minimum household level? => adequacy evaluation
  - Is the prevalence of vitA deficiency among preschool aged children lower than say 20% following the food fortification programme? => adequacy evaluation

Impact evaluation

- Timing
  - Only when monitoring shows appropriate implementation of the fortification programme
  - How quickly does the fortification programme impact the biochemical indicators of interest?
    - Supplementation versus fortification
    - 6-9 months for detectabel effect on iron status
    - Salt iodization
      - 1-2 years for detectable changes in goitre
      - Few weeks in detectable urinary iodine

Impact evaluation

- Confounding factors
  - Factors which affect the ability of individuals to respond to fortification
  - Examples:
    - Parasite infections -> loss of micronutrients
    - Iron status:
      - Inflammation and infections impact heamoglobin and serum ferritin levels
      - Combine indicators for iron status with infection indicators

Minimum requirements

- Well planned monitoring and evaluation system:
  - Clear responsibilities for data collection
  - Feedback loops for information flow -> actions
- Regulatory monitoring is essential
  - Sharing of information
  - Follow up of corrective measures
- Household monitoring is essential
  - General appraisal of the impact
  - Low cost but often neglected
  - Dependent on donor support
- Impact evaluation
  - Continuation, modification, expansion or termination

Summary

- ✓ A well designed, well managed monitoring and evaluation system is essential for ensuring the success and sustainibility of any food fortification programme => formulate and budget this from the early planning stages
- ✓ Some degree of regulatory monitoring is critical. Internal monitoring is a must. When this is carried out, it is usually sufficient to confirm compliance on the retail level (commercial monitoring). If not the case, both external monitoring at factory level as in retail is necessary.

Summary

- ✓ Impact evaluations should only be carried out once it has been established through regulatory and household monitoring, that the programme has achieved a predetermined level of operational efficiency.
- ✓ Although rigorous impact evaluations of food fortification programmes are ugently needed, not all programmes will require the most costly and sophisticated designs => select the most appropriate evaluation for every particular situation

http://www.who.int/nutrition/publications/micronutrients/9241594012/en/