MONITORING FLOUR FORTIFICATION TO MAXIMIZE HEALTH BENEFITS:

A MANUAL FOR MILLERS, REGULATORS, AND PROGRAMME MANAGERS

World Health Organization

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Monitoring flour fortification to maximize health benefits: a manual for millers, regulators, and programme managers

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PREFACE

Flour fortification is the practice of deliberately increasing the content of one or more essential micronutrients in flour. Fortification of wheat and maize flours with vitamins and minerals is considered a cost–effective strategy for addressing micronutrient malnutrition and nutrition-associated health outcomes.

Designing and planning a flour fortification programme requires consideration of certain key elements, including programme monitoring and evaluation procedures to check that fortified foods contain the intended amount(s) of micronutrient(s) and that they are being consumed by the target population in adequate amounts. It is important that fortification programmes are monitored to ensure that they are working effectively, thereby assuring a nutritious and safe fortified end-product for the population.

The development of fortification monitoring systems that can be properly implemented and maintained requires careful planning. This fortification monitoring manual focuses primarily on wheat and maize flours in countries where these food staples are industrially processed and is intended for stakeholders of the country's fortification programme who have interest in and/or authority for setting up monitoring. Stakeholders may include: the government agencies that oversee fortification; the government agencies that monitor fortification, such as inspectors and staff of the food control authority; industry partners that fortify or are part of the supply chain, such as millers, flour importers, and premix manufacturers; research institutions; consumer-protection groups; fortification programme managers; and international organizations that provide technical assistance to food and nutrition programmes.

This manual distinguishes two main categories of monitoring – regulatory monitoring and household or consumption monitoring. Regulatory monitoring includes four subtypes of monitoring: internal, external, import, and commercial, which collectively aim to provide consumers with fortified flour that is of high quality, safe, and adequately fortified. Consumption monitoring involves households and their members. Each chapter is organized such that the body gives a high-level overview followed by practical and technical materials in annexes.

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GLOSSARY

The terms included in this glossary are defined in the context of flour fortification programmes and monitoring systems.

Accessibility or **access** refers to the potential acquisition of fortified flour by consumers. There are many variables that affect the ability of a household or person to access fortified flour, such as product cost, household purchasing power, market availability (or social provision), and awareness of the benefits of fortification to name a few.

Addition rate (also called **feed rate)** refers to the amount of a fortificant or fortificant premix that is added to flour during the fortification process. It is typically expressed as grams per tonne (or grams per metric ton). For production purposes, the addition rate may be expressed over a period of time, such as grams per minute.

Adult male equivalent (AME) refers to the energy intake of each family member in proportion to the energy intake of an adult male. It is typically used with surveys that provide information on apparent intake. The AME of an adult male is always assumed to be 1. Although it varies among authors, a child aged 2–3 years is about 0.37 AME, and an adult woman (18–29 years), neither pregnant nor lactating, is about 0.74 AME. For pregnant and lactating women energy intake is around 1 AME. The AME approach is often used to provide information on consumption when apparent intake is calculated through indirect means such as national balance sheets, household economic surveys, and similar methods that do not collect food intake information directly from individuals but through secondary analysis of reports of food availability, access, and acquisition.

Apparent intake is the approximated amount of a food (and its nutrients) that a consumer may ingest. It is calculated through indirect means such as national balance sheets, household economic surveys, and similar methods that do not collect food intake information directly from individuals but through secondary analysis of reports of food availability, access, and acquisition. The results can be expressed as per capita or, if assuming intake proportional to energy requirement, per adult male equivalent.

Auditing involves actions by government food control authorities to check for execution and performance of quality assurance practices and systems at flour mills. It is an aspect of external regulatory monitoring.

Batch (also called **lot)** refers to the quantity of flour produced in a single manufacturing run. For this manual, the terms batch and lot are synonymous.

Bioavailability is the portion of a micronutrient that can be digested, absorbed, and used for normal functions in the human body. For example, iron can be absorbed from less than 5% to nearly 20% of what is ingested, depending on the composition of the diet and the iron status of the consumer. Iron from vegetarian sources typically has a lower bioavailability than iron from animal products. Absorption inhibitors such as fibre and phytic acid decrease the absorption of iron. Absorption enhancers such as vitamin C can increase the bioavailability of iron.

Brand is a unique design, sign, symbol, set of words, or a combination of these employed to create an image that identifies a [flour] product and differentiates it from its competitors.

Certificate of conformity (also referred to as a **certificate of analysis** in the context of food fortification) is a document certifying that batches of fortified flour and premix comply with the country's fortification standard and relevant specifications. The term **certificate of conformity/analysis** (CoC/A) is used in this manual.

Commercial monitoring, in the context of fortified flour, is the process of collecting and analysing product samples and reviewing product packaging at retail stores and other food distribution sites to confirm that the product follows specifications, such as fortificant content and labelling requirements, as outlined in the fortification standards.

Compliance refers to the fulfilment of technical specifications as outlined in fortification standards. Food producers typically monitor their own compliance through quality assurance and control procedures. Food producers are also monitored for compliance by food control authorities.

Composite sample is defined as a blend (usually of equal portions) of single samples from a batch or a production day (e.g. five or as specified in the standards or food control procedures).

Consignment is a shipment of flour and can include several batches from different brands and producers.

Consumers are individuals who use goods and services.

Consumption is the act of eating and ingesting a food.

Consumption monitoring refers to procedures and actions aimed to assess, in individuals and populations, the change in nutrient intake that can be attributed to the consumption of fortified flour. The objectives are to track fortified flour coverage, micronutrient provision, fortified flour utilization, and micronutrient utilization. Formerly known as household/individual monitoring, in this manual the term used is **consumption monitoring**.

Coverage is the proportion of the surveyed population that consumes fortified flour during a predetermined period of time. Coverage may be disaggregated by criteria such as age, sex, economic situation, geographical area, ethnic group, and others.

Decay of micronutrients is the loss of micronutrients over time. It could refer to the transformation into another substance or to the loss of biological activity.

Demographic and health surveys are generally nationwide representative household surveys conducted at regular intervals (e.g. about every 5 years) in many countries. They are a potential source of consumption monitoring information (e.g. fortified flour coverage, micronutrient provision, fortified flour utilization and micronutrient utilization) if relevant questions are added to the survey.

Enforcement is defined as consistent implementation of regulatory monitoring procedures by government food control authorities to ensure that flour mills, retail and distribution centres, and importation sites adhere to fortification regulations and standards.

Enrichment is synonymous with fortification in this manual and refers to the addition of micronutrients to a food irrespective of whether or not the nutrients were originally in the food before the fortification processes.

External monitoring refers to the activities and actions carried out by government food control authorities to ensure that flour (a) is produced in a manner that is expected to achieve the specifications of the fortification standards and (b) actually conforms to said specifications. These actions are referred to as **auditing** and **inspection**, respectively.

Feeder (also referred to as **a doser/dosifier**) is the equipment used to add fortificants or the fortificant premix to the flour.

Food vehicle is a food product, such as wheat flour, that is fortified through the addition of fortificants. The term "vehicle" is derived from the fact that these food products are the means by which additional vitamins and minerals are provided to those who consume them.

Fortified flour intake refers to the average daily consumption of fortified flour.

Flour extraction rate is the proportion of flour that is extracted or milled and retained from a given amount of wheat.

Flour-based foods are foods made with flour such as bread, tortillas, and roti.

Fortifiable flour refers to industrially produced flour that could be fortified according to national/regional/local legislation and standards. It is contrasted with **fortified flour**, which refers to flour that is definitively fortified according to qualitative tests, quantitative tests, or a product packaging review. For example, a country's fortification standard requires all type A industrially produced wheat flour to be fortified. Thus, 100% of type A wheat flour is **fortifiable flour**. However, a survey may find that only 65% of type A wheat flour is actually fortified. This is the percentage of **fortified flour** in the country.

Fortified flour refers to flour that is definitively fortified according to qualitative tests, quantitative tests, or a product packaging review.

Fortificants are the chemical sources of micronutrients, such as sodium iron ethylenediaminetetraacetate (NaFeEDTA) or ferrous fumarate (compounds of mineral iron), retinyl palmitate (a compound of vitamin A), and folic acid (a compound of folate) that are added to a food product during the fortification process.

Fortification is the practice of deliberately increasing the content of one or more essential micronutrients in foods (in this manual, flours) to improve its nutrition profile and provide a public health benefit with minimal risk to individual health.

Good manufacturing practices (GMPs) are basic principles of facility operation that are implemented to produce high-quality products, such as flour, in a consistent, safe manner.

Hazard analysis and critical control points (HACCPs) focus on food safety management systems in food manufacturing sites and include measures to minimize or eliminate food safety hazards.

Household consumption and expenditure surveys are a family of nationally representative appraisals carried out at the household level for economic, but not food intake, purposes. The information obtained through these surveys can, however, be used to approximate both food coverage and intake either per capita or per adult male equivalent. Because of

the approximate nature of these estimations, they are defined as reach or apparent intakes, respectively.

Import monitoring includes the actions undertaken by food control authority inspectors and customs personnel at border entry points to ensure that flour entering the country is fortified according to the specifications of the fortification standards.

Indicators are specific measurable factors that can be used to describe the attributes of a flour fortification programme and to assess whether the programme is achieving its objectives. This manual describes indicators for regulatory monitoring and consumption monitoring.

Internal monitoring refers to the procedures, actions and tests carried out by flour millers to (i) manufacture flour in a manner that is expected to achieve the specifications of the fortification standards and (ii) ensure that the final product adheres to said specifications. Internal monitoring includes quality assurance and quality control activities.

Inspection refers to actions taken to verify the compliance of a product with specifications included in relevant standards. Collecting and analysing samples is one way for food control authorities to inspect fortified wheat flour from mills, border control sites, and retail stores.

Intake is the amount of food (and its nutrients) that is ingested per person. In some instances, approximated or estimated values identified as apparent intake values might be calculated using secondary analysis of household-applicable data, such as from household consumption and expenditure surveys.

International Organization of Standards (ISO) is an independent, nongovernmental membership organization that develops voluntary international standards for businesses and manufacturing facilities to adopt.

Iron spot test is a rapid, low-cost test used to determine whether a sample of flour is fortified with iron. Dark red spots are an indication of fortification. Under certain circumstances, the iron spot test is considered a semiquantitative method but for consistency it is characterized as a qualitative method in this manual.

Lot (also called **batch)** refers to the quantity of flour produced in a single manufacturing run. For this manual, the terms lot and batch are synonymous.

Marker nutrient is a single micronutrient that is analysed qualitatively to determine whether flour is fortified or quantitatively to ascertain if the flour is compliant with the fortification standard. Other nutrients are expected to be proportionate in quantity to the marker nutrient based on the premix composition.

Micronutrients is a collective term for specific vitamins and minerals that the human body requires daily in small quantities. Although calcium is not strictly a micronutrient, it is often included in this definition.

Micronutrient intake from fortified flour is the estimated additional amount of micronutrients delivered to each consumer via the consumption of fortified flour. It is calculated from the additional micronutrient content provided by fortificants in the fortified flour (i.e. micronutrient provision) and the amount of the fortified flour the consumer eats (i.e. fortified flour utilization).

Monitoring is the continuous collection, analysis and interpretation of data related to programme implementation (inputs, activities, outputs and outcomes). The main purpose of monitoring is to enable programme managers to assess programme performance and, if needed, to intervene with changes in a timely manner.

Micronutrient content (provision) of fortified flour is the average additional content of micronutrients provided by fortificants as determined in samples of fortified flour. Micronutrient provision is used in conjunction with fortified flour intake to estimate micronutrient intake (utilization).

Premix is a blend of micronutrient fortificants and other specialty ingredients that facilitate the precise addition of the target dosage of micronutrients to the food vehicle through a feeder/dosifier.

Quality assurance (QA) refers to planned activities that are conducted during the food manufacturing process to avoid mistakes, maintain safety, and ensure that the final product meets relevant standards. Example activities related to food fortification include: obtaining a certificate of conformity or analysis from premix companies, maintaining appropriate mill records, and regularly checking the addition rate of the feeder/dosifer.

Quality control (QC) refers to the tests and assessments conducted on flour to document that

it adheres to fortification standards. One example is analysing the marker nutrient in a sample of flour to make sure that the quantity is within the allowable range as specified by the fortification standards. Either the test is conducted at a mill laboratory or the mill manager sends a flour sample to an independent laboratory for analysis.

Regulation is a legislative instrument through which governments make the application of a fortification standard compulsory. It defines institutional roles and responsibilities for checking compliance and describes penalties for lack of compliance. In some countries, technical specifications (standards) are also included as part of the regulation. In other instances, the regulation simply refers to a standard. In this manual, the terms regulation and standard are used interchangeably.

External, commercial, and import monitoring are the procedures and actions that are implemented by government food control authorities to ensure that the fortified flour available to consumers complies with the specifications of the fortification standards. It includes several components: external monitoring at flour mills, import monitoring a border entry points, and commercial monitoring at retail and food distribution locations.

Regulatory monitoring includes four subtypes of monitoring: internal, external, import, and commercial, which collectively aim to provide consumers with fortified foods that are of high quality, safe, and adequately fortified.

Representative is an example of a class or group. The class or group can be a population or population group or a class, for example a food or food type, a brand product or product batch.

Restoration is the addition of essential nutrients to foods to restore amounts originally present in the natural product, which were unavoidably lost during processing (such as milling), storage, or handling.

Segregation of micronutrients refers to the physical separation of micronutrients in the fortified flour. It could refer to the accumulation of a micronutrient at the bottom of a flour package during storage at extreme weather conditions.

Specifications are the technical criteria that flour should meet to be commercialized in a country. Specifications might cover product appearance, weight, nutrient content, packaging, allowable storage and transportation conditions, and inspection requirements, among others. Standards typically describe the technical specifications for fortified flour in detail.

A **standard** is a document approved by a recognized standard-enacting body that lists the technical specifications required for defined types of fortified flour and applies for a defined geographical area, such as a region or country**.** Standards may be voluntary or compulsory. However, manufacturers are obliged to follow the technical specifications if they wish to make a relevant claim, such as that a product is fortified. In this manual the terms regulation and standard are used interchangeably.

Standard operating procedures (SOPs) are detailed, written instructions aimed at helping operators achieve uniformity in the performance of a specific function.

Stratification is the defined unit/level at which the average micronutrient content will be representative and comparable.

STEPwise approach to surveillance (STEPS) is a simple, standardized method by which nationally representative household surveys are conducted with support from the World Health Organization. They are a potential source of consumption monitoring information (e.g. fortified flour coverage, micronutrient provision, fortified flour utilization and micronutrient utilization) if relevant questions are added to the survey.

Tonne is a unit of mass equal to 1000 kg. It is sometimes referred to as a metric ton. The term tonne is used throughout this manual.

Total quality management (TQM) is a comprehensive and structured approach to managing a company or organization that envisions constant product improvement as a result of regular feedback and applicable operational changes. TQM procedures may be created as part of an established set of standards, such as in accordance with ISO, or a company can establish its own procedures.

1

CHAPTER 1

INTRODUCTION

Flour fortification is the practice of deliberately increasing the content of one or more essential micronutrients in flour. Fortification of wheat and maize flours[1] with vitamins and minerals is considered a cost–effective strategy to address micronutrient malnutrition and nutrition-associated health outcomes, such as prevention of neural tube defects *(1)*. Other terms frequently used in flour fortification are enrichment and restoration. Whereas enrichment is synonymous with fortification, restoration refers to the addition of vitamins and minerals to restore the amounts originally present in the natural wheat and maize grains that are unavoidably lost during milling, storage, or handling.

Where wheat and maize flour are staple foods, a grain-based fortification programme can reach multiple sectors of the population with relatively low investment costs. The intervention is also practical because it does not require individuals to change their dietary behaviours. The main attribute of flour fortification is the use of an existing food delivery system that can reach a large proportion of the population without extensive inputs, particularly when the flour is processed centrally. Other food vehicles used for fortification with vitamins and minerals in public health programmes include rice, edible oils, margarine, salt, sugar, seasonings, and condiments. The number of countries with legislation mandating wheat flour fortification rose from 33 in 2004 to 86 in 2021 *(2)*. In 16 countries, the additional fortification of maize flour and corn meal extends the reach and potential impact of flour fortification as some individuals may consume maize flour or corn meal but not wheat flour.

Designing and planning a flour fortification programme requires consideration of certain key elements. These include: (i) defining and setting nutritional goals (i.e. framing decisions about how much micronutrient(s) to add to which foods); (ii) programme monitoring and evaluation (i.e. establishing procedures to check that fortified foods contain the intended amount of micronutrient(s) and that they are being consumed by the target population in adequate amounts); (iii) communicating and marketing fortification programmes (i.e. informing the target population about the benefits of fortification so that they chose to consume fortified foods) *(1)*.

Fortification programmes must be monitored to confirm that they are working effectively, thereby ensuring the population is receiving a nutritious and safe fortified end-product. The development of fortification monitoring[2] systems that can be properly implemented and maintained requires careful planning. This manual focuses primarily on wheat and maize flours in countries where these food staples are industrially processed. The principle for monitoring other industrial processed foods would be similar to those found in this manual. Point-of-use fortification or fortification of flours that are not industrially processed, such as those processed in chakki or hammer mills, will not be covered in this manual.

In flour fortification programmes, monitoring may serve some or all of the following purposes *(adapted from 3)*.

- Educate stakeholders about realistic expectations for the programme.
- Generate a shared understanding of the programme performance among the stakeholders.
- Document linkages between the roles and activities of the different stakeholders and overall programme operations.
- Assess the provision and accessibility of the fortified flour or subproducts across the country.
- Demonstrate accountability for resources expended.
- Provide a platform for discussion, exchange of ideas, and decision-making among diverse stakeholders to improve the benefits.

Therefore, this manual is intended for stakeholders of the country's fortification programme who have interest in and/or authority for setting up monitoring of the programme. Stakeholders may include government agencies that oversee fortification; government agencies that monitor fortification, such as inspectors and staff of the food control authority; industry partners that fortify or are part of the supply chain, such as millers, flour importers, and premix manufacturers; research institutions; consumer-protection groups; fortification programme managers and international organizations that provide technical assistance to food and nutrition programmes.

[1] Some countries do not clearly differentiate between maize or corn "meal" and "flour". The monitoring protocols presented in this manual apply to both.

[2] Monitoring refers to the ongoing collection, analysis, and interpretation of indicators on programme fortification components (inputs, activities, outputs, and outcomes) to assess how well the programme is being executed *(1)*.

Although monitoring and impact evaluations are often discussed in tandem, this manual focuses solely on monitoring. An impact evaluation assesses the change in nutritional status or other health outcomes of the target population that can be attributed to fortification. It therefore serves a very different purpose. Impact evaluations have been discussed with regard to fortification in other publications *(1, 4–10)*.

There are numerous resources available to help stakeholders develop and implement flour fortification programmes accompanied by monitoring systems. One resource is the *eCatalogue of indicators for micronutrient programmes (11)*, produced by the World Health Organization (WHO) and the United Stated Centers for Disease Control and Prevention (CDC) and hosted at the *WHO Vitamin and mineral nutrition information system*. This eCatalogue contains a non-comprehensive register of standard process and impact indicators that can be downloaded and adapted to the country context for tracking the performance of public health programmes that implement micronutrient interventions, including wheat and maize flour fortification. The eCatalogue is a dynamic digital resource and new indicators are added as they become available. The primary audience for the eCatalogue is advisors or programme managers engaged in monitoring or evaluation of public health programmes, particularly vitamin and mineral interventions. The utility, feasibility, propriety, and validity of these indicators have not been systematically evaluated by either WHO or CDC. Most of the information for process indicators comes from practice-based evidence.

This manual covers selected WHO/CDC indicators for monitoring fortification programmes. The use of these standardized monitoring indicators can facilitate comparison of results and sharing of knowledge across programmes worldwide *(3)*. In brief, this manual aims to:

- present a general monitoring framework to assist with the design and implementation of monitoring systems for flour fortification programmes;
- facilitate the use of standard WHO/CDC indicators;
- provide examples of practical tools which may be used for monitoring purposes;
- highlight relevant examples from existing fortification programmes;
- serve as a resource for training persons involved in the design, implementation, and management of flour fortification monitoring systems.

The manual is not intended to provide a comprehensive monitoring plan for all situations but serves as an overall guiding document. It complements other resources available, including the *Flour millers toolkit (12),* the East, Central and Southern African Health Community (ECSA-HC) series of food control manuals *(13)*, the Micronutrient Initiative *Fortification handbook (14)*, the WHO *Guidelines on food fortification with micronutrients (1)*, the *Regulatory monitoring of national fortification programs* policy guidance of the Global Alliance for Improved Nutrition (GAIN) *(15)*, and others *(16,17)*.

The design and components of monitoring systems will vary according to the maturity of the programme and the resources available. This manual distinguishes two main categories of monitoring: regulatory monitoring and household or consumption monitoring. Regulatory monitoring includes four subtypes of monitoring: internal, external, import, and commercial, which collectively aim to provide consumers with fortified flour that is of high quality, safe, and adequately fortified. Consumption monitoring involves households and their members.

Chapters 2–6 guide the reader through the steps involved in designing and implementing a monitoring system. Each chapter is organized such that the body gives a high-level overview followed by practical and technical materials in annexes.

- **Chapter 2: Monitoring steps for flour fortification programmes**
  Provides an overview of the CDC *Framework for program evaluation in public health* and its application to monitoring flour fortification programmes. The chapter describes the monitoring steps to guide flour fortification stakeholders in the development and adaptation of monitoring systems.
- **Chapter 3: Quality management by the industry – internal monitoring**
  Focuses on the procedures, actions and tests carried out by millers at flour manufacturing sites to produce flour in a manner that is expected to achieve the technical specifications as detailed in the country fortification standard and to ensure that the final product actually adheres to said specifications.
- **Chapter 4: External, import and commercial monitoring**
  Describes the critical elements of the monitoring by the government on external, import and commercial monitoring and presents some examples to illustrate the main points. Key WHO/CDC indicators that will help fortification stakeholders assess the progress of a fortification programme are also highlighted throughout this chapter.
- **Chapter 5: Consumption monitoring**
  Focuses on the additional micronutrient content provided to a population via the consumption of fortified flour and the percentage of the priority population benefiting from fortification. Consumption monitoring is needed to ensure that the expected nutrition and health benefits, as proposed during the programme planning stage, are probable. This chapter gives a detailed description of four consumption-related WHO/CDC indicators.
- **Chapter 6: Review and synthesis of monitoring information**
  Highlights the role of multisector alliances in compiling, reviewing, synthesizing, distributing and using monitoring data.

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CHAPTER 2

MONITORING STEPS FOR FLOUR FORTIFICATION PROGRAMMES

INTRODUCTION

Developing a comprehensive monitoring system will increase the potential for flour fortification programmes to improve the micronutrient intake of populations and thereby decrease the risk of clinical micronutrient deficiencies and negative health outcomes. Monitoring systems are often regarded as merely secondary elements of flour fortification programmes, when in fact they should be integrated from the outset. CDC developed a *Framework for programme evaluation in public health (1)* that has been applied to monitoring systems for nutrition programmes, including flour fortification and point-of-use fortification of foods with micronutrient powder *(2–4)*. For the purposes of this chapter, these six steps include the basic actions to design, carry out, and utilize information from the flour monitoring system:

1. **Engage stakeholders**
2. **Describe the programme**
3. **Focus the design**
4. **Gather credible evidence**
5. **Justify conclusions**
6. **Ensure use and share lessons learnt**

Each of the steps is guided by standards for assessing the quality of a monitoring system. These standards have been adapted for monitoring and are grouped into the four categories that are derived from 30 specific standards *(5)*.

1. **Utility** – the system meets the needs of the intended users and supports adjustments to improve programme performance.
2. **Feasibility** – the system is practical, pragmatic, and sustainable.
3. **Propriety** – the system is conducted in a manner that is both legal and ethical.
4. **Accuracy** – the system produces findings that are correct and convey information in an accurate manner.

These four categories are the core of the six steps. They can be used to assess the quality of an existing monitoring system and should guide the formation of the steps for a new monitoring system. However, they will not be addressed further in this manual.

This chapter will use the monitoring steps as a model to guide flour fortification stakeholders in the development and adaptation of monitoring systems. An ideal monitoring system will be overseen by a multisector alliance and will encompass all aspects of monitoring, including internal monitoring (Chapter 3); external, import, and commercial monitoring (Chapter 4); and consumption monitoring (Chapter 5). Data obtained through monitoring processes are useful for describing the flour fortification programme, but simply collecting monitoring information is insufficient. The data must be periodically analysed and synthesized. Programme stakeholders should then utilize the monitoring results to track progress towards programme goals, ensure accountability, celebrate achievements, and inform programme or relevant policy changes as needed.

STEP 1: ENGAGE STAKEHOLDERS

Stakeholders are persons who have an investment (stake) in a programme, often based on their expertise or work affiliation. Many countries with flour fortification programmes have an alliance of stakeholders that represents the public, private and civic sectors and consistently guides and influences fortification efforts. This entity can be called a steering group, task force, working group or national committee. In this manual, however, the term **multisector alliance** will be used.

This multisector alliance should be formed early in the planning process of both the fortification programme and the monitoring systems to decrease the risk that significant concerns and/or technical issues will arise after fortification policies have been enacted. The multisector alliance may be formed specifically for the flour fortification programme or it may be incorporated into a larger health, nutrition, or fortification coalition. For example, if the country already has a salt iodization programme and a multisector group to oversee that initiative, it may be useful for the flour fortification alliance to join with this group. The following are examples of important characteristics of a multisector alliance.

- The alliance is composed of stakeholders that represent the public, private, and civic sectors.
- The alliance meets regularly. This may entail meeting frequently early in the process, then every 6 months once the programme is initiated, and on an ad hoc basis as necessary.
- Ideally, the alliance should have a mandate for recommending or even instituting programme changes based on monitoring data results or inputs from a range of public entities, such as consumer associations, millers, and academicians. As described below, the monitoring mandate may be derived from an existing legal document, which promotes sustainability by ensuring that decisions and allocated resources are in line with government policies *(6, 7)*.

Whenever possible, high-level stakeholders should be part of the alliance. These individuals can be effective at building momentum for monitoring activities and can assume the political risks for unpopular findings. They include those who can: increase the credibility for flour fortification efforts; implement activities that are central to flour fortification monitoring; advocate for changes to institutionalize flour fortification; and fund and authorize continuation or expansion of the flour fortification programme.

Stakeholders of fortification programmes are divided into the following three principal, non-mutually exclusive groups. Many, but not all, stakeholders would be represented in the multisector alliance.

1. Those **involved in programme operations**:
    - ministry of health officials and staff members;
    - autonomous nutrition institute;
    - food industry representatives (millers, bakers, and others);
    - farmers, fertilizers producers;
    - ministry of finance officials and staff members;
    - national and local legislators;
    - premix manufacturers and/or importers;
    - importers of flour;
    - import/customs officials;
    - food control inspectors;
    - united nations agencies and relevant donors;
    - scientific and academic groups.

2. Those **served or affected by fortification:**
    - general population plus groups vulnerable to nutritional anaemia, folate-preventable neural tube defects, and other micronutrient deficiencies;
    - retail store managers, wholesalers, millers, bakers;
    - civic sector advocacy organizations (e.g. spina bifida associations and micronutrient coalitions).

3. Primary **users of the monitoring results:**
    - persons responsible for management and administration of the flour fortification programme operations (e.g. millers, regulatory authorities, and others);
    - national level programme managers;
    - donors;
    - members of the national fortification alliance.

For monitoring, it is important to identify the stakeholders that will provide, analyse, synthesize and use the data. The specific individuals involved with monitoring efforts may be members of the multisector alliance, individuals employed by an entity represented in the alliance (such as the ministry of health), or they may be outside the alliance altogether.

All tasks and responsibilities should be clear. Everybody needs to know what is expected from them and have specific tasks. Although individual tasks should not overlap, sharing and discussing results among the alliance members should be mandatory.

STEP 2: DESCRIBE THE PROGRAMME

The general fortification programme description is written by flour fortification stakeholders. It includes multiple important topics but should ultimately help stakeholders achieve a common understanding and a sense of programme ownership. This feeling of ownership increases the likelihood of an effective flour fortification initiative. In addition, the description will serve as the basis for subsequent decisions regarding programme monitoring. A programme description should generally cover the following.

- **Statement of need**
  The statement describes the problem. It may include information about the nature, causes, consequences, and magnitude of the nutrition problem as well as the population affected.
- **Expected effects**
  This section includes the short-term and long-term goals and objectives of the programme. It should also explain the expected outcomes of the programme.
- **Contextual factors**
  Contextual factors to consider include: current consumption of flour to be fortified; prevalence of micronutrient inadequacies (if not mentioned in the statement of need); complementary nutrition interventions in the country; partners involved; programme designation (mandatory versus voluntary); regulatory requirements (fortificant compounds and amounts); and capacity of the milling industry to fortify *(4)*.
- **Stage of development**
  The stage of development describes the maturity of the programme *(2)*. The three stages are as follows.
    i. Planning (or development) stage.
    ii. Implementation stage – this encompasses the early (including piloting) and middle years of the programme. During this stage, careful attention is given to identifying and correcting problems as they arise.
    iii. Maintenance stage – this stage is characterized by the consistent, successful operation of a programme. In this period, the focus shifts to maintaining a high level of performance while still monitoring for possible problems.

- **Resources**
  A list of resources needed to implement and monitor the programme should be incorporated. Issues to think about include: time, training and staff development needs, financial input, equipment/technology, and infrastructure *(2, 4)*. The sustainability of the monitoring system must be considered, as building a system requires the long-term commitment of multiple stakeholders, a workforce capable of supporting the system, programme resources, and the political will to use the information for future programme changes. If resources are scarce – as is the case for most countries – a simple sustainable system with a few key indicators may perform better in the long run than a complex system that overloads available resources.
- **Activities**
  Programme activities describe what the programme currently does, if already functional, and what it will do in the future to have a health impact. A description of programme activities includes specific steps and strategies. This section should also explain how the fortification programme relates to other programmes in the country, such as supplement distribution.
- **Logic model** *(2, 4, 8)*
  A logic model is a graphic description that specifies the programme's inputs, activities, outputs, and outcomes in the short, medium, and long term. The *WHO/CDC logic model for micronutrient interventions in public health* serves as a generic template *(9, 10)*. A logic model for the fortification of maize flour and corn meal with vitamins and minerals in public health was developed for the *WHO guideline: fortification of maize flour and corn meal with vitamins and minerals (11)* and can provide a common framework and understanding among stakeholders from different contexts and with different needs. **Fig. 1** shows a logic model adapted for maize flour fortification.

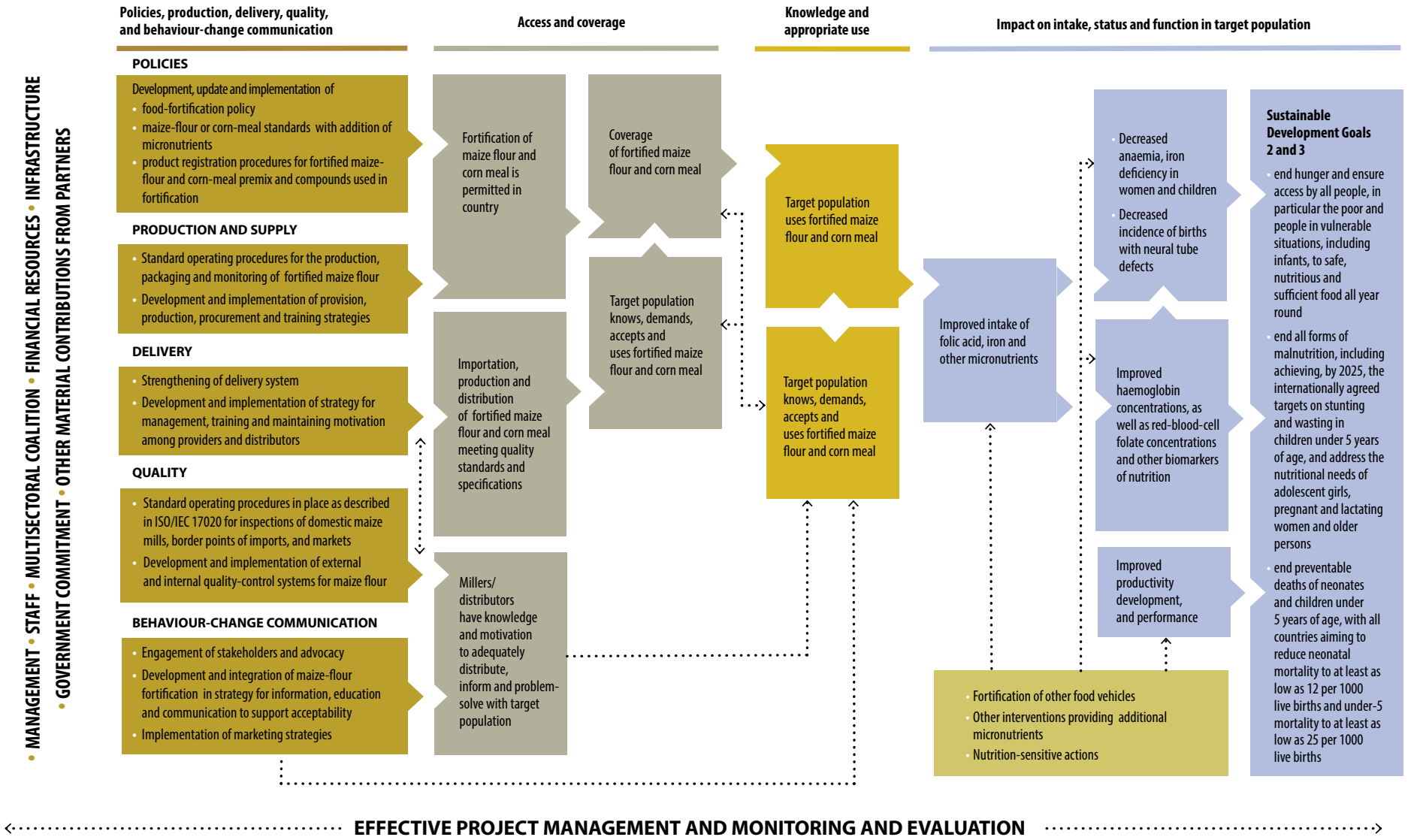
Fig. 1. Logic model for fortification of maize flour and corn meal with vitamins and minerals in public

The information in the programme description, including the logic model, is useful for connecting the planning of a flour fortification programme with its monitoring component. The programme description also helps to frame the monitoring by (i) communicating the fundamental purpose of the programme; (ii) serving as a basis for determining whether the planned activities will lead to the expected impact; (iii) identifying, and helping to solve, potential operational and logistic problems; and (iv) improving everyone's understanding of the overall programme *(4)*. An example of a programme description can be found in the **Chapter 2 Annex.**

STEP 3: FOCUS ON THE MONITORING DESIGN

Once the fortification programme has been described, activities and expected outcomes should be clearly understood. The next step is to focus on the design of the monitoring system, specifically to decide where to concentrate efforts. It is important for the stakeholders to collectively decide on the purpose of the monitoring activities, the questions they want answered by the system activities, and the intended uses and users. These factors might vary depending on the maturity of the flour fortification programme, for example if the monitoring system is initiated at the outset of the programme or it is initiated a few years after the programme commenced. Clearly articulating the purpose(s) of the fortification programme and monitoring system will help to guide the design of the system. Some examples are listed below.

1. **Gaining insight**
   - Identifying barriers to high-quality flour fortification at the mills or manufacturing facilities.
   - Understanding the acceptability of fortified flour or foods made from wheat or maize flour in the population.
   - Identifying barriers to commercialization, transport, or distribution.


Policies, production, delivery, quality, and behaviour-change communication
Access and coverage
Knowledge and appropriate use
Impact on intake, status and function in target population
POLICIES
Development, update and implementation of
• food-fortification policy
• maize-flour or corn-meal standards with addition of micronutrients
• product registration procedures for fortified maize-flour and corn-meal premix and compounds used in fortification
PRODUCTION AND SUPPLY
• Standard operating procedures for the production, packaging and monitoring of fortified maize flour
• Development and implementation of provision, production, procurement and training strategies
DELIVERY
• Strengthening of delivery system
• Development and implementation of strategy for management, training and maintaining motivation among providers and distributors
QUALITY
• Standard operating procedures in place as described in ISO/IEC 17020 for inspections of domestic maize mills, border points of imports, and markets
• Development and implementation of external and internal quality-control systems for maize flour
BEHAVIOUR-CHANGE COMMUNICATION
• Engagement of stakeholders and advocacy
• Development and integration of maize-flour fortification in strategy for information, education and communication to support acceptability
• Implementation of marketing strategies
Fortification of maize flour and corn meal is permitted in country
Coverage of fortified maize flour and corn meal
Importation, production and distribution of fortified maize flour and corn meal meeting quality standards and specifications
Target population knows, demands, accepts and uses fortified maize flour and corn meal
Millers/ distributors have knowledge and motivation to adequately distribute, inform and problem-solve with target population
Target population uses fortified maize flour and corn meal
Target population knows, demands, accepts and uses fortified maize flour and corn meal
Improved intake of folic acid, iron and other micronutrients
• Decreased anaemia, iron deficiency in women and children
• Decreased incidence of births with neural tube defects
Improved haemoglobin concentrations, as well as red-blood-cell folate concentrations and other biomarkers of nutrition
Improved productivity development, and performance
• Fortification of other food vehicles
• Other interventions providing additional micronutrients
• Nutrition-sensitive actions
Sustainable Development Goals 2 and 3
• end hunger and ensure access by all people, in particular the poor and people in vulnerable situations, including infants, to safe, nutritious and sufficient food all year round
• end all forms of malnutrition, including achieving, by 2025, the internationally agreed targets on stunting and wasting in children under 5 years of age, and address the nutritional needs of adolescent girls, pregnant and lactating women and older persons
• end preventable deaths of neonates and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1000 live births and under-5 mortality to at least as low as 25 per 1000 live births
• MANAGEMENT • STAFF • MULTISECTORAL COALITION • FINANCIAL RESOURCES • INFRASTRUCTURE
• GOVERNMENT COMMITMENT • OTHER MATERIAL CONTRIBUTIONS FROM PARTNERS
EFFECTIVE PROJECT MANAGEMENT AND MONITORING AND EVALUATION

2. **Assessing effects**
    - Providing information on programme coverage to help decide whether the fortification programme should be adjusted, continued, or halted based on the benefits, costs, and risks.

3. **Changing practices**
    - Identifying corrective actions to improve unexpected difficulties in the programme.

Factors, such as the available resources, the scope of legislative authority for data collection, and the capacity of the government agencies to collect data, will also impact the design of a monitoring system.

Stakeholders who will ultimately use the results of the flour fortification monitoring system to inform policy decisions should be included in the design phase. These individuals are likely to come from the public sector and may also be part of the multisector alliance. For example, someone responsible for food control in the country would be a useful participant. Likewise, the intended use of information collected should be decided in advance with input from other stakeholders. To ensure that the proposed monitoring system is politically viable, both sceptics and supporters should be consulted for inputs at the design phase *(1)*.

Indicators are specific measurable factors that can be used to describe the attributes of a flour fortification programme and to assess whether the programme is achieving its objectives *(4)*. Stakeholders should determine the indicators that are feasible to track and provide the best evidence of programme progress in the context of their country. Although multiple indicators are advised, selecting too many indicators could overwhelm programme resources (human and financial), resulting in poor data quality and/or stakeholder burnout. Finding a balance is essential.

Fig. 2 shows a logic model adapted from the *WHO/CDC logic model for micronutrient interventions in public health* for a hypothetical flour fortification programme designed to improve iron and folate status in a target population of children and women of reproductive age *(3)*. Circles have been placed in various parts of **Fig. 2** to clearly indicate where key WHO/CDC indicators align with the logic model. The numbers written in the circles coordinate with the number of the indicator as shown in the accompanying **Table 1.** Orange circles represent regulatory monitoring indicators (see **Chapter 3** and **Chapter 4**). Green circles represent consumption monitoring indicators (see **Chapter 5**). Not all countries with flour fortification programmes will collect data for these nine indicators, but they will be the focus of this manual.

Fig. 2. Logic model of a flour fortification programme designed to improve folate and iron status in women and children *(adapted from 3, 9)*

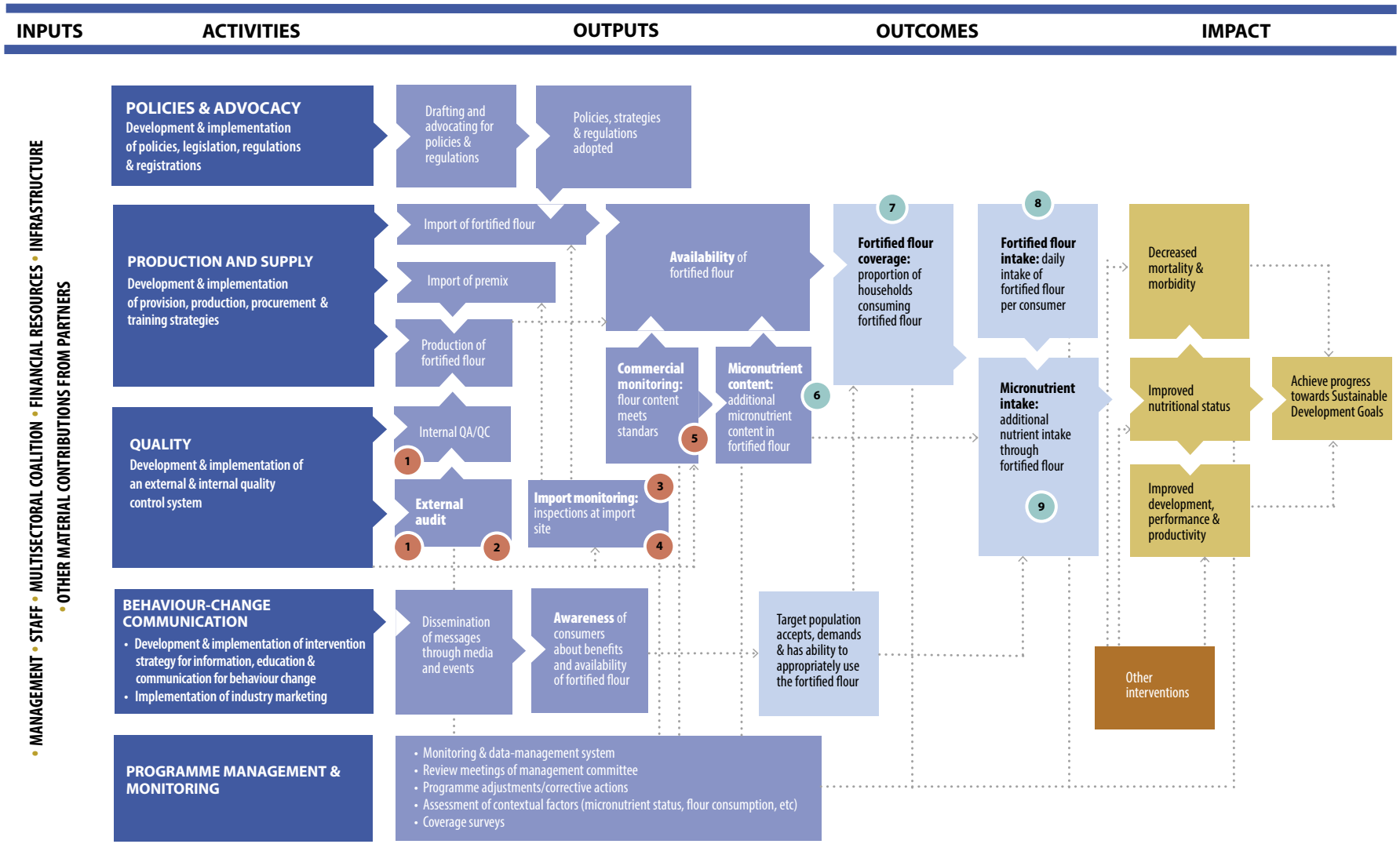


Table 1. Selected flour fortification monitoring indicators described in this manual[a]

Regulatory monitoring (Chapter 4)	
WHO/CDC indicator	Quality-assurance and quality-control procedures in place at large-scale flour mills
WHO/CDC indicator	Samples of flour from mills meet fortification specifications according to country standards
WHO/CDC indicator	Certificate of Conformity for imported fortified flour
WHO/CDC indicator	Samples of imported fortified flour tested meet fortification specifications
WHO/CDC indicator	Retail and market samples of flour and products made from flour meet fortification specifications
Consumption monitoring (Chapter 5)	
WHO/CDC indicator	Average additional content of micronutrients in fortified flours (micronutrient provision)
WHO/CDC indicator	Households consuming fortified flour (fortified flour coverage)
WHO/CDC indicator	Average daily intake of fortified flour (fortified flour consumption)
WHO/CDC indicator	Average additional amount of micronutrients delivered daily by consumption of fortified flour

[a] The full list of indicators can be found in the WHO/CDC *eCatalogue of indicators for micronutrient programmes*.

Once the stakeholders have determined the indicators that are appropriate for their monitoring system, the following questions should be addressed for each indicator *(2, 3)*.

1. Who will collect the indicator data?
2. How will the indicator data be collected?
3. How frequently will the indicator be collected?
4. Who will receive and analyse the indicator data?
5. How frequently will the results be reported?
6. How will the results be reported (e.g. report, presentation, media coverage)?
7. To whom will the results be reported?

An expanded list of indicators, (including the ones in this manual) can be found in the *WHO/CDC eCatalogue of indicators for micronutrient programmes (11)*, hosted at the WHO *Vitamin and mineral nutrition information system*. The catalogue indicators can be downloaded and adapted to the country context. Additional data on indicators can be obtained from the WHO *Global health observatory* (GHO). The GHO theme pages provide data and analyses on global health priorities. Each theme page provides information on global situations and trends, using core indicators, database views, major publications, and links to relevant webpages.

STEP 4: GATHER CREDIBLE EVIDENCE

Gathering credible evidence based on the monitoring system design is a critical aspect of any flour fortification programme. The standard for credibility varies depending on the questions to be answered as well as the stakeholder requirements. Factors that typically influence the credibility of findings include: the choice of indicators, the source of information/data, and the quality and quantity of information available *(1)*. In this manual, the steps for gathering data for external, import, and commercial monitoring and consumption monitoring are described in depth in **Chapter 4** and **Chapter 5**.

Milling industry personnel and representatives of the food control authority will collect data for the regulatory monitoring indicators. These indicators largely ensure that flour is fortified properly. Government employees who conduct health surveys or representatives of research institutions will obtain the data for the consumption monitoring indicators. Consumption monitoring assesses the coverage of the programme and the contribution to the nutritional status of the population.

In some cases, data may be collected from multiple sources. It should be noted that, to the extent possible, existing sources of information should be assessed first for utility and accuracy (e.g. monthly cost of a food basket, household consumption and expenditure surveys) before creating new information collection systems. The use of several sources can provide multiple perspectives and may allow triangulation of results, thus increasing the integrity of the data. Stakeholders need to agree that the sources of information capture each indicator appropriately in terms of quantity (amount of evidence gathered) and quality.

Unfortunately, some types of evidence may not be of adequate quality or may not be disclosed for monitoring purposes. Two examples are: (i) information on quality control from government food control inspectors may not be collected frequently enough, tested appropriately, or made publicly available; (ii) millers may not keep adequate records or may decline to share their logs with inspectors. Furthermore, the availability of resources may constrain collection of survey data to estimate indicators, such as the percentage of the target population consuming fortified foods. In the above situations, consideration should be given to revising the indicator or removing it from the monitoring programme.

The information gathering process should be transparent and well documented in the monitoring system design. For each indicator, the timing and frequency of data collection should be determined as well as how the information will be managed, analysed, used, shared and approved administratively. Furthermore, there should be a plan in place for initial and refresher training of staff. Adequate financial, material, and technological resources should be available for each separate activity.

STEP 5. JUSTIFY CONCLUSIONS

Each time data are collected, they must be analysed, synthesized, reviewed, and reported. The stakeholders must appropriately understand the information and interpret it against programme objectives, so they can justify their conclusions and recommendations. Periodic reports or presentations relaying the data findings, conclusions, and recommendations should be shared among all stakeholders. The multisector alliance often plays a significant role in reviewing and interpreting data, disseminating information, and encouraging changes to the fortification programme based on the monitoring results. Representatives of the government or local research institutions typically analyse the data and author the reports.

STEP 6: ENSURE USE OF RESULTS AND SHARE LESSONS LEARNT

Ensuring the use of monitoring findings may be the most important step *(8)*. The results of monitoring should be disseminated through periodic written reports, publications and/or public presentations. Without purposeful effort, findings and recommendations will be neither disseminated nor used to improve programme performance. A systematic approach to monitoring is essential to follow programme progress and to verify where programme compliance and success have been realized, while also helping to identify constraints in the implementation of programme activities. Thus, a well-functioning monitoring system provides decision-makers at different levels with timely information that will allow them to track progress against the planned targets and take corrective action when required.

The following are activities that help ensure the use of monitoring information *(adapted from 2, 8)*.

- Involve key stakeholders from the start to collect information needed for decision-making and prepare them for the eventual use of findings.
- Provide information and feedback to primary users and stakeholders throughout the process by establishing a system for routinely reviewing results, discussing action steps, and scheduling follow-up meetings.
- Schedule follow-up meetings to facilitate the use of monitoring information for informed decision-making and suitable action.
- Disseminate the monitoring information and lessons learnt widely to all relevant audiences in a timely and user-friendly manner that meets the needs of the audience.

Once this sixth step is concluded, a new round is initiated, and the monitoring process continues. If few changes have occurred since the monitoring system commenced, some steps may be reconsidered and addressed quickly.

CHAPTER 2: ANNEX

1.1 Description of the wheat flour fortification programme for Fortopia (a fictitious country)

Statement of need

Vitamin and mineral intake needs to improve among the population in Fortopia as indicated by the prevalence of nutritional anaemia and neural tube defects (NTDs).

Anaemia is a condition in which the number of red blood cells or the haemoglobin concentration within them is lower than normal. Haemoglobin is needed to carry oxygen around the body *(12)*. The most common causes of anaemia include nutritional deficiencies, particularly inadequate levels of certain vitamins and minerals.

In Fortopia, 31.4% of non-pregnant women of reproductive age are anaemic. This is classified as a moderate public health problem by WHO. Taking no action will leave this population vulnerable to the risks of pregnancy complications caused by anaemia and will negatively impact work productivity.

Among preschool children in Fortopia, 42.5% are anaemic. In this age group, iron deficiency hinders mental and physical development.

NTDs are serious birth defects associated with the mother having insufficient levels of folic acid around the time of conception. During the first month of a healthy pregnancy, the neural plate folds into a tube, leading to the development of the spinal cord and the brain. When this process is not fully completed, it results in NTDs. Three of the most common NTDs are spina bifida, encephalocele, and anencephaly; the latter is always fatal. The International Classification of Diseases (ICD) codes for each are: spina bifida – ICD10 Q05-Q005.9; encephalocele – ICD10 Q01-Q01.9; anencephaly – ICD10 Q00.0-Q00.1. The March of Dimes estimates that Fortopia has 20 NTDs per 10 000 births.

Expected effects

The short-term objective of the programme is fortification of all imported and domestically produced, industrially milled wheat flour. In the long term, the programme is expected to raise the normal intake of iron, folic acid, riboflavin, and vitamin B_{12} among the estimated 97% of Fortopia's population who consume wheat flour. In turn, the nutritional status and functional outcomes of the population will improve.

At least two factors must be in place before the expected effects can be realized *(4)*.

1. Foods made with industrially produced fortified wheat flour must be regularly consumed by at least 80% of the population.

2. The fortification programme must operate successfully consistently for 12–18 months.

The inclusion of iron to flour in Fortopia will decrease the risk of iron deficiency and iron-deficiency anaemia among the population. In time, the prevalence of iron sufficiency, evaluated through blood sampling, is expected to improve at the national level. This will positively impact adult workplace productivity, mental and physical development in young children, and pregnancy outcomes.

The inclusion of folic acid to fortified wheat flour in Fortopia should lead to a decreased prevalence of NTDs. Hospital systems will track NTD-affected births using the ICD codes and will report the data to the ministry of health on a biannual basis. Countries with a consistently well-run wheat flour fortification programme report a NTD prevalence of fewer than 10 per 10 000 births.

Children born with anencephaly typically die hours to a few days after birth. Those diagnosed with encephalocele and spina bifida require extensive medical care. Reducing the incidence of these birth defects in Fortopia is expected to avert significant health-care expenditures.

Contextual factors

Fortopia has recently prepared a comprehensive plan to address nutrition insufficiencies, which includes nutrition education at health clinics and secondary schools, distribution of vitamin A supplements to high-risk groups, and wheat flour fortification. An advantage of industrial fortification is that it does not require consumers to change their eating habits because the added nutrients are in the foods they traditionally consume.

The amount of wheat flour available per person per day is 548 g. Large-scale fortification is generally considered feasible in flour mills that are industrial, meaning they have a milling capacity of at least 20 tonnes per day. All of Fortopia's 330 wheat flour mills are classified as industrial and are thus expected to participate in the fortification programme. The flour will be fortified with iron, folic acid, vitamin B_{12}, and riboflavin in the form of premix.

Fortopia will make industrial fortification mandatory for several reasons. Most importantly, a mandatory fortification programme is more likely than a voluntary (or market-based) fortification initiative to ensure that the fortified product is available to consumers throughout the country. Fortopia will empower its regulatory authorities to monitor the fortification programme to ensure compliance with national fortification standards and relevant specifications. Also, mandatory fortification creates a business environment where all millers must fortify and thus incur similar expenses.

Flour millers in Fortopia will bear the cost of:

- fortification equipment;
- staff training;
- internal monitoring activities (ongoing throughout the year);
- procurement of vitamin and mineral premix.

The Government of Fortopia will bear the cost of:

- relevant training for food inspectors, laboratory staff, a target group of doctors and nurses, and survey enumerators;

- external, import and commercial monitoring activities (ongoing throughout the year);
- consumption monitoring activities (at least every other year).

Because the estimated wheat flour consumption among the population of Fortopia is high, minimal amounts of nutrients need to be added to each tonne of flour. Fortopia will follow the WHO recommendations shown in **Table 2.**

Table 2. WHO recommendations followed by Fortopia

Nutrient	Compound	Concentration (mg/kg)[b]
Iron	NaFeEDTA	15
Folate	Folic acid	1.0
Vitamin B_{12}	Cianocobalamin	0.008
Vitamin B_2	Riboflavin[a]	4.0

NaFeEDTA: sodium iron ethylenediaminetetraacetate.

[a] Riboflavin is not included in the WHO recommendations. This is the minimal amount needed to replace wheat's natural riboflavin that is removed in the milling process.

[b] For an availability of 548 g of wheat flour per person per day.

Stage of development

Planning

A group of leaders representing the public, private and civic sectors (the multisector alliance) has been advocating for wheat flour fortification in Fortopia for 14 months. As part of the planning process, they have considered the population's nutritional needs, ascertained the amount of wheat available for human consumption, conducted a milling industry assessment, developed fortification standards, and drafted legislation. Development of a monitoring plan, fortification logo, advocacy materials, and a list of approved premix suppliers are underway.

Implementation

Once the legislation is passed, Fortopia will move into the implementation stage. During this stage, millers will be expected to equip their mills, train their staff, and order premix. Government authorities and laboratory staff will be trained to conduct external, import, and commercial monitoring activities. A targeted group of doctors and nurses will be trained to systematically identify and record NTD-affected births.

Maintenance

After the initial implementation phase, the flour fortification programme will be maintained through monitoring efforts. Flour millers will engage in internal monitoring activities. Government inspectors will be responsible for external, import, and commercial monitoring tasks. If problems with the fortification process or with the distribution of fortified flour are identified through monitoring efforts, responsible parties must address the concerns in a timely manner.

Consumption monitoring, to estimate the change in nutrient intake that can be attributed to the consumption of fortified flour, will be conducted **at least** every other year. This form of monitoring will require recruitment and training of survey enumerators and other critical personnel involved in consumption monitoring.

Resources

The resources available include – but are not limited to – the following.

- Long-term commitment from leaders in the public, private, and civic sectors. They are expected to devote time, share knowledge, advocate, and seek financial support.
- Advocacy materials to persuade decision-makers and inform the public and milling industry.
- The fortification logo.
- Data related to nutrition, NTDs, and the milling industry for the planning phase of the programme**.**
- Database to input monitoring information and reports.
- Permanent website for meetings of the multisector alliance.
- Funding for procurement of fortification supplies and monitoring efforts,

Activities

- Form a multisector alliance – **completed**
- Analyse nutrition and wheat flour availability data – **completed**
- Conduct industry analysis to determine the number of industrial sized mills and their equipment needs – **completed**
- Prepare a training plan and materials – **completed**
- Draft fortification legislation – **completed**
- Establish fortification standards specifying the types and amounts of nutrients that should be added to flour – **completed**
- Develop a fortification logo and advocacy materials – **in progress**
- Draft the logic model (a graphic description specifying the programme inputs, activities, outputs, and outcomes in the short, medium, and long term) – **in progress**
- Establish a monitoring plan – **in progress**
- Establish a list of approved vitamin and mineral premix suppliers – **in progress**
- Determine who will pay for the various aspects of the fortification programme – **completed**
- Pass legislation to require fortification; pass fortification standards
- Purchase and equip mills with feeders and premix
- Develop a monitoring database and determine the host website
- Conduct training
- Start fortification!

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CHAPTER 3

QUALITY MANAGEMENT BY THE INDUSTRY – INTERNAL MONITORING

INTRODUCTION

Many countries have pre-existing standards for flour that specify the desired characteristics of the product, such as protein and moisture content. Some well-known examples are the *Codex standard for wheat flour 152-1985 (1)*, the *Codex standard for whole maize (corn) meal 154-1985 (2)*, and the *Codex standard for maize (corn) 153-1985 (3)*. It is advisable to incorporate the fortification standards for flour into any flour standards that already exist or are in preparation.

All flour mills need to monitor the flour production process internally to ensure that flour of consistent quality is produced. **Internal monitoring** refers to the procedures and tests carried out by the flour producers (mills) to manufacture flour as detailed in the standards. It includes **quality assurance** (QA) and **quality control** (QC) (**Table 1**). QA refers to the activities that are undertaken during production to ensure that the flour will meet the standards, and QC refers to tests and assessments of the flour to document and prove that it meets the standards.

When fortification is included in the flour standards, millers will need to add fortificants to flour during the milling process if they want to claim that their product is fortified. Likewise, mill staff will need to monitor the fortification processes to ensure the resulting fortified flour is consistently produced as detailed in the standards. This chapter describes the two components of internal monitoring, QA and QC.

Key WHO/CDC indicators that will help fortification stakeholders assess the progress of a fortification programme are also highlighted throughout. An overview of the indicators can be found in Chapter 2 and Chapter 6, regulatory monitoring indicators are described in Chapter 4 and consumption monitoring indicators are described in Chapter 5. Furthermore, technical details and examples of relevant monitoring tools are either presented in the annexes, or key references are provided for further reading.

Table 1. Internal monitoring for fortified flour

Sector	Component	Subcomponent	Responsible entity	Purposes	Key procedures monitored
Industry	Internal monitoring	Quality assurance	Mill procurement, production, QC personnel, and storage personnel	Implement necessary procedures to manufacture fortified flour that complies with (national) fortification standards	Checklist 1: Quality assurance
		Quality control	QC personnel of the mill	Confirm that fortified flour complies with (national) standards	Checklist 1: Quality control

3.1 Quality management systems

Mill managers should integrate QA and QC protocols for fortification into the general monitoring procedures of the mill. Most large mills implement several systems aimed at facilitating the production of safe and high-quality flour that will satisfy the requirements of producers, large-scale buyers, and consumers.

These include the following (Annex 3.1).

- International Organization of Standardization (ISO)
- Hazard analysis and critical control points (HACCPs)
- Good manufacturing practices (GMPs)
- Standard operating procedures (SOPs)
- Total quality management (TQM)

When a flour fortification programme commences, the QA/QC procedures pertaining specifically to the fortification initiative should be integrated into the existing management system in each mill site. This monitoring approach facilitates preventive measures at all stages of the food production chain so that underfortified products can be promptly identified and remedied *(4, 5)*.

Mills will need to review SOPs to ensure that all fortification processes follow established quality requirements. For example, the quality procedures put in place to procure high-quality raw materials for flour production should be applied to the procurement of premix for flour fortification.

3.2 Quality assurance procedures for fortified flour

For production of fortified flour, a mill will need to add QA procedures to those already in place for the production of flour. QA for fortification covers the procurement and appropriate addition of premix to the flour. When a fortification programme starts, procedures need to be put in place to ensure that the appropriate fortificants are added to the flour according to the standards. It should be noted that mills that produce flour for export and for national consumption might need to adhere to multiple premix formulations and flour requirements for the various markets served. Ensuring a controlled process provides confidence that quality requirements of the flour are consistently fulfilled during production.

The departments and personnel responsible for carrying out QA protocols at the mill may vary depending on the size of the mill. Minimum QA and QC procedures (**Checklist 1**) are discussed in detail in the sections that follow. Mill managers should inform their staff that inspectors may visit at any time and that they need to be able to demonstrate, with records, the processes that are followed to ensure flour is fortified appropriately.

Training of personnel is essential to ensure that millers have the capacity for adequate internal self-monitoring so that any deviations from the set standards can be corrected immediately, maintaining fortified flour that is of consistent quality at all times *(6)*.

Checklist 1. Minimum fortification quality assurance/quality control procedures for mill personnel

Quality assurance

- ✓ Premix is provided by an approved supplier and accompanied by a CoC/A for each batch/lot procured by the mill (**Chapter 3.2.1**).
- ✓ Quantity of the premix procured is in accordance with the quantity of flour that is regularly produced at the mill (**Chapter 3.2.2**).
- ✓ Premix is appropriately stored and used by expiry date (**Chapter 3.2.3**).
- ✓ Premix feeders are installed, verified as working correctly, and periodically maintained (**Chapter 3.2.4**).
- ✓ Premix dosed/added in accordance with fortified flour production rate (**Chapter 3.2.5**).
- ✓ Fortified flour is packaged, labelled, and stored according to specifications (**Chapter 3.2.6**).

Quality control

- ✓ Record keeping is done for single and composite flour samples (**Chapter 3.3.1**).
- ✓ Flour is regularly confirmed as fortified through qualitative tests (**Chapter 3.3.2**).
- ✓ Average content of nutrients is within acceptable range of variation around the target content as defined by the (national) fortification standards (**Chapter 3.3.3**).

3.2.1 Premix is provided by an approved supplier and accompanied by a certificate of conformity/analysis for each batch procured by the mill

Premix for flour is often imported into a country producing fortified flour and may be subject to special inspection by food and drug regulatory agencies. Premix is classified in some countries as a pharmaceutical product rather than a food product owing to the high vitamin and mineral content. In some countries, the institution

responsible for ensuring the quality of imported drugs and pharmaceuticals evaluates suppliers and provides a nationally approved supplier list. This, for instance, is practised in South Africa *(7)*. Where such a scheme is not in place, the millers will need to manage their own supplier assurance programme or may use the services of an internationally recognized provider of micronutrient premix. GAIN maintains a list of approved suppliers[3] and has established a mechanism for procuring vitamin and mineral premix from suppliers with proven high-quality systems and processes[4]. Information and guidance for establishing an industrial standard on reducing risks related to adulterated food premixes entering the food production chain are provided in the *Code of practice for food premix operations (8)*.

At reception of a premix consignment at the mill, before accepting and paying for the premix, the batches/lots are inspected to verify the premix consignment against **Checklist 2**.

Checklist 2. Inspection of premix consignment/purchase order at the mill

- ✓ A CoC/A is provided for every batch or lot number that forms part of the consignment (see **Annex 3.2.1.1** for an example of a CoC/A).
- ✓ All CoC/A parameters should be within the purchase specification limits. **Annex 3.2.1.2** provides a checklist to verify the CoC/A of premix or flour.
- ✓ Boxes are intact and where damage is done to the boxes, the contents are checked to ensure that the plastic lining is not broken and that the premix has not been exposed to any contamination.
- ✓ The label on the boxes has not been tampered with and key information is indicated, such as product name and code, batch/lot number, contact information for the supplier, and expiration or best before date. The premix must be traceable to the manufacturer.
- ✓ Mill personnel should always check that information on the label of the incoming premix box (product description and code) matches with product purchase specification.
- ✓ The premix expiry date should be within acceptable limits and beyond the expected usage date based on the mill's production forecast. A minimum of 75% of the premix life remaining on delivery is a useful guide.

If requirements above are satisfied, then the premix consignment is accepted and an entry is made in the premix inventory form (**Annex 3.2.2**, **Table 3**). If any of the above are not satisfied, the acceptance of the premix could still be considered, depending on further evaluation of the affected safety and quality criteria. If the risks are unacceptable, the premix is rejected.

A good practice is that each type of premix used at the mill is tested and compared against the CoC/A or specifications on a scheduled basis so that supplier performance and reliability can be monitored. This is frequently done by sending a sample of premix to an external laboratory to quantify the nutrients of interest. Ideally, however, the mills run or use a supply channel that ensures a test is done on every consignment that is received from a premix company. Large mills may order premix approximately three to four times per year. The analysis results are filed by the quality department of the mill. If results are unsatisfactory, the premix supplier needs to be informed and the premix replaced.

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[3] A list of approved suppliers can be found on the GAIN website: http://gpf.gainhealth.org/suppliers/current-suppliers

[4] The GAIN premix facility sources single micronutrients and micronutrient blends from carefully and continually assessed producers and blenders of a full range of both liquid and powdered micronutrients. GAIN ensures standardization of suppliers through an approval scheme whereby each supplier must undergo a detailed technical inspection that is conducted both remotely and onsite by an internationally recognized certification body that is accredited for food safety programmes. These include the International Featured Standards, British Retail Consortium, GLOBALG.A.P, Quality Standard, ISO 9001, ISO 14001, ISO 22000, ISO 45001 (which replaced ISO 18001 in March 2021), and Foundation Food Safety System Certification (FSSC) 22000. Follow-up audits are performed on a scheduled basis and any supplier not conforming to GAIN's specified standards is excluded from their supply pool. The supplier assessment scope is bespoke to GAIN and tailored to the industry, but it is built upon the core elements of relevant global food safety standards and aligned to Global Food Safety Initiative equivalence, with particular emphasis on FSSC 22000, ISO 22000 (on food safety management systems, and *Codex CXC-1969 General principles of food hygiene*, which incorporates a standard approach to HACCPs. Where supplied nutrients are defined in the *Food chemicals codex* established by the United States Pharmacopeia, this requirement for conformity is detailed in the GAIN supply specification and forms part of subsequent verification activities. All batches of materials supplied to GAIN's clients are verified by a third-party laboratory and the results of testing detailed in a CoC/A. The GAIN premix facility issues a quality complaint to the supplier laboratory if results show a deviation from the specifications.

3.2.2 Quantity of the premix procured is in accordance with the quantity of flour that is regularly produced at the mill

On receipt of a premix shipment, an inventory list is prepared to record the quantity of each batch/lot and the best before date and/or expiration date as shown on the CoC/As. An example of a premix inventory form can be found in **Table 3 in Annex 3.2.2**.

Tracking the premix procurement through a premix storage inventory and ensuring premix stocks are in line with the use reduces the risk of a stock-out. Depending on the time needed to procure premix shipments, a minimum premix storage threshold should be set. When the amount of premix falls below this quantity, another shipment should be ordered.

Typically, a large mill receives premix three or four times during a calendar year. The premix expiry date should be with acceptable limits at the time of reception and well beyond the expected usage date based on the mill's production forecast. A minimum of 75% of the life remaining on delivery is a useful guide. Buying premix in bulk has advantages, but the volume purchased should reflect the mill's normal production capacity to avoid unnecessary waste. On the other hand, ordering when stocks are too low can result in stock-outs when premix is not delivered on time because of challenges related to premix transportation and importation.

Mill production personnel keep track of the amount of flour produced in relation to the quantity of premix used. The ratio of the premix used and flour produced will indicate whether premix addition can be expected to be adequate. **Table 4 in Annex 3.2.2** provides a template that facilitates verification of the ratio of flour and premix during production. **Table 5 in Annex 3.2.2** uses the template in an example.

3.2.3 Premix appropriately stored and used by expiry date

Premix must be handled and stored appropriately to ensure that its quality is maintained. **Checklist 3** lists the points for mill personnel to follow for this purpose.

Checklist 3. **Storage and inventory of premix**

Premix should ideally be:

- ✓ kept in storage facilities appropriate for food ingredients and separate from storage facilities used for mechanical parts and fuel;
- ✓ kept at a low temperature according to the recommended instructions, as dry as possible, and without direct exposure to sunlight;
- ✓ kept in a well-ventilated area and stacked away from the wall;
- ✓ kept off the floor on pallets; and
- ✓ used on a first-expired-first-out basis.

The premix should be kept in a cool (ideally well below 30°C because some vitamins are heat sensitive), dry (to avoid mould and bacterial growth) storage facility where the boxes are placed on pallets to allow ventilation. Where storage conditions are not optimal, storage time should be reduced to a minimum. Boxes should be arranged using the first-expired-first-out method to provide easy access in the order of their expiry dates. **Annex 3.2.3** provides an example and figure to illustrate how this should be done.

3.2.4 Premix feeders are installed, verified as working correctly, and periodically maintained

Premix is added to flour using either a batch or a continuous process. When premix is added to the flour in batch production, the required quantity of premix is added into the batch mixer at one time in proportion to the flour quantity of the batch. This can be done manually or automatically. In mills that use a continuous process, premix feeders are installed at the front half of the flour collection conveyor and the packaging section (*see 9 section 3 Setting up the mill for fortification*) to ensure adequate blending before packaging; this can be referred to as an in-line system. Where several flour lines exist, all

the flour streams should be led to a single conveyor where the fortification process takes place before packaging. The premix is delivered to the flour in a continuous manner and at a rate that is proportional to the flour flow over a defined period. This operation is typically carried out automatically through electronic feeders that deliver the premix either by weight or by volume. If the flour flow is constant, the rate of premix delivery should be consistent.

The premix addition rate of the automatic feeders needs to be checked at the beginning of a production run and every time the milling process restarts following a major shutdown for any reason. The assessment must also be conducted when a new premix product is used.

The feeder should receive periodic maintenance according to the manufacturer's instructions. Results of performance checks and maintenance services should be recorded and made available for examination by inspectors.

3.2.5 Premix dosed/added in accordance with production rate of fortified flour

When a batch process is used, the premix is added to the flour all at once. The amount of premix added must correspond to the amount of flour produced in the batch. If the flour is fortified continuously, particularly during production of large volumes, the rate of addition must be routinely checked by production supervisors. It is important to know the exact flow rate of flour per hour as this dictates the amount of premix to add over a predetermined amount of time. In mills where the flour flow rate fluctuates, the dosing equipment (feeder/dosifier) should have the capacity to respond to these changes and adjust the addition rate accordingly. To verify that feeders are adding premix at the rate entered in the mill's control panel, the premix amount discharged by the feeder in 1 minute needs to be collected and weighed. This should be repeated at least three times to calculate the average, standard deviation, and the coefficient of variation (the standard deviation divided by the average) *(10)*. **Table 6 of Annex 3.2.4** presents an example of a control sheet to collect data for keeping track of the checks on addition rate.

There are certain situations that always necessitate checking the performance of the feeder/dosifier, such as when the production line stops because of a power outage or when mill personnel realize that the nutrient content of the flour is outside the acceptable range. In addition, each mill should define the frequency of routine performance checks. Ideally, these should be done multiple times per shift; at the very least, they should be carried out at the beginning of every shift or when premix is added to the feeder *(11)*.

The amount of premix added to flour is derived from the fortification standards and the premix concentration and is provided by the premix supplier. Any dilutions to the premix to facilitate mixing should be taken into account when determining the addition ratio (also called blending or mixing ratio). **Annex 3.2.5** provides an example of preblend preparation and presents an example of a premix-to-preblend addition rate conversion table (**Annex 3.2.5 Table 7**).

3.2.6 Fortified flour packaged, labelled, and stored according to specifications

The mill must ensure that the fortified flour is packaged, labelled, and stored according to the requirements/regulations of the recipient country. Fortified flour should be packaged to maximize protection of the added micronutrients against humidity, insect infestation, light, and oxygen. Label information is for the consumer, so should be legible and presented in a language that the consumer can easily understand. The label should include: an ingredient list, the batch/lot number, the expiry date or best before date, some indication that the flour is fortified, and contact details for the company that produced the flour. Additionally, the label should display the national food fortification logo where applicable. Specific information on labelling requirements can be obtained from the local standard for food labelling. Suggestions for appropriate storage of the fortified flour should appear on the label and should inform the consumer to keep the fortified flour in a cool, dry place and away from direct sunlight. The same conditions for storage apply to the producer when the flour is in the warehouse pending dispatch.

3.3 Quality control procedures for fortified flour

The QC function aims to confirm and document that the flour is fortified and meets the relevant standards. The mill's QA/QC procedures outline how samples are collected for this purpose, including taking individual samples at regular intervals or from each batch of flour produced by designated mill personnel.

3.3.1 Record keeping for single and composite flour samples

If the mill uses batch system production, ideally at least three single samples (500 g) are taken from the mixer (bottom, middle, and top) using a sampling spear or scoop. If the flour is already packaged, then samples are collected from bags selected at random from the batch.

In the case of continuous production, the frequency of sampling depends on the reliability of the feeder. Several single samples (500 g) are collected at the end of the packaging line at regular intervals. This occurs at least at the start and end of each production run (often 8 hours, which usually represents one batch) and in regular intervals in between (typically every 2 hours) or as per sampling schedule in the QA plan *(10–12)*.

The collected samples are labelled (**Table 2**) and recorded in the sample list (see **Annex 3.3.1**, **Tables 8** and **9**).

Table 2. Sample label

Name of mill
Date of sample collection
Type of flour
Batch number
Sample code

A practical approach is to perform a qualitative test each time a single sample is collected to determine whether the flour sample is fortified. If all single samples from one batch or production day are confirmed as fortified, then equal portions of each single sample are combined to make a composite sample for quantitative analysis, which is typically stored in a container. A composite sample is defined as a blend of single samples (e.g. five or as specified in the standards or food control procedures), which are usually of the same size, from a batch or production day. Composite samples are mixed thoroughly, labelled as in **Table 2**, recorded in the sample inventory list (see **Annex 3.3.1**, **Table 9**), and stored for a month in the mill's sample inventory. Composite samples, rather than single samples, are sent to the laboratory for quantitative analysis of micronutrient content (see **Chapter 3.3.3**).

3.3.2 Fortified flour is regularly confirmed as fortified using a qualitative method for testing the marker nutrient

Designated mill personnel should take samples of the fortified flour to test for the presence of at least one added marker nutrient. When the micronutrients that are added to the flour come packaged as premix, one can assume that the presence of a single micronutrient means the others have been added to the flour as well.

The **iron spot test** is easy to perform and commonly used to detect the presence of iron added to flour at production level (**Annex 3.3.2.1**). This is a qualitative test, thus is used only to confirm that the flour is fortified and not to determine the amount of iron in a flour sample. A positive iron spot test provides confirmation that the premix is being added to the flour and that the feeder and mixing process are generally working. A qualitative method for **testing vitamin A** in fortified flour is described in **Annex 3.3.2.2**.

Identification of individual flour samples that test negative in a qualitative assessment is an important indicator that something is wrong with the fortification process and that immediate action should be taken. If all samples are fortified, a composite sample is prepared from all single samples at the end of each shift or for each batch and kept for a month in the sample inventory.

3.3.3 Checking that average nutrient content and its allowable variation range accord with standards

Quantitative testing of the micronutrient content of samples is used to confirm not only that the end-product is fortified but also that it meets the desired fortification criteria (i.e. on average, the content corresponds to the standard and the variation of the content is within an acceptable range).

In general, quantitative analysis should be done on composite samples, rather than on single samples, at a mill laboratory or an external laboratory (**Annex 3.3.3**). This saves time and resources by reducing the analytical burden. In addition, results from testing composite samples better reflect the average quality of the batch/lot.

Composite samples should be periodically tested for the content of at least one marker nutrient (i) as appropriate for the production volume[5]; (ii) as indicated by the mill's QA/QC protocol; or (iii) if changes in the production process data signal a need for verification. The composite samples are analysed to determine the average micronutrient content of the batch/lot and the variation of that average micronutrient content from the targeted amount. Where more than one micronutrient is added, a marker nutrient (e.g. iron, zinc, folic acid, or vitamin A) can be chosen rather than testing for every single micronutrient. It is assumed that the other micronutrients will have a similar pattern of compliance based on information provided in the CoC/A of the premix. At least once per year, it is advisable for the mill to check the content of all or the main micronutrients added to the flour in one composite sample. **Annex 3.3.3.1** describes quantitative methods for analysing iron, vitamin A, and other nutrients in flours. Samples should be analysed as soon as possible after collection – ideally within 2 weeks and no more than 4 weeks (1 month).

It is not necessary for each mill to have costly analytical equipment to conduct the quantitative tests as external analytical laboratories can be used. What is important, however, is for the mill to have a procedure in place to regularly confirm that the fortified flour is conforming to standards.

In principle, fortified flour should maintain a relatively uniform micronutrient content for the same batch/lot within an acceptable range of variation around the target average. If this is not the case, the reasons should be investigated, and corrective measures implemented. **Chapter 4**, **Annex 4.3** discusses fortification standards and how to compare results with them.

The determination of the extent of variation between single samples is not routine and should be determined experimentally when production is initiated at the mill, or when a major change to the production process has been implemented and adjusted to reduce variation to a minimum. **Annex 3.3.3.2** provides examples of such variations measured in actual industry data.

Plotting quantitative testing results on a chart will enable production personnel to visualize the actual premix addition level in relation to the expected addition level (**Annex 3.3.3.3**, **Fig. 4**).

Results should be systematically filed to enable easy reporting, reviewing, and traceability of the fortified flour if requested by food authority inspectors.

Checking the micronutrient content of fortified flours should be seen more as a tool for documenting the quality and compliance of the fortified flour rather than as a requirement for ensuring acceptable performance of the fortification process. For the latter, QA practices are more practical, appropriate, efficient, and cost–effective.

In summary, internal monitoring focuses on the procedures, actions, and tests carried out by millers at flour manufacturing sites to (i) produce flour in a manner that is expected to achieve the specifications of the fortification standards and (ii) ensure that the final product actually adheres to those specifications.

[5] Production volume per production line less than 20 tonnes/day = quarterly; production 20–50 tonnes/day = monthly or two samples quarterly; production more than 50 tonnes = two samples every month.

CHAPTER 3: ANNEXES

3.1 Quality management systems

A mill that subscribes to the principles of these quality management systems is likely to produce consistently high-quality flour.

- The ISO 9000 family of quality management system standards are designed to help organizations ensure that product quality systems are in place and meet the needs of consumers and stakeholders while satisfying statutory and regulatory requirements. The ISO 22000 standard is a further development that focuses on food safety management systems and includes measures to minimize or eliminate food safety hazards (see HACCPs).
- HACCPs are used by many food producers to ensure safety and quality compliance based on a critical analysis of what could go wrong and identification of points where control measures need to be put in place to avoid such issues.
- The attainment of product quality standards and for product safety in the HACCPs system is supported by globally established GMPs and SOPs.
- GMPs are basic principles of operation needed to produce a consistent, high-quality product such as fortified flour. Some areas that are addressed by GMPs include:
    - using appropriate building/premises and equipment,
    - acceptable transportation and storage,
    - trained personnel,
    - manufacturing control processes,
    - sanitation and pest control, and
    - recall systems and record keeping.
- Compliance with GMP requirements entails minimum sanitary and processing requirements applicable to all food processors.
- SOPs are detailed, written instructions aimed at helping operators achieve uniformity in the performance of a specific function. For example, the SOP for wheat flour production would specify the amount of water to be added to a tonne of wheat berries for conditioning (accounting for the moisture content of the grain).
- TQM is the practice of instilling and institutionalizing a mindset of continually improving the ability to deliver high-quality flour and services to customers.

3.2 Internal monitoring: quality assurance and quality control by millers

3.2.1 Quality assurance/internal monitoring: inspection for flour premix by millers

3.2.1.1 Example of a certificate of conformity/analysis for flour premix

CERTIFICATE OF ANALYSIS

Premier Food Additives, 14137 Vitamins Boulevard,

New City, Nutriland Tel: +777-314-220-0000

Inspection lot	26599342800	
Materials	PFA0676656-7	
Lot number	PFA23022014	
Lot size	500 kg	
Date of manufacture	November 2013	
Best before date	October 2015	
Test	**Specification**	**Result**
Form	Powder	Passes test
Colour	Yellow–grey	Passes test
Odour	Faintly present	Passes test
Vitamin A palmitate	10.00–20.00 g/kg	17.20 g/kg
Pyridoxine hydrochloride	11.50–15.50 g/kg	12.00 g/kg
Folic acid	1.50–3.20 g/kg	2.02 g/kg
Cobalamin B_{12}	14.60–18.50 µg/kg 0.015–0.019 mg/kg	15.80 µg/kg 0.016 mg/kg
Thiamine mononitrate	8.20–12.20 mg/kg	10.10 µg/kg
Riboflavin	5.2–8.2 mg/kg	6.52 mg/kg
Niacinamide	45.00–65.00 mg/kg	55.80 mg/kg
Iron	35.00–45.00 mg/kg	40.10 mg/kg
Zinc	40.00–60.00 mg/kg	51.20 mg/kg

Storage recommendation: Keep in tightly closed containers below 25 °C, protected from light and humidity.

This is to certify that the lot number **PFA23022014** was manufactured in accordance with the requirements of ISO 22000-2005 and confirmed with the above specification when dispatched from our warehouse

Premier Food Additives	14137 Vitamins Boulevard	Tel: +777-314-220-0000
Date of analysis: 15 November 2013	Name/position:	Signature:

3.2.1.2 Verification of the certificate of conformity/analysis

If a premix or flour consignment is made up of several batches, every batch will need a separate CoC/A. Items to be checked on the CoC/A include those in **Checklist 4**.

Checklist 4. Certificate of conformity/analysis checklist

- ✓ Date of analysis
- ✓ Batch number and date of manufacture
- ✓ Close to specified amount of each micronutrient in the premix or flour and within the acceptable range (minimum–maximum)
- ✓ Other parameters are in accordance with supply specifications (e.g. moisture, particle size, microbiology)
- ✓ Use by date, best before date, or expiry date
- ✓ Laboratory or supplier identification details (name, address, and telephone number)

3.2.2 Quantity of the premix procured is in accordance with the quantity of flour produced at the mill

Table 3. Premix storage inventory *(adapted from 10, 13)*

					Premix movement from storage				
Date of premix movement	Premix type (compound & concentration)	Premix supplier	Production date/batch number	Expiry date/ best before date	Premix received (kg)	Premix dispatch (kg)	Dispatch location (production/ external)	Accepted & QC review done (Checklists 2 & 4)	New premix stock (kg)

Table 4. Flour and premix production log and premix reconciliation *(adapted from 10, 13)*

		Food vehicle produced			Premix used in production					Reconciliation		
				(A)					(B)	(C)	(D) = (B)/(A)	(D)/(C)
Date	Shift (time)	Food vehicle type	Batch/ production date	Production volume (tonnes)	Premix type	Premix supplier	Premix production date/batch number	Premix expiry date/ best before date	Volume (g)	Target addition/ incorporation rate (ppm)	Actual addition/ incorporation ratio (ppm)	% of target addition ratio

ppm: parts per million.

Premix use must be recorded in relation to flour produced to determine the regular requirement of premix. In **Table 4**, the premix addition rate is 400 g per tonne of flour. The mill produces about 120 tonnes of flour and uses about 48 500 g (48.5 kg) of premix per week. This is about 6.9 kg per day and 208 kg per month (or 30 days). Any purchases of premix should ensure provision of premix at this rate. A minimum premix storage threshold should be set, bearing in mind the amount of time needed to procure premix shipments. When the amount of premix falls below this quantity, another shipment of premix should be ordered. If the maximum amount of time to deliver the premix is 6 weeks, then at an average premix usage of 48.5 kg/week, the minimum buffer stock would be at least 291 kg (6 x 48.5 kg).

Table 5. Example of a completed flour and premix production log and premix reconciliation

			Food vehicle produced			Premix used in production					Reconciliation		
					(A)					(B)	(C)	(D) = (B)/(A)	(D)/(C)
Week	Date	Shift	Food vehicle type	Batch production date [time]	Production volume (tonnes)	Premix type	Premix supplier	Premix production date (week [W]/ year) [batch number]	Premix expiry date/best before date	Volume (g)	Target addition/ incorporation rate (ppm)	Actual addition/ incorporation ratio (ppm)	% of target addition ratio (D)/(C) x 100
25	19/06/2017	Shift 1	Whole-grain flour (100% extraction)	19/06/2017 [04:00]	8.125	WF premix country spec 2011	Premix producer 1	W12/2017 [2117:00]	31/07/2018	3260	400	401	100.3%
	19/06/2017	Shift 2	Whole-grain flour (100% extraction)	19/06/2017 [13:00]	4.063	WF premix country spec 2011	Premix producer 1	W12/2017 [2117:00]	31/07/2018	1630	400	401	100.3%
	19/06/2017	Shift 2	Whole-grain flour (100% extraction)	19/06/2017 [15:00]	12.188	WF premix country spec 2011	Premix producer 1	W22/2017 [3014:30]	31/09/2018	4890	400	401	100.3%
	20/06/2017	Shift 1	Whole-grain flour (100% extraction)	20/06/2017 [04:00]	11.333	WF premix country spec 2011	Premix producer 1	W22/2017 [3014:30]	31/09/2018	4447	400	392	98.1%
	20/06/2017	Shift 2	Whole-grain flour (100% extraction)	20/06/2017 [13:00]	5.667	WF premix country spec 2011	Premix producer 1	W22/2017 [3014:30]	31/09/2018	2223	400	392	98.1%
	21/06/2017	Shift 1	Whole-grain flour (100% extraction)	21/06/2017 [04:00]	11.800	WF premix country spec 2011	Premix producer 1	W22/2017 [3014:30]	31/09/2018	4800	400	407	101.7%
	21/06/2017	Shift 2	Whole-grain flour (100% extraction)	21/06/2017 [13:00]	5.900	WF premix country spec 2011	Premix producer 1	W22/2017 [3014:30]	31/09/2018	2400	400	407	101.7%
	22/06/2017	Shift 1	Whole-grain flour (100% extraction)	22/06/2017 [04:00]	7.250	WF premix country spec 2011	Premix producer 1	W22/2017 [3014:30	31/09/2018	2985	400	412	102.9%
	22/06/2017	Shift 2	Whole-grain flour (100% extraction)	22/06/2017 [13:00]	7.250	WF premix country spec 2011	Premix producer 2	W33/2017 [1130]	31/10/2018	2985	400	412	102.9%
	23/06/2017	Shift 1	Whole-grain flour (100% extraction)	23/06/2017 [04:00]	10.000	WF premix country spec 2011	Premix producer 1	W23/2017 [514:30]	31/12/2018	4033	400	403	100.8%

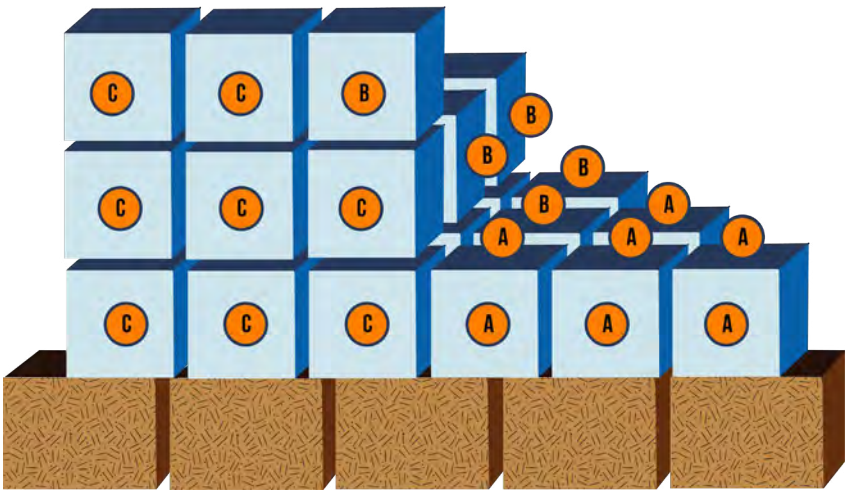
			Food vehicle produced			Premix used in production					Reconciliation		
					(A)					(B)	(C)	(D) = (B)/(A)	(D)/(C)
Week	Date	Shift	Food vehicle type	Batch production date [time]	Production volume (tonnes)	Premix type	Premix supplier	Premix production date (week [W]/ year) [batch number]	Premix expiry date/best before date	Volume (g)	Target addition/ incorporation rate (ppm)	Actual addition/ incorporation ratio (ppm)	% of target addition ratio (D)/(C) x 100
	23/06/2017	Shift 2	Whole-grain flour (100% extraction)	23/06/2017 [13:00]	5.000	WF premix country spec 2011	Premix producer 1	W23/2017 [514:30]	31/12/2018	2,017	400	403	100.8%
	24/06/2017	Shift 1	Whole-grain flour (100% extraction)	24/06/2017 [04:00]	8.000	WF premix country spec 2011	Premix producer 2	W23/2017 [514:30]	31/12/2018	3225	400	403	100.8%
25	24/06/2017	Shift 2	Whole-grain flour (100% extraction)	24/06/2017 [13:00]	8.000	WF premix country spec 2011	Premix producer 2	W23/2017 [614:30]	31/12/2018	3225	400	403	100.8%
	25/06/2017	Shift 1	Whole-grain flour (100% extraction)	25/06/2017 [04:00]	5.417	WF premix country spec 2011	Premix producer 1	W23/2017 [614:30]	31/12/2018	2150	400	397	99.2%
	25/06/2017	Shift 2	Whole-grain flour (100% extraction)	25/06/2017 [13:00]	10.833	WF premix country spec 2011	Premix producer 1	W23/2017 [614:30]	31/12/2018	4300	400	397	99.2%
					Weekly total: 120.826					Weekly total: 48 570		Weekly average: 402	Weekly average: 100.5%

ppm: parts per million.

3.2.3 Quality assurance/internal monitoring: storage and inventory of premix at the mill

Premix boxes should be arranged using the first-expired-first-out method to provide easy access in the order of their expiry dates. To allow easy identification (the labels are typically very small), personnel should mark all the boxes belonging to the same batch/lot with the same letter, such as A, B or C (**Fig. 1**). The dispatch of boxes to the production area will start with all boxes labelled A, followed by those labelled B, and so on.

Fig. 1. Marking premix boxes



In some instances, the premix may be diluted with flour to form a preblend (Annex 3.2.5). These dilution procedures must be documented and the preblend labelled appropriately to indicate when it was produced. Preblend is prepared from the premix lot that has the nearest expiry date.

3.2.4 Quality assurance/internal monitoring: periodic performance verification for automatic feeders by millers

To give an example, if the premix addition rate is 500 g per tonne and the flour flow is 10 tonnes per hour, the feeder should add 5000 g per hour (500 g/tonne x 10 tonnes/hour). This is the same as 83.3 g per minute. The procedure for checking performance requires collection of premix discharged by the feeder over a fixed time. In the example in **Table 6**, the collection time is 1 minute each for three samples. The mass of premix is recorded in all cases and, as shown in the table, the mass will vary to some extent. The average amount of premix discharged is calculated in grams per hour. An average premix discharge amount under 5000 g per hour is too low, resulting in underfortified flour and indicates the need to adjust the feeder (e.g. shift 1 in the table). Recording the amounts discharged (as in **Table 6**) will enable production personnel to compare the average premix addition level with the expected addition level and make adjustments when required.

Table 6. Control sheet to track amounts of premix discharged by an automatic feeder *(adapted from 13)*

			Amount of premix discharged (g)								
Date	Shift (time)	Discharge time (min)	Check 1	Check 2	Check 3	Average	SD	CV%	Premix (g/h)[a]	Adjusted?	Responsible
23/06/2017	Shift 1	1	80.6	83.1	80.2	81.30	1.57	1.9	4878	Yes	
23/06/2017	Shift 1	1	85.5	82.1	83.7	83.77	1.70	2.0	5026	No	
24/06/2017	Shift 2	1	83.8	82.6	85.8	84.07	1.62	1.9	5044	No	
25/06/2017	Shift 3	1	84.5	85.1	82.5	84.03	1.36	1.6	5042	No	
26/06/2017	Shift 4	1	83.7	84.7	82.2	83.53	1.26	1.5	5012	No	

SD: standard deviation; CV%: coefficient of variation expressed as a percentage.

[a] Premix (grams per hour) = 60/(discharge time [minutes]) x amount of premix discharged (g).

3.2.5 Preparation of preblend

Preblend is a combination of premix and wheat flour that is prepared by some mills to improve the distribution of the micronutrients in the wheat flour. This mixture is blended and stored in a similar manner as premix. A feeder/dosifier is still used, but the addition rate will obviously be higher to compensate for the dilution of premix in flour.

As an example, a producer uses premix with an addition rate of 500 g per tonne. In order to facilitate better integration of the micronutrients into the flour stream, the premix is diluted using flour from the inventory prior to being added to the feeder/dosifier. The miller mixes 25 kg of the premix from the supplier with two 50 kg bags (100 kg) of the flour. This is a dilution of 25 to 100 to form a preblend or a 1 to 5 ratio. The preblend would then have to be added at a rate that is five times more, or 2500 g per tonne, to achieve an addition rate of 500 g of premix per tonne of flour (see example in bold in **Table 7**).

Table 7. Premix to preblend addition rate conversion table

25 kg boxes of premix	50 kg bags of flour	Premix weight (kg)	Flour weight (kg)	Dilution factor	Standard addition rate of premix (g/tonne)	Actual addition rate of preblend (g/tonne)
1	1	25	50	3	400	1200
1	2	25	100	5	400	2000
1	3	25	150	7	400	2800
1	4	25	200	9	400	3600
1	1	25	50	3	500	1500
1	**2**	**25**	**100**	**5**	**500**	**2500**
1	3	25	150	7	500	3500
1	4	25	200	9	500	4500
1	5	25	250	11	500	5500

3.3 Quality control of flour by the mill

3.3.1 Record keeping for single and composite flour samples

Single samples collected are labelled with a unique sample code and recorded in a sample form. Laboratory results of single samples can be recorded next to the respective sample.

Composite samples are assigned and labelled with a unique composite sample code. The composite sample code is recorded next to the single sample included in the composite.

Table 8. Sample form

Date of sample collection	Flour type/ brand	Production date/batch number	Sample code	Sample amount (g)	Iron (qualitative test)	Composite sample code (if applicable)

Laboratory results of composite samples are recorded next to the respective composite sample code.

Table 9. Composite sample inventory list

Composite sample code	Flour type/ brand	Production date/batch number	Number of single samples	Sample amount (g)	Sample analysis date	Iron content (quantitative test) unit_____	Measurement of uncertainty of laboratory method (±X%)

3.3.2 Qualitative method for testing the marker nutrient in fortified flour

3.3.2.1 Qualitative method for testing iron in fortified flour

Most countries that fortify flour include iron as one of the micronutrients. Thus, the simple and inexpensive iron spot test is the most appropriate method for confirming fortification. The iron spot test is based on a method by the Association of American Cereal Chemists *(14)* where the reaction of **ferric iron** – Fe (III), the oxidized form of iron from any source – in an acidic medium, with a solution of potassium thiocyanate (KSCN) forms an insoluble red pigment. Other types of iron, such as **ferrous iron** – Fe (II) – and elemental iron can also react in a similar manner but need to be oxidized first to the ferric form with hydrogen peroxide before adding the KSCN. NaFeEDTA already has the iron in the ferric form and so the addition of hydrogen peroxide is not necessary.

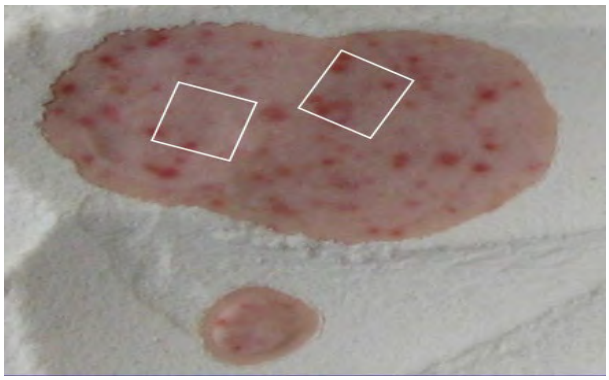


Fig. 2. Iron spot test on fortified flour

The appearance of red/pink spots confirms fortification with iron. Because of the intrinsic iron in flour, even flour that is not fortified will develop a red/pink hue where it has contact with the reagents, but no spots will be visible. More spots indicate a higher iron content in the flour; fewer spots indicate a lower iron content. **Fig. 2** shows the importance of adequate mixing to ensure an even spread of nutrients in the flour. The figure also shows that sampling amounts do matter for the iron spot test. A small sample (depicted by the squares) would provide different iron contents for the same sample.

Ferrous iron (ferrous sulfate or ferrous fumarate) can specifically be identified by formation of an insoluble bright blue pigment called Turnbull's blue via a reaction with potassium ferricyanide, but this reaction has lower sensitivity than the reaction with KSCN. The reaction with KSCN is rapid with ferrous sulfate but can be slow with ferrous fumarate or electrolytic iron. Therefore, it may be necessary to wait a few minutes after adding the hydrogen peroxide *(15)*.

Recommended practice is always to perform a qualitative test on the individual samples that are included in a composite to confirm added iron content before performing the quantitative iron analysis.

3.3.2.2 Qualitative method for testing vitamin A in fortified flour

Vitamin A can also be determined qualitatively using a chromogenic reaction where a solution of either trifluoroacetic acid or trichloroacetic acid is added to vitamin extracts in organic solvents such as dichloromethane. The formation of a blue colour is an indication that the flour contains vitamin A. However, since the content of vitamin A in flour is low, the iron spot test is preferred.

3.3.3 Quantitative methods for testing fortified flour samples and recording and reporting the results

3.3.3.1 Quantitative methods for analysing iron, vitamin A, and other micronutrients in flour samples

3.3.3.1.1 Quantitative methods for analysing iron in fortified flour

Most quantitative methods begin by treating a certain amount of flour with acid solutions or ashing the flour to produce a solution of iron. This solution is then used to determine total iron content via visible spectrophotometric or atomic absorption spectrophotometric methods. Irrespective of the method, the amount of iron determined will be the sum of the added and intrinsic iron *(12, 15–17)*. This is why many standards will list **total iron content**. When the total content is tested, variations of the intrinsic content of the flour need to be taken into account in the acceptable range of the nutrient content.

Advances in iron testing have provided methods where only the added iron can be extracted and tested, especially in the case of NaFeEDTA *(18)* and ferrous sulfate *(17)*.

In addition, portable devices now exist for the quantitative measurement of total iron content of fortified flour. Rapid quantification methods measure the colour reaction in a reagent vial and calculate the iron content in mg per litre. They are used to measure iron in vitamin premixes and flour, among other foods *(19)*.

3.3.3.1.2 Quantitative methods for analysing vitamin A in fortified flour

To quantify vitamin A in a sample of flour, the vitamin A is extracted into organic solvents and then reacted with either trifluoroacetic acid or trichloroacetic acid *(17)*. The formation of a blue colour is an indication that the flour contains vitamin A. It can be quantified using an ultraviolet spectrophotometer (reading the absorbance of the solution at 620 nm) or by using a scale of blue colours whereby the colour intensity correlates with the content of vitamin A *(12, 15, 17)*.

There is an adaptation of the method to be used in a single-wavelength spectrophotometer. Water is added to the flour and shaken vigorously to extract the vitamin A into a water/alcohol solution. A portion of this is injected into specially procured vials used to measure the fluorescence, which is related to the concentration of vitamin A in the fortified flour *(20)*[6].

3.3.3.1.3 Quantitative methods for analysing other nutrients in fortified flour

The *Fortification handbook* of the Micronutrient Initiative (now known as Nutrition International) *(12)* provides a method for determining the amount of folic acid in a flour sample; the ECSA-HC *Manual for laboratory methods for fortified foods (15)* includes a test for riboflavin; and the USAID *Manual of methods for determining micronutrients in fortified foods (17)* includes methods for the aforementioned micronutrients plus thiamin and niacin. Most of the testing options are based on official methods of the Cereals & Grain Association (formerly the American Association of Cereal Chemists).

3.3.3.1.4 Ensuring reliability of laboratory results

Any laboratory used regularly for the routine analysis of micronutrients in fortified flour should be certified in the analysis of all micronutrients of interest. At least twice a year, the laboratory should compare its results with the results of a certified external reference laboratory, for example, by participating in a laboratory QA and standardization programme[7]. If the difference in results between laboratories is not within an acceptable variation of the analysis method, then the reasons for the variation should be investigated by the laboratory and corrected as necessary. Laboratory results should be reported together with the measurement uncertainty to enable comparison of the results to the fortification standard and correct interpretation.

3.3.3.2 Example of variation of iron content in flour tested from one mill during calibration of fortification system

At the launch of fortification at a mill in Uganda, single flour samples were collected every 30 minutes for 10 hours.

[6] iCheck™ Fluoro (BioAnalyt, Teltow, Germany) for vitamin A (https://www.bioanalyt.com/product/icheck-fluoro/)

[7] CDC Laboratory quality assurance and standardization programs (http://www.cdc.gov/labstandards/)

To help the mill calibrate the feeder/dosifier correctly, the iron content was tested quantitatively for each sample (**Fig. 3**).

Fig. 3. Variation in iron content in flour samples from one mill tested during calibration of fortification system

Sample ID	Iron content (mg/kg)
1	47.3
2	57.6
3	51.5
4	48.6
5	35.6
6	28.3
7	35.1
8	36.1
9	57.8
10	33.8
11	29.1
12	30.0
13	66.9
14	48.8
15	35.0
16	73.7
17	65.2
18	60.0
19	64.8
20	65.9

	Parameters based on the standard	Actual results from the mill
Average iron content	50 mg/kg	49 mg/kg
Range	40–60 mg/kg	28–74 mg/kg
Standard deviation	±10 mg/kg	±15 mg/kg

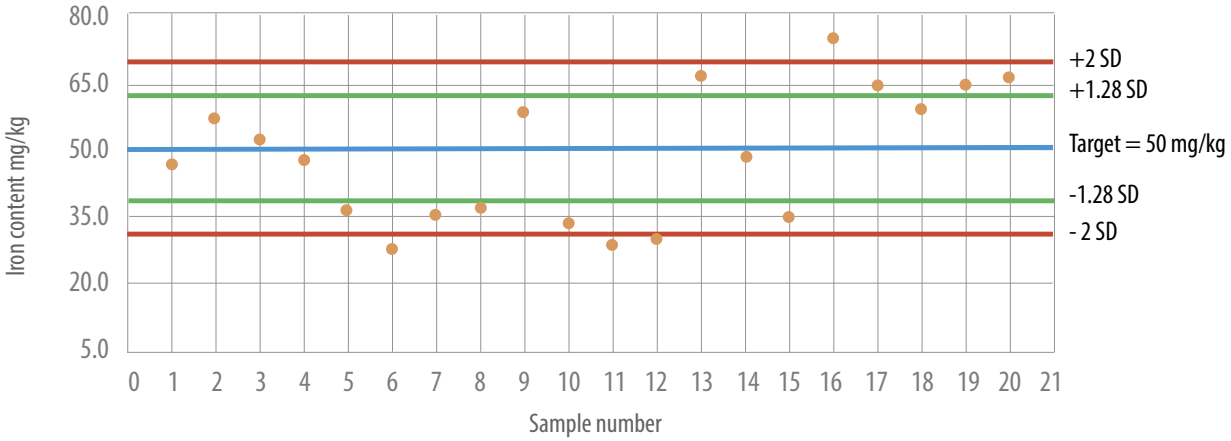
The mill was expected to add iron at a content of 50 mg/kg with a range of 40–60 mg/kg according to the (national) fortification standard. The average content during the calibration was found to be 48.6 mg/kg; this compared well with the target value of 50 mg/kg. However, results from single samples fell within a range from 28.3 to 73.7 mg/kg, demonstrating a variation that was much larger than the proposed variation (calculated as the standard deviation) of ±10 mg/kg. The actual standard deviation was ±14.8 mg/kg. If sample number 14 (48.8 mg/kg) had been the marker for compliance, the lot would have passed. However, if sample number 11 (29.1 mg/kg) had been the marker for compliance, the lot would have failed. Indeed, if a single sample were used as a basis for QC for a 10-hour shift, there is a 55% probability (11/20 samples) that the lot/batch will be classified as noncompliant. Using the average is a robust indicator; there is no need to base QC on many analytical determinations.

In summary, it is preferable to use composite samples instead of single samples as this saves resources and time invested in analytical work.

3.3.3.3 Plotting quantitative testing results

Plotting quantitative testing results on a chart, such as in **Fig. 4**, will enable production personnel to visualize the actual premix addition level in relation to the expected addition level. The results are plotted to show the trend over time, as indicated by the orange dots.

Fig. 4. Control chart for iron in flour



In a good system, results will fluctuate around the target and 80% are expected within 1.28 standard deviations (SD) of the mean. Results that are consistently beyond these limits indicate problems with the mixing. Results below or above 2 SD are not acceptable.

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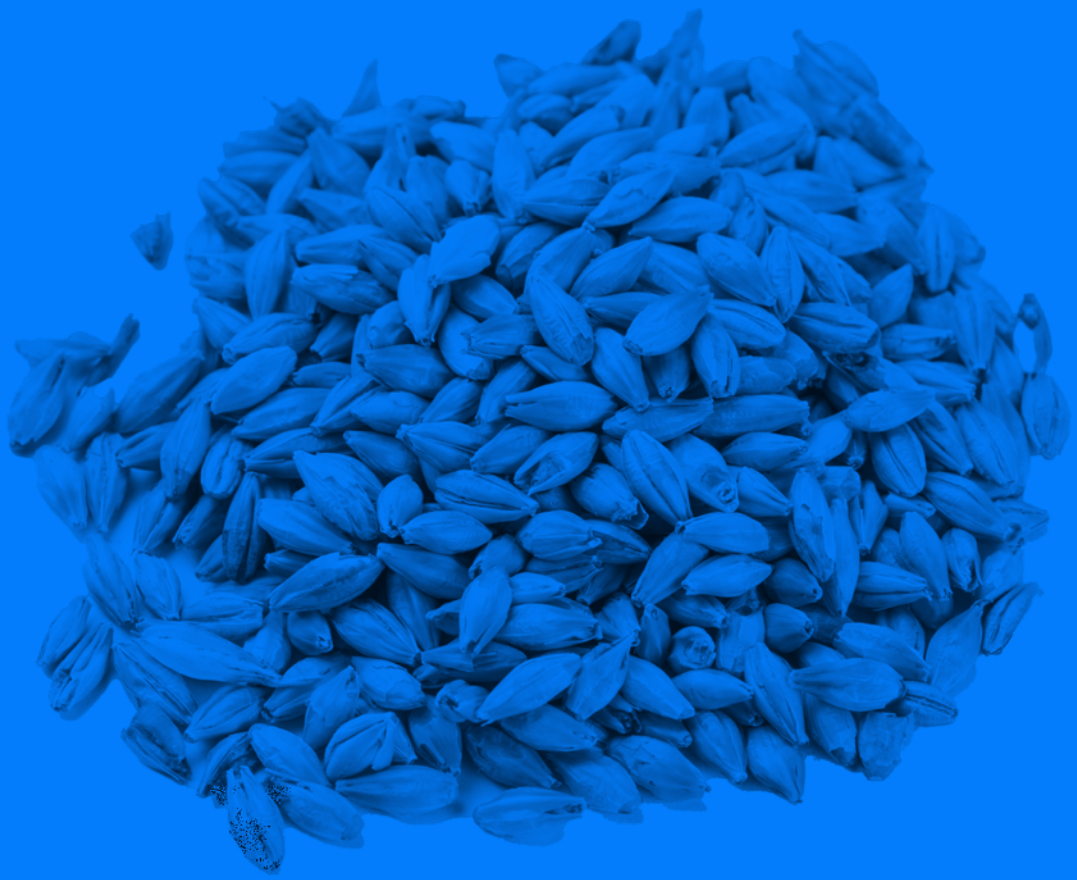


4

EXTERNAL, IMPORT, AND COMMERCIAL MONITORING

INTRODUCTION

External, import, and commercial monitoring are the procedures implemented by government entities responsible for food safety (hereafter referred to as the food control authority/authorities) to ensure that the flour available to the population complies with the standards on flour fortification. For the purpose of this manual, a standard is defined as a document approved by a recognized standard-enacting body that lists the technical specifications required for defined types of fortified flour and applies for a defined area, such as a region or country. Standards may be voluntary or compulsory. However, if a manufacturer wants to make a relevant claim, such as that a product is fortified, compliance with the technical specifications is obligatory.

The food control authority's task is to enforce legislation. Inspectors have the authorization to enter production sites to verify that QA/QC procedures are adequate and to take flour samples from production sites, import sites, and retail outlets to confirm the flour quality. As part of the flour fortification programme planning process, the roles and responsibilities of the inspectors or representatives of the food control authority need to be clearly defined in writing and sufficient resources for their activities should be allocated. The food control authority can be housed within the ministry of health, ministry of trade, bureau of standards, food and drug agency, or any other unit responsible for supervising food safety and quality in the country.

This chapter describes the critical elements of the monitoring by the government: external, import, and commercial monitoring (summarized in **Table 1**). It presents examples to illustrate the main points and describes the steps required to define a monitoring plan (**Annex 4.1**). The key WHO/CDC indicators that will help stakeholders assess the progress of a fortification programme are also highlighted throughout. Technical details and examples of relevant monitoring tools are presented in the annexes. Additional indicators are described in **Chapter 3** and **Chapter 5** and overviews of the indicators referred to in this manual can be found in **Chapter 2** and **Chapter 6**.

Table 1. Government monitoring of fortified flour: components, their purpose, and standard indicators[a]

Sector	Component	Subcomponent	Purpose	Key indicators collected by regulatory authorities
Government	4.1 External monitoring	4.1.1 QA: Audit	Verify that QA activities are performed according to plan	WHO/CDC indicator: Quality-assurance and quality-control procedures in place at large-scale flour mills
		4.1.2 QC: Inspection	Confirm that fortified flour complies with the fortification standards	WHO/CDC indicator: Samples of flour from mills meet fortification specifications according to country standards
	4.2 Import monitoring		Confirm that flour entering the country is fortified in the country of origin and complies with fortification standards	WHO/CDC indicator: Certificate of Conformity for imported fortified flour WHO/CDC indicator: Samples of imported fortified flour tested meet fortification specifications
	4.3 Commercial monitoring		Confirm that all flour available to the consumer in the marketplace complies with quality, packaging, labelling, fortification content as indicated in the fortification standards	WHO/CDC indicator: Retail and market samples of flour and products made from flour meet fortification specifications

[a] The full list of indicators can be found in the WHO/CDC *eCatalogue of indicators for micronutrient programmes*.

Where fortification of all or specific types of flour is adopted (mandatory or voluntary), food control authorities are required to conduct external monitoring of the authorized mills that fortify flour. **Fortified flour** refers to flour that is confirmed to be fortified while **fortifiable flour** refers to flour that should be fortified based on legislative mandate. For all the indicators described, both "fortified" and "fortifiable" can apply. For example, if the flour consumed is confirmed to be fortified, then as the term "fortified flour intake" can be used. If the flour consumed is supposed to be fortified based on legislative decree but fortification is unconfirmed, then consumption of that flour can be noted as "fortifiable flour intake". For convenience, all the indicators are referred to as "fortified" in this chapter and corresponding annexes.

External monitoring refers to the activities and actions carried out by government authorities to verify that QA/QC procedures at mills are conducted appropriately, and that the final product complies with the (national) standards for flour. Verifying compliance with QA procedures is referred to as **auditing**, whereas QC procedures to confirm flour quality are referred to as **inspection**.

The objective of external monitoring is to verify that fortified flour consistently conforms to standards. More attention should be put on adherence to QA procedures that ensure consistent production of flour that meets product specifications than on QC of the end-product (testing of flour samples). A focus on QA procedures will help millers detect any issues early and avoid corrective actions postproduction that result in loss of time and resources.

For all imported flour, irrespective of volume, government authorities in charge of food control have the responsibility to inspect fortified flour at import sites (**import monitoring**).

Government authorities also have the prerogative to verify that flour available to consumers in the marketplace meets the fortification standards. **Commercial monitoring** confirms that locally produced and imported fortified flour available in the market complies with packaging, labelling, and fortification standards. This type of monitoring is particularly important in areas where borders are porous, and flour may easily bypass import controls. Commercial monitoring provides important information about the fortification content of fortified flour in the marketplace. This information can be used to identify flour producers/suppliers/brands with poor fortification conformity that need to be monitored more closely, as well as to estimate the potential coverage of fortified flour and micronutrient (vitamin and/or mineral) provision to consumers. The results of commercial monitoring might not be directly used for legislative enforcement purposes, but they give important information to direct and prioritize external and import monitoring activities.

Food inspectors have food control responsibilities and monitor parameters in various food products, including flour. General flour characteristics that are monitored include protein and moisture content. To make the monitoring of fortification practicable and sustainable, the monitoring protocols for the fortification programme should be integrated into ongoing inspection procedures and flour sampling schedules. Where food control authorities already monitor flour and collect flour samples to test general flour parameters, collection of data specific to fortification can be integrated into existing forms and report templates. Sample volumes may need only be increased as required for the additional nutrient analyses relevant to fortification (qualitative and/or quantitative). The total number of samples to be collected and analysed will depend on available resources and the testing capacity of government laboratories.

Laboratories may need to invest in equipment or personnel to conduct these further analyses. The food control authority needs to ensure that sufficient government funds are allocated to support the monitoring responsibilities for flour fortification. Budget needs for monitoring should be discussed during the programme planning phase. The ECSA-HC *Manual for commercial inspection of fortified foods* provides details on budget planning *(1)*.

4.1 External monitoring

External monitoring is the process of reviewing the QA/QC procedures at each mill where flour is fortified. **Auditing** refers to the process of reviewing internal mill documentation to ensure that fortification procedures are implemented appropriately. **Inspection** refers to the process of confirming that the flour quality complies with standards.

Mill personnel should be aware that the mill will be visited, possibly unannounced, by inspectors from the food control authority at least annually, and that they will be held accountable for complying with the fortification standards *(2)*. They should therefore always be ready to demonstrate, with records, the procedures that are followed to ensure proper and consistent production of fortified flour. Details of auditing and inspection processes are described in subsequent sections.

4.1.1 Quality assurance: audit

WHO/CDC indicator: Quality-assurance and quality-control procedures in place at large-scale flour mills

Inspectors must review mill records for QA/QC activities during their visit and observe the fortification process to ensure fortified flour meets the fortification standards. **Box 1** summarizes the QA/QC activities for fortification that the government inspector should check during the audit. A general audit checklist is presented in **Annex 4.2.**

Box 1. Essential quality-assurance and quality-control activities subject to auditing by government inspectors

Quality assurance

- ✓ Premix is provided by an approved supplier and accompanied by a CoC/A for each batch/lot procured by the mill (see **Chapter 3.2.1**)
- ✓ Quantity of the premix procured is in accordance with the quantity of flour being produced at the mill (see **Chapter 3.2.2**)
- ✓ Premix is appropriately stored and used based on date of expiry (see **Chapter 3.2.3**)
- ✓ Premix feeders are installed, verified to be working correctly, and are periodically maintained (see **Chapter 3.2.4**)
- ✓ Premix dosage is in accordance with fortified flour production rate (see **Chapter 3.2.5**)
- ✓ Fortified flour is packaged, labelled, and stored according to specifications (see **Chapter 3.2.6**)

If the mill records and production process are deemed satisfactory, it is expected that the mill is procuring quality premix and producing high-quality fortified flour that meets the flour specifications. At the end of the visit, the inspector should debrief the QC manager or mill manager about any noted noncompliance or unsatisfactory activity. A specific period of time to rectify any issue should also be prescribed. **Annex 4.2** presents a format for registering the main findings and recommendations of an audit/inspection visit.

4.1.2 Quality control: inspection

WHO/CDC indicator: Samples of flour from mills meet fortification specifications according to country standards

The purpose of QC inspection is to periodically confirm that fortified flour meets the requirements of fortification standards. To confirm adequate fortification, flour samples can be collected at the mill by an inspector for quantitative analysis (**Annex 4.3**). To use the results for legal purposes and action, inspectors need to ensure that the sampling and sample handling meet an internationally acceptable protocol providing a defined level of uncertainty, such as the *Codex general guidelines on sampling (CAC/GL 50-2004) (3)*.

To determine the average micronutrient content (and variation) and to compare it to the target value, the minimum sampling can be followed in **Annex 4.3** and **Annex 4.3.1**. The samples can be taken from three places in the mill: (i) the flour sample inventory; (ii) the packaging line; (iii) the warehouse. Ideally, millers should keep an inventory of composite samples prepared from regularly collected single samples from the packaging line of the production of the day or shift following a standard sampling protocol.

The inspector can take composite samples from the mill's sample inventory or, if not mixed into composite samples, sets of a minimum of five single samples from the same production day or shift. If budget is available

to conduct several laboratory analyses, then composite samples from at least two batches/shifts/days should be collected and analysed to enable a calculation of variation.

If inventory samples are not available, then samples can be taken directly from the packaging line or the warehouse. A set of a minimum of five single samples from the packaging line are collected in regular intervals or from randomly selected bags from a batch/lot in the warehouse storage facilities.

The inspector will provide the sample(s) from the inspection visit to the appropriate regulatory laboratory for analysis. If single samples are collected, the laboratory will confirm fortification of each single sample and then prepare a composite sample by mixing equal parts of samples from the same batch or production day. The laboratory will quantitatively analyse the content of at least one nutrient in the composite sample.

The average of all composite samples gives a good estimation of the average content of the flour produced across batches[8]. If a set of composite samples was collected and analysed individually, the coefficient of variation across shifts or batches can be calculated.

The average content should be close to the target addition and should fall within the acceptable range. If the average falls outside the range for one of the composite samples, and the audit of the production process showed no weaknesses, then composite samples from further shifts/batches can be taken to verify whether the average across sample results moves closer to the target with each additional sample result and to review the coefficient of variation. This would indicate that, despite variation, the target average is still achieved. Further information on sampling can be found in the WHO *Guidelines on food fortification with micronutrients (4)*, in the ECSA-HC *Manual for external monitoring of fortified wheat flour (5)*, and **Annex 4.4.**

If serious failures or indications of noncompliance were identified during the audit/inspection, the producer is informed that immediate investigation and correction should be initiated. A follow-up visit should be planned after a reasonable period of time to allow the producer to implement the required corrective actions. During this second visit, the government inspector will focus on those issues that necessitated this extraordinary visit. If the corrective actions have not been executed, the food control authority should work with the flour mill to understand the constraints and problems more thoroughly. Ultimately, however, fines and penalties according to law may be imposed if the flour mill fails to show a commitment to make the required changes. It is imperative that the flour producers are informed of the consequences for failing to fortify or failing to comply with the fortification standards prior to or when the flour fortification programme commences. The food control authority needs to have the will and the capacity to follow through with these consequences if necessary.

4.1.2.1 Preparation of single samples for external monitoring

The mill usually collects a single sample from the packaging line from the same batch/lot at regular intervals. For example, this can be done at the start and end of each production run and at regular intervals in between (typically every 2 hours) or as per sampling schedule outlined in the QA plan *(6)*. If the mill stores these as single samples in their sample inventory, then inspectors can collect a set from the inventory. The inspectors can either select these inventory samples or collect a defined number of single samples of flour directly from the warehouse and/or the packaging line in the mill as indicated in the inspection guidelines and procedures. If the results are to be used for legal purposes an internationally acceptable sampling protocol, such as the *Codex general guidelines on sampling (CAC/GL 50-2004)* needs to be used *(3)*.

To estimate the average content, a minimum of five single samples should be collected from the batch/lot from the packaging line or from the warehouse. Each single sample is checked qualitatively for a marker fortificant (e.g. iron) by the mill laboratory in the presence of the inspector. If one sample fails the qualitative test, it should be noted as a failure and must be reported as such to the QC manager of the mill immediately to take corrective action. When all samples register as fortified on qualitative testing, the single samples from a batch can be mixed in equal parts (e.g. 500 g each) to prepare a composite sample for quantitative analysis.

[8] The variance estimate of the sample (precision) and thus the accuracy of the average micronutrient content of a composite sample increases (estimate is closer to the true value) the more single samples are included. The more samples are included, the closer the average should move towards the standard target.

4.1.2.2 Preparation of composite samples for external monitoring

Because numerous factors can contribute to variation (**Annex 4.3** and **Annex 4.3.2**), the average content of micronutrients in the flour is best determined by quantitative testing of a composite sample rather than of multiple single samples (**Box 2**). Quantitative analysis of composite samples saves time and resources by reducing the analytical burden. Composite samples should be made from at least five single samples, as defined in the QA/QC protocol of the miller or the inspection guidelines and procedures. The single samples are tested qualitatively and equal portions of the single samples (if they all tested positive) will be included in the composite sample. Any negative qualitative test will require immediate action without requirement of a quantitative test.

Each mill should store samples from a batch, shift, or production day as part of its QC procedures. These daily composite samples are stored for up to a month in the mill's inventory. During inspection, the inspector can select randomly from the inventory. A daily composite sample of at least 1.5 kg is desirable, since this allows the sample to be split into three replicates of at least 500 g each. Samples are sealed in an air-tight container or bag. One sample is tested quantitatively by the mill's usual laboratory. One is taken by the inspector for quantitative testing of one or more micronutrients by the government laboratory. One is reserved for reference in case discrepancies arise between the government laboratory and the mill laboratory results. The reserved samples are discarded after the inspection report is sent and accepted by the mill. **Annex 3.3.2** outlines quantitative methods for testing micronutrients in flour.

Box 2. Implications of using laboratory analysis results for regulatory decision-making *(adapted from 7)*

Although laboratory analysis plays a critical role in monitoring, it is just one component of the process. Laboratory results alone do not provide definitive evidence of compliance or noncompliance; they need to be interpreted in conjunction with auditing information obtained at the mills and inspection of CoC/As at the mills or import sites. QC results indicating poor performance should trigger a thorough investigation of the production process.

Analysis of micronutrients in premix and fortified flour requires sophisticated laboratory capability. Ideally, laboratories should be certified for the specific micronutrients being measured. Laboratory analyses are subject to several sources of variation including the intrinsic variation of micronutrient content in the flour, equipment variation, and variation in the content of micronutrients added during fortification. Because of several factors (see **Annex 4.3.2**), including the high magnitude of nutrient dilution in the flour (e.g. 2–4 mg/kg for folic acid), the nutrient results can vary significantly depending on the sample taken.

In Chile and Indonesia, laboratory analyses of flour samples are conducted for four of the five and five of the five required micronutrients, respectively. Because of the wide margin of error (especially for folic acid) and the complex testing protocols, the laboratory results may have different ranges of variation for different micronutrients. Nonetheless, they influence regulatory decisions and have led to tension between industry and government authorities. In both countries, passing inspection requires satisfactory content of all micronutrients tested.

In Chile, controversy arose when the results for one mill showed content passed for three of the four nutrients tested, leading millers to ask why the micronutrients added through the same premix can lead to results that are disproportionate to the requested micronutrient content of the premix. In the case of Indonesia, mills may add higher content of premix to ensure that they pass inspection for all micronutrients.

In addition to the difficult interpretation of results for multiple micronutrients, the number and quantity of laboratory tests conducted can be a burden to the state laboratories and represent a significant cost to the monitoring system. Solutions to overcome this situation include greater use of composite samples and identification of a subset of required micronutrients (marker micronutrients) that could reflect the overall quality of the product. For example, South Africa requires testing of vitamin A and one other micronutrient (either riboflavin or niacin) as markers of adequate fortification. This saves the cost and time required to analyse all eight micronutrients required by the country's fortification standards.

4.1.3 External monitoring reporting

A report should be provided to the QC or mill manager within a short period of time after the audit/inspection visit. Recommendations and corrective actions required should be fed back immediately and, if flour sample results are taken, results should be reported ideally within a maximum of 4 weeks. The report should include the observations taken during the visit, state the results of the sample analyses, and specify recommendations and corrective actions to take for improvement if necessary (**Annex 4.2**). The producer passes the audit/inspection if no issues of noncompliance were identified or, if identified, were resolved; the QA procedures are in place; and, if samples were taken, the composite samples comply with the standard. **Annex 4.3** and **Annex 4.3.1** provide more details on the comparison with the standard.

A report of all audit/inspection visits should be sent to the food control authority (see **Chapter 6** for further information on reporting). For each mill that is expected to fortify, the summary report should list the following.

- The inspection date.
- Whether the key QA procedures are in place (this can include details about the individual items in the QA/QC checklist).
- If samples were taken:
    - the number of single samples taken by batch or production day (at least five single samples in each composite sample from the packaging line, the warehouse, or the inventory);
    - the percentage of samples that were fortified (all single samples or a composite sample of all single samples);
    - the average micronutrient content of the marker nutrient of the composite sample (if the composite sample or all single samples were previously confirmed to be fortified);
    - the variation of the marker nutrient across batches (if multiple composites were collected);
    - the average content of the marker nutrient of all samples analysed;
    - pass/fail for the audit/inspection visit and any follow-up action required.

A summary report of all audit/inspection reports can also be shared with multisector alliance and anyone else interested in the fortification programme.

4.2 Import monitoring

Import monitoring aims to certify that all fortified flour and premix coming from outside the country meet the fortification standards. This type of monitoring is especially important when a country has a mandatory flour fortification programme and imports a significant (subjectively defined) amount of flour. It ensures all fortified flour that is imported competes under the same conditions with locally produced flour. Imported premix also needs to be monitored to certify that the vitamins and minerals used for fortification are of high quality and comply with the local standard.

Import monitoring inspections are conducted by border inspectors and can be done in conjunction with customs personnel. For every consignment that is inspected, the border control inspectors need to fill out forms similar to the example in **Annex 4.5.1** for each lot of flour included in the consignment. The information for each inspection is then summarized in monthly reports using a form similar to the example in **Annex 4.5.2**, which includes the results of qualitative testing for the presence of a micronutrient marker in the flour by the government food analysis laboratory (quantitative testing may also be done). Further information on this topic can be found in the ECSA-HC *Manual for inspection of fortified foods at importation sites* *(8)*.

4.2.1 Certificate of conformity/analysis for imported fortified flour meets fortification specifications according to standards

WHO/CDC indicator: Certificate of Conformity for imported fortified flour

Border inspectors verify and record the quality of imported flour. Where significant volumes of food made with flour are imported, fortification specifications need to be included in the respective food standard to avoid large volumes of imported unfortified flour or foods made with unfortified flour. Each imported consignment should be accompanied by a CoC/A for each batch/lot of fortified flour (**Annex 4.5.3.2**). The CoC/A indicates that the flour complies with the corresponding fortification standards. **Annex 4.5.3.1** provides a checklist of points that customs personnel should verify on the CoC/A prior to accepting a consignment of fortified flour. Ideally, each consignment of flour with a CoC/A should also be checked using a qualitative test (e.g. iron spot test) to confirm the presence of fortificants.

All imported flour should be labelled according to the fortification standards. Packaging quality and label information should be verified for each lot/batch of flour imported to confirm that the label includes all the required information (i.e. contact details for the company that produced the flour, the lot/batch number, the expiry or best before date, the ingredient list, and some indication that the flour is fortified).

4.2.2 Imported fortified flour meets fortification specifications according to standards

WHO/CDC indicator: Samples of imported fortified flour tested meet fortification specifications

For every consignment of imported flours all CoC/As need to be inspected as part of the clearing process. The CoC/A confirming compliance can be sufficient, but countries are encouraged to have some capacity for qualitative testing (e.g. with the iron spot test) to facilitate decision-making at import sites. The consignment is then allowed to enter the country. For all new suppliers importing flour into the country, the border inspectors should confirm (i) the reliability of the CoC/A and (ii) the adequacy of micronutrient content for each flour type/producer/brand in the first consignment.

Depending on the volume of traffic, a plan is devised for random sampling for quantitative analysis of consignments of known suppliers/importers after inspection of the CoC/A. This is done by: (i) determining the feasible number of consignments that can be sampled and analysed in a month or quarter; (ii) estimating the number of consignments entering the importation site during this period; and then (iii) calculating the interval X by dividing the consignments by the sample size. Every Xth consignment imported should be sampled. Importers that import more consignments will consequently be inspected more often.

For every Xth consignment, samples are collected randomly from various places in each flour type/producer/brand/batch included in the consignment, following an internationally acceptable sampling protocol such as the *Codex general guidelines on sampling (CAC/GL 50-2004) (3)*. At least five samples are taken from each type/producer/brand/batch. If flour of the same type/producer/brand/batch is split into several containers/trucks, at least one single sample should be taken from each container/truck per type/producer/brand. If the flour is packaged in bags/packages, personnel should select bags/packages randomly and take a sample from each selected bag/package using a sampling spear. Samples should be mixed in equal parts to make a composite sample of about 1500 g by type/producer/brand. This sample should be divided into three parts. One part is sent to a government laboratory to assess the micronutrient content quantitatively (**Annex 4.4**), the second part can be analysed by the importer. The third part of the sample is reserved for reference in case discrepancies arise between the results of the government laboratory and the importer.

The test results will determine the average nutrient content that will be checked against the CoC/A values and the flour standards. As in the case with inspection of locally produced products, the average micronutrient content of a brand should be near to the expected target value and within the acceptable micronutrient content range defined by the standards.

The company/person authorized to import the brand will be notified if the results fail to comply with the fortification standard and advised that subsequent imports will not be released until quantitative testing indicates appropriate fortificant content. Using the CoC/A and qualitative testing of single samples to confirm compliance will not resume until confidence in the brand and the importer has been restored. If the consignment is approved, the supplier/brand will be registered and a CoC/A for a certain time period (e.g. 6 months) can be given to the

importer to facilitate future imports. The importer will be subject to only random sampling for quantitative testing in the future to ensure continued compliance.

4.2.3 Premix is provided by an approved supplier and accompanied by a certificate of conformity/analysis

Micronutrient premix, which is added to flour during the milling process, is often imported into a country where fortified flour is produced and may be subject to inspection by the food and drug agency. Because of their high micronutrient content, premixes are classified in some countries as a pharmaceutical product rather than as a food product. The institution responsible for the quality of imported drugs and pharmaceuticals should evaluate potential suppliers prior to starting the flour fortification programme and prepare a nationally approved list. This list can be revised as necessary.

It is important that the customs and food control personnel refer to a checklist when importing consignments of premix. **Annex 4.5.3.3** provides a checklist of points to verify. As with fortified flour, premix shipments should come with a CoC/A. **Annex 4.5.3.2** shows an example of a CoC/A for flour, **Annex 3.2.1.1** in Chapter 3 shows an example of a CoC/A for premix.

For every new supplier of premix, customs and food control personnel need to confirm the reliability of the CoC/A by sending a sample of the premix to the assigned laboratory. Premix has a high content of micronutrients and is expected to be homogenous when provided by an approved supplier. Ideally, all the main micronutrients in the premix are analysed to confirm that the composition of the premix is adequate. Details of premix sampling methods are provided in the ECSA-HC *Manual for external monitoring of fortified wheat flour (5)*.

4.2.4 Import monitoring reporting

Customs officials at each importation site should prepare a monthly report of the flour and premix that entered into the country over the last month, disaggregated by importer, flour producer, and brand (depending on the detail of the customs tracking system already used). The report should indicate:

- the amount/volume of flour and flour premix presented at the import site;
- the number of flour and premix consignments/shipments presented at the import site;
- the number of flour and premix consignments/shipments of which all lots were accompanied by an appropriate CoC/A;
- the number of consignments/shipments of which producers/brands were tested qualitatively;
- the number of consignments/shipments of which all tested lots were fortified (as confirmed by qualitative testing);
- the number of consignments/shipments of which flour of producers/brands were tested quantitatively;
- the number of consignments/shipments of which flour of all tested producers/brands were fortified in accordance with the fortification standards.

A copy of this report should be sent to the food control authority, the multisector alliance, and anyone else interested in the fortification programme (**Chapter 6**).

The food authority compares the results of each producer and/or brand to the standards and notifies the company/person authorized to import the flour type/producer/brand.

4.3 Commercial monitoring

Commercial monitoring ensures that locally produced or imported fortified flour complies with flour and fortification standards in terms of micronutrient content, safety and sanitation, packaging and labelling, and other key technical specifications. All activities related to this form of monitoring take place in the marketplace, as the term commercial suggests. Commercial monitoring is particularly important in areas where borders are porous and unfortified flour may easily bypass import controls. This can happen when a neighbouring country's government subsidizes flour or has price controls on the commodity. The main aim is to assess the quality of flour available to

the population in order to identify supply channels of flour of inadequate quality that require follow-up to identify the cause and ensure corrective action. Unknown brands or producers are noted and investigated to determine their location, to ensure they are registered, and, more importantly, to ensure that the flour is not imported outside the legal and controlled channels. The purpose of commercial monitoring is not to identify offenders and take legal action but to prioritize follow-up action through inspections at the import and production site and/or the supply chain *(1)*.

4.3.1 Fortified flour collected in distribution centres and retail outlets is packaged and labelled as specified in standards

The market inspection involves checking that all locally produced or imported flour offered at distribution centres and retail outlets is packed in original bags and labelled according to (national) standards. All the required information should appear on the label of package, such as contact details for the mill that produced the flour, the batch/lot number or production/expiry/best before date, the ingredient list, and some indication that the flour is fortified. Without adequate labelling, inspectors cannot identify and provide valuable information to the suppliers of flour that do not comply with the fortification standards. It should be noted that counterfeits of well-known brands may exist, and government and food industries should work together to continuously monitor, investigate, and prevent flour of suboptimal quality being made available to the consumer.

4.3.2 Flour at the retail level meets fortification standards

WHO/CDC indicator: Retail and market samples of flour and products made from flour meet fortification specifications

An annual sampling plan needs to be defined. The level of stratification, the frequency of sample collection, and the total number of samples to be collected and analysed over a year are dependent on the available government budget and capacity to collect and test market samples. Prior to initiating commercial monitoring, stakeholders must determine: (i) the number of single samples that will constitute one composite sample during a data collection round and (ii) the total number of composite samples that will be collected to represent each producer, brand, and/or flour type in a defined area. The sampling method must be followed as closely as possible every time commercial monitoring takes place since major deviations from the set numbers will skew the quantitative analysis results. Inspectors should obtain flour samples in a systematic manner, ideally at several time points throughout the year, from the primary retail outlets (e.g. retail stores, wholesale distribution centres, temporary market stalls, and/or producers of food made with flour, such as bakeries) within the main markets/provinces of the country.

The *Fortification assessment coverage toolkit (9)* and reports of completed market assessments *(10–12)* provide further guidance and a set of templates for the planning and implementation of a market assessment.

4.3.2.1 Sampling plan

Steps for inspectors and executing partners to define the sampling plan for commercial monitoring are as follows.

1. Identify the geographical divisions (or provinces) where they operate.
2. Identify the regions/provinces where import sites/ports are found, and where the mills are positioned. This is done because products from mills close to import sites/ports are more likely to present variations in levels of fortification.
3. Identify the number of local mills/producers and estimate the production volume and their percentage contributions to the total flour supply to the population.
4. Identify the number of flour importers, their import volume, their type/producer/brands, and their percentage contribution to the total flour supply. Prepare a list of producers and their brands of flour with their respective market share (**Annex 4.6.1**). Products or producers that supply large volumes should be prioritized.
5. Identify those products or suppliers for which recent monitored results are available from inspection at the production or import level. Products or suppliers with no performance record or poor performance should be prioritized.

6. Determine laboratory capacity and budget to test samples per period of time. Ask the laboratories for an estimate of the number of samples they realistically/feasibly analyse at any given time. Ideally, every year each local flour producer should be inspected at the local production site and each flour importer should be inspected at the import site as part of import inspection. The steps for planning and prioritizing monitoring activities between production, import, and market levels are shown in **Annex 4.1.**
7. Define the stratum or level of disaggregation[9] at which the average micronutrient content in flour is to be measured and compared to investigate quality differences in the flour supply. This can be for the producer, brand, and/or flour type in the country or a region as follows.
    a. By flour type (a): Composite samples and results should be representative for the flour type in a defined area/market.
    b. By producer/mill (a and b): Composite samples and results should be representative for flour supplied by the respective producer in a defined area/market.
    c. By brand (a, b, and c): Samples collected and results should be representative for flour brand supplied by the respective producer in a defined area/market. For composite samples representative for a producer and/or brand, single samples should be collected from the different batches and ideally from different regions/markets.
    d. By area/market, such as region or country (c and/or b, and/or a and d): Samples collected and results should be representative for a defined flour type, and/or respective producer, and/or flour brand in the respective area.
8. At one time point, collect 10 single samples (or a minimum of five) from different batches or retail outlets for each unit/stratum and combine in equal parts to form a composite sample for quantitative analysis.
9. Conduct sample collections and analyses at different time points over a year to achieve a larger and more representative sample of the production across the year. Testing one or several composite samples at a minimum of two different time points over the year for each defined stratum is recommended. Sampling is repeated for each stratum as defined per monitoring level (for an overview of recommended sampling and analyses see **Annex 4.4**).
10. Ensure that each single sample collected from a different batch/lot is tested at the laboratory with a qualitative test to identify any unfortified batches and that the result is recorded. Ensure that quantitative analysis is performed on the composite sample to determine the average micronutrient content for the defined stratum.

Annex 4.1 and **Annex 4.6** provide examples of the process and tables of sampling plans.

4.3.2.2 Single sample collection

The number of single samples obtained for each stratum and mixed in a composite sample should be defined. The average micronutrient content should be based on a composite sample comprising equal parts of 10 single samples (or a minimum of five) per unit/stratum collected from different batches/lots or retail outlets. Single flour samples can be collected in the geographical divisions (or provinces) where inspectors work or from market hubs supplying the highest number of people.

Consumers often buy flour-containing foods that have been prepared in advance by manufacturers. The manufacturer purchases fortified flour to make those foods. In these cases, it is convenient to sample on the premises where flour is used as an ingredient for making foods. For example, bakeries would be the place to collect samples of wheat flour that is used to make bread.

[9] The stratum or level of disaggregation is the defined unit for which the average micronutrient content will be representative and comparable. In most cases, the brand products from the same production site are the appropriate level of disaggregation for a food because their quality is expected to be the same and consistent. Geographical disaggregation may become of interest if any major issues in the supply chain are expected to affect brands dispatched and sold across different regions/areas.

4.3.2.2.1 Single sample collection of labelled flour from the market

Ideally, 10 single samples[10] (or a minimum of five) should be collected from each stratum/unit for which the average micronutrient content is to be measured (see **Annex 4.6**). If samples are analysed to determine the average content of a brand in a region, then the same number of single samples should be taken from each producer/flour type/brand/region (see **Annex 4.6.2.1**).

At retail stores, distribution points, and bakeries, single samples are collected from the packaged flour. The smallest level of packaging is preferred and ideally a whole package is collected for testing. In the case of large packages, at least 300 g should be sampled from at least three different places in the flour sack using a sampling spear and then mixed. Inspectors record the collected information in a sample collection form (see example in **Annex 4.6.3**).

The total amount of flour required for the analysis forms the basis for determining the size of each composite sample. Composite samples that are too small increase the error of the estimate.

4.3.2.2.2 Single sample collection of unlabelled flour from the market

If flour is not properly labelled and cannot be identified by brand or producer, then the inspector is not normally expected to take a sample to determine the micronutrient content. Instead, s/he should register the location where the flour was found. Inspectors should later investigate the site and work with the owners to ensure that only flour that adheres to fortification standards (including labelling) is stocked. Otherwise, no actions are expected from the local inspectors unless they discover a situation that is a risk to human health, such as the presence of rodents or flour stored with pesticides. In such a situation, inspectors would be acting in their capacity as general health inspectors rather than as inspectors of fortified foods.

For the purpose of determining the average micronutrient content of the flour in the market, samples can be collected for analysis from unlabelled flour. As the producer and brand cannot be identified, 10 single samples (or a minimum of five) should be collected from the unlabelled flour or from each unlabelled flour type in each area/region for which micronutrient content is to be determined.

4.3.2.3 Adjusting the sampling plan to the capacity

Sometimes budgets and laboratory capacity are limited and only one composite sample can be tested by producer/flour type/brand per time point. In such cases, the single samples can be pooled for the country by mixing equal parts of all the samples collected across an area/region to reflect the average nutrient content delivered in the area/market (see **Annex 4.6.2.1** and **Annex 4.6.2.2** for examples of sampling plans). To further reduce the laboratory samples required, only one composite sample can be tested for each producer/flour type. Single samples from different brands of the same producer and flour type can be pooled in equal parts to form a composite sample of the producer. Pooling samples by producer or brand will provide the average micronutrient content by producer across brands or of a brand across regions. However, further disaggregation by brand per producer or by region per brand will not be possible without further analysis.

For even further reduction of the number of laboratory samples, the focus can be placed on testing the main producers each year that supply the majority (ideally more than 80%) of the market share. An additional subsample of producers that supply the remaining volume can be randomly selected and tested.

Single samples of unbranded flour (sold in bulk) can be pooled by flour type by mixing equal parts from different producers (if known) or different samples of that flour type collected from different retail outlets in a market. Composites for flour sold in bulk should be formed in each market visited (from the different retail outlets comprising this market) because the source/suppliers in different markets can vary.

[10] Ten samples is the standard number used for most sampling schemes. In the United States, data for nutrition labelling must be based on 12 samples. However, strictly speaking the required sample size depends on the variability of the micronutrients being measured. To determine the adequate sample size, the expected mean, standard deviation, and acceptable error of the micronutrient in the food is required. This information can come from data in the literature or from previous local assessments of the foods, or if no such data are available, from intuitive guesses *(13)*.

4.3.3 Sample analysis

At the assigned laboratories, all single samples should first undergo a qualitative test for the presence of fortificants to verify that all single samples collected from a different batch/lot are fortified. It is important to determine the percentage of single samples that are fortified and those that are not. There are instances when noncompliance for a generally compliant brand is localized. For example, if 50% of the single samples are not fortified and 50% are fortified according to standard, the composite samples will indicate that the product contains only half of the target amount. This could then be misattributed to an inadequate addition rate at production. The solution in this example would be to investigate first why 50% of the single samples are not fortified.

Next, the laboratory will prepare composite samples by mixing a predetermined number of single samples of one stratum/defined unit (e.g. brand in a region) that were collected from different batches in the retail outlets. Single samples from different packages and batches/lots of the same brand collected from different retail outlets in the same area/region are mixed in equal parts. This forms a composite sample of the stratum (brand in a region) for analysis (see **Annex 4.6.2**).

The laboratories will then conduct a quantitative analysis for one or more micronutrients for each composite sample. The results for the tested micronutrient(s) should be close to the target micronutrient content in the fortification standards and should fall within the acceptable range of variation. If possible, the laboratory should test for the added micronutrient, rather than for the total micronutrient to determine the added amounts. If the total content of a nutrient is assessed (i.e. added content plus intrinsic content), then the average intrinsic content of the flour type should also be identified through analysis of unfortified samples. This allows the added nutrient content to be calculated.

If noncompliance is observed for a specific national producer or brand, the manufacturer should be informed of the issue. Audit/inspection visits to those manufacturers should be prioritized and planned to occur promptly (see **Chapter 4.1.2** for external inspection). If a foreign producer or brand is found to be noncompliant, the importers will be advised and asked to inform their producers to correct subsequent lots. Border inspectors will be informed to pay close attention to those producers or brands found to be noncompliant (see **Chapter 4.2** for import inspection).

4.3.4 Commercial monitoring reporting

The regulatory authority responsible for commercial monitoring should produce biannual or quarterly reports (depending on sample collection frequency) noting the average content of each micronutrient analysed for the different flour types, producers, and brands assessed during commercial monitoring. The number of single samples to be combined should be defined (see **Annex 4.6.2** for examples of sampling plans). If brands are stratified by region, then the report/table is prepared for each region.

A copy of the reports should be sent to the food control authority, the multisector alliance, and anyone else interested in the fortification programme (see **Chapter 6**).

The market assessment report should present the following results by stratum/defined unit (flour type, producer, and brand, disaggregated by geographical division).

- Number of single samples taken.
- Number and percentage of single samples confirmed as fortified.
- Average micronutrient content of composite samples. (Based only on composites where all single samples were confirmed as fortified prior to analysis.)
- Number and percentage of composite samples below, within, or above the (national) standard range.

The report should summarize the total number of producers and brands for which samples were collected and tested. The following are then calculated (i) the percentage of all producers and brands for which samples were collected and tested; (ii) the percentage of the all producers and brands tested for which fortification was confirmed in 100% of samples; and (iii) the percentage of all producers and brands tested for which standards

were met. The percentages indicate the proportions of producers and brands that were assessed by commercial monitoring and their performance.

4.4 Consolidate reports of governmental food control

Data are collected by the inspectors through external, import, and commercial monitoring activities and compiled regularly (e.g. quarterly, semi-annually) for review by the regulatory authority. The inspectors should review the data to define the quality of the fortified flour across regions and report the results for the key indicators shown below. These reports provide the basis for reacting to any cross-cutting issues and defining region-specific actions of flour supplied to the population.

A summary of the results collected through audits/inspections should also be compiled by the regulatory authority and shared with the multisector alliance or key stakeholders of the fortification programme, ideally quarterly but at least annually. These aggregated reports provide an overview of external, import, and commercial monitoring efforts as well as the fortification of flour produced and imported and made available to the population. For further information on fortification programme reporting, see **Chapter 6**.

4.4.1 External monitoring report

WHO/CDC indicator: Quality-assurance and quality-control procedures in place at large-scale flour mills

WHO/CDC indicator: Samples of flour from mills meet fortification specifications according to country standards

For an external monitoring report, a list of all mills in the country that have the capacity to fortify flour should be compiled. The report should indicate the following for each mill:

- the date of most recent inspection;
- the date of follow-up visit;
- whether QA/QC procedures are in place;
- individual items in the QA/QC checklist;
- the number of flour samples collected;
- whether flour samples were fortified;
- whether flour samples meet the standards;
- the average micronutrient content (and variation) of the tested flour samples;
- whether the audit/inspection was passed.

If further information was collected, such as flour production volumes and premix utilization, these data can also be added to the report.

For aggregation, the last row of the report summarizes:

- the number of mills that were audited/inspected;
- the number of mills that were revisited for follow-up;
- the total number of mills that had QA/QC procedures in place during the reporting period;
- the total number of mills that passed inspection
- the percentage of mills expected to fortify that were audited/inspected;
- the percentage of audited/inspected mills that have QA/QC procedures in place;
- the percentage of mills where flour samples were tested that met the standards.

The percentage of mills expected to fortify that were audited/inspected shows to what extent inspectors have managed to check the mills that are producing fortified flour in the country. This percentage should correspond to the planned audit/inspection coverage of mills during the reporting period. An indication of the proportion

of mills that are performing well out of all mills audited/inspected is given by (i) the percentage of audited/inspected mills that have QA/QC procedures in place and (ii) the percentage of mills where flour samples tested met the standards are calculated. This proportion can also be determined for the period in which all mills have been audited/inspected to determine the percentage of all mills audited/inspected that are complying with the fortification standard. By adding the total production of the producers conforming to the standard, the proportion of total local production of fortified flour that is fortified according to the standard can be estimated.

4.4.2 Import monitoring report

WHO/CDC indicator: Certificate of Conformity for imported fortified flour

WHO/CDC indicator: Samples of flour from mills meet fortification specifications according to country standards

An import monitoring report will present information for each flour consignment/shipment, ideally disaggregated by brand and/or producer/importer/supplier. The report should include:

- the number of flour consignments/shipments inspected;
- the number of consignments/shipments that included a CoC/A conforming with the standards;
- the number of consignments/shipments for which samples were collected and analysed;
- the average micronutrient content of those consignments that had samples analysed;
- the number of consignments/shipments that met the (national) standard;
- the pass rate of consignments/shipments inspected.

If further information was collected, such as flour and premix import volumes, these can also be added to the report.

For aggregation, the report summarizes for a defined period:

- the total number of flour consignments/shipments;
- the total number of flour consignments that were inspected;
- the total number of flour consignments that had CoC/As indicating conformity with the standard;
- the total number of flour consignments with flour samples tested;
- the total number of flour consignments with flour samples tested that met standards;
- the percentage of all imported flour consignments that were inspected;
- the percentage of all inspected flour consignments with CoC/As indicating conformity with the standard;
- the percentage of all inspected flour consignments for which fortification was confirmed in flour samples.

The percentage of all imported flour consignments/shipments that were inspected shows to what extent inspectors have managed to check the quality of flour entering the country. The percentage of all inspected flour consignments with CoC/As, and for which fortification was confirmed, give an indication of the proportion of the imported inspected consignments that are performing well.

By adding the total supply/import of the producers/brands conforming with standards, the proportion of the total imported fortified flour supply that is fortified according to standards can be estimated.

4.4.3 Commercial monitoring report

WHO/CDC indicator: Retail and market samples of flour and products made from flour meet fortification specifications

The commercial monitoring report provides the following data by stratum/defined unit (flour types, producers, brands and geographical division):

- the number of collected single samples;
- the number of collected single samples fortified;
- the average additional micronutrient content of the flour.

The additional micronutrient content of the flour is calculated by subtracting the intrinsic content from the total content that was measured.

For aggregation, the report summarizes:

- the total number of brands and/or producers for which samples were collected and tested;
- the total number of brands and/or producers for which fortification was confirmed;
- the total number of brands and/or producers that meet the standards;
- the percentage of all producers and/or brands for which samples were collected;
- the percentage of producers and brands for which fortification was confirmed,
- the percentage of producers and brands that meet the standards.

These percentages give an indication of the proportion of producers and brands covered by commercial monitoring and how well producers and brands performed.

Where results are stratified by region the national average by producer/flour type/brand can be calculated. The regional results can be weighted by the proportion of the respective producer's/brand's total market volume supplied to each region. In this case the results can be presented as flour volume as a proportion of the total flour volume.

To calculate an overall national average fortification content of flour, the results of each producer/flour type/brand/region can be weighted according to the respective market share of the producer/flour type/brand in the region and/or country. The weighted average by region is calculated by multiplying the regional result of the respective type/producer/brand by the proportion of the regional market share of the type/producer/brand (see **Annex 4.6.1**).

The additional micronutrient content through fortified flour can be used to estimate the additional micronutrient intake of different population groups when information on flour intake exists. This requires linking the fortification content of flour as assessed at retail level to average intakes of the flour that falls under the fortification standard by the population group (**Chapter 5**).

Table 2 provides an example of a commercial monitoring report format.

Table 2. Commercial monitoring report format

Region/area	Producer/ production site	Flour type	Brand name	Number of single samples collected	Number of single samples fortified	Percentage of single samples fortified	Average content of marker nutrient (ppm ±10% MU) (fortified samples)	Content of marker nutrient relative to target of 50 (range: 35–65) ppm		
								Below standard	Within standard	Above standard
Central	Lala Miller	Bread wheat flour	Best	5	5	100%	55±5.5	–	X	–
Central	Talu Miller	Bread wheat flour	Snowwhite	5	5	100%	48±4.8	–	X	–
Central	Talu Miller	Cake flour	Florella	5	0	0%	–	X	–	–
Central	Attu Miller	Bread wheat flour	Attu No1	0	–	–	–	–	–	–
Central (overall)	3	2	4	3	2	66%	51±5.1	1	2	0

% all producers tested:	% of all brands tested:	% of tested brands that are fortified:	% of tested brands below standard:	% of tested brands within standard:	% of tested brands above standard:
2/3 = 66%	3/4 = 75%	2/3 = 66%	1/3 = 33%	2/3 = 66%	0%

MU: measurement uncertainty; ppm: parts per million.

CHAPTER 4 ANNEXES

4.1 External, import, and commercial monitoring: wheat flour monitoring plan

The steps to define a monitoring plan are as follows.

1. Identify geographical divisions used by government or relevant ministries such as the ministry of health under which each inspector works. Among these, identify the regions/provinces where import sites/ports exist and where the mills are positioned.
2. Determine the total imported volume and local flour production volume, because monitoring efforts at the import or production site should be proportionate to the local flour supply volume.
3. Establish the number of importers and local mills/producers and estimate the production or import volume and the percentage of their contributions to the total flour production/supply. Prepare a list of producers and their brands of flour, together with their respective market share (**Annex 4.6.1**). Producers or importers that supply large volumes should be a priority. This does not mean that smaller suppliers can be ignored, rather that the frequency of checks should be in line with the supply volume. Each supplier's fortification performance history should be documented. Suppliers with no performance record or a history of poor performance should be moved up the priority list.
4. At import, even if the documentation of a consignment and performance history of an importer/ production site are satisfactory, or if the records and audit of the production process show good performance, flour samples are taken occasionally to confirm the product meets the fortification standard.
5. At the import sites, documentation of all flour imports should be checked, and the fortification process should be audited at all the production sites that can be visited.
6. Compliance checks of the flour through quantitative laboratory analysis need only happen intermittently for confirmation. For each selected producer/flour type/product brand, multiple samples are collected that can be combined to form a composite sample for analysis to reduce costs. The recommended number of samples and analyses is provided for each monitoring point in **Annex 4.4.**
7. If the number of products that cannot be inspected at the import or local production sites are too numerous, periodic checks can be carried out at the market level (**commercial monitoring**). Both imported and locally produced products can be found at this level and checks can be done to verify packaging, labelling, and storage. Samples can be taken to confirm compliance with fortification standards.
8. The total number of producers or products for which samples can be analysed over a year needs to be determined and attributed across the import, production, and market monitoring activities.
9. Determine laboratory capacity and available budget to test samples over the year. Ask the laboratories to estimate a realistic/feasible sample processing capacity per time period.

4.2 External monitoring: audit and inspection

The table below is guidance for the development of an audit checklist – encompassing food fortification, food safety and food quality – to be implemented by government food inspectors during their visits to flour manufacturing sites. This basic checklist can be used to develop an audit checklist, encompassing food fortification, food safety and food quality, to be implemented by government food inspectors during their visits to flour manufacturing sites.

Inspection registry:	**Date of inspection:**	
Mill name:	**Mill representative:**	
Address:	**Telephone:**	
Points of verification (These are the key points for flour fortification only, thus this list should be included in the existing audit checklist for food safety and quality)	**Adequate? (Yes/No)**	**Remarks**
1. GENERAL		
1.1 Cleaning and sanitation		
1.1.1 All the openings of the drains should be covered with metal grills to avoid entry of rodents and garbage in the drains leading to blockage		
1.1.2 Waste collection bins in all the areas		
1.1.3 Periodic disposal of waste		
1.1.4 Different types of waste should be collected separately for easy disposal		
1.2 Staff facilities and toilets are available		
1.2.1 Adequate number of toilets for male and female staff		
1.2.2 Separate changing rooms for male and female staff		
1.3 Staff wearing protective clothing (Staff should wear gloves, facemasks, foot coverings, laboratory aprons, head caps, and uniforms)		
1.4 Staff maintaining personal cleanliness as per the regulations		
1.4.1 Staff should trim their nails and should not apply nail paint as it can cause contamination		
1.4.2 Staff should not wear any jewellery or other accessories		
1.5 Personnel are well trained in the tasks they perform in their respective areas		
1.5.1 Records of orientation/induction or refresher training		
1.5.2 Orientation/induction training of new staff in their respective areas		
1.5.3 Regular refresher training of the staff in their respective areas and relevant records maintained		
2. WRITTEN INSTRUCTIONS AND PROCEDURES		
2.1 Premix specifications verification and handling during receipt and storage of premix		
2.2 First-in-first-out policy		
2.3 Premix dilution and addition instructions		
2.4 Feeder/churner installation and verification process		
2.5 Internal quality control (QC) standard sampling protocol (Number of samples, sample quantity, frequency, place, sample preparation)		
2.6 Qualitative test for micronutrients in food (if applicable) (Qualitative test instructions – method, reagents, equipment, result recording)		

2.7 Quantitative test for micronutrients in food (Quantitative test instructions – method, result recording)		
2.8 General instructions on when and how to do hand washing, how to wear hand gloves and face masks, etc.		
2.9 Food standards for fortified flour		
3. PREMIX AND PRODUCTION AREA		
3.1 Premix is provided by certified premix supplier		
3.2 Each batch of premix is accompanied by a certificate of conformity/ analysis (CoC/A) (Last batch of premix is accompanied by a CoC/A)		
3.3 Quantity of the premix procured is in accordance with the quantity of fortified flour that is regularly produced at the production site		
3.4 Premix inventory (details of receiving the premix from the supplier) is up to date (i.e. for at least the last 3 months)		
3.5 Premix is stored under adequate conditions		
3.5.1 Low temperature		
3.5.2 Dry conditions		
3.5.3 No direct exposure to sunlight		
3.5.4 Well-ventilated area		
3.5.5 Stacked away from the wall		
3.5.6 Kept off the floor on the pallets		
3.6 Premix used on first-in-first-out basis (Premix boxes should be arranged such as to provide easy access in the order of their expiry dates)		
3.7 Logbook maintained on the consumption of premix (when issued to the relevant person in the production area)		
3.8 Micro-dosifier/premix feeders/churners installed appropriately (Feeder installed as per production process feeder installation (begin of mixing line to allow maximum mixing time)		
3.9 Dosifiers/churners verified as working correctly and periodically maintained		
3.10 Premix dilution, if applicable, is done correctly (Premix is diluted as per the quantity of the food to be fortified)		
3.11 Premix level in the feeder is above the minimum level during visit to the production area (The observed premix level in the feeder is above the minimum premix level)		
4. PACKAGING SECTION		
4.1 Labelling of packaged fortified food as per standards		
4.1.1 Nutritional value (nutrients and their amounts) of the product is declared on the label		
4.1.2 National fortification logo displayed on the packet (front or back)		
4.1.3 Fortificants (added micronutrients) are mentioned in the list of ingredients, e.g. in addition to the usual ingredients, added iron (source of iron), folic acid, and vitamin B_{12} in the ingredient list		

5. LABORATORY		
5.1 Sampling of flour done regularly for internal QC following a standard sampling protocol		
5.2 Preparation of composites for QC on daily basis, if applicable		
5.3 Available laboratory equipment and valid reagents (not expired) for testing micronutrients qualitatively		
5.4 QC samples of each food batch/load/production day are analysed using qualitative or semiquantitative test		
5.5 Records of fortified flour samples regularly analysed quantitatively		
6. WAREHOUSE		
6.1 Fortified flour packaged in a way that maximizes protection of the added micronutrients against humidity, insect infestation, and oxygen		
6.2 Fortified flour is stored adequately in the warehouse		
6.2.1 Low temperature		
6.2.2 Dry conditions		
6.2.3 No direct exposure to sunlight		
6.2.4 Well-ventilated area		
6.2.5 Stacked away from the wall		
6.2.6 Kept off the floor on the pallets		
6.3 First-expired first-out system applied to dispatch of fortified flour from the warehouse		

SECTION	**7. NONCOMPLIANCES** (List the noncompliances found and remarked upon in the sections above)	**8. SUGGESTIONS FOR IMPROVEMENT**

Inspector:	Received by (mill representative):
Signature:	Signature:
Date:	Date:
Supervisor (name and signature):	Date:

4.3 Fortification standards for flour

The fortification standards will ideally present a target content and an acceptable range for each micronutrient that will be added to flour. The target content that the flour should contain is based on the average consumption of fortifiable flour and the nutrient needs of the population. The acceptable range should take account of variations of the true content resulting from:

- mixing capacities at the mills;
- separation during transport;
- losses/degradation during transport and storage;
- overage that may be added to the flour to account for expected losses;
- the intrinsic micronutrient content in the flour (where total iron or other fortificant is defined in the standard).

When manufacturers add fortificants to flour, they need to account for the potential losses that will occur during distribution and storage (i.e. overage). The added amount at production is usually set 20–30% higher than the amount that is expected to reach the consumer for vitamins, and 3–5% higher for minerals *(4)*. The manufacturer needs to determine the appropriate overage to use to ensure that the product retains a content of each micronutrient that is within the standard range throughout the duration of its commercial life.

It is imperative that the target content is determined with the goal of increasing the micronutrient intake among the population to address relevant public health concerns while also ensuring programme safety by avoiding excessive micronutrient intakes. Details on how this is done can be found in the WHO *Guidelines on food fortification with micronutrients (4)*.

If the standard range is to be compared with any laboratory test result, then the range also needs to include uncertainty associated with the analytical assays. **Annex 4.3.2** provides further discussion on all types of variations and their implications.

Fig. 1. **Average retail target content, production target addition, and range**

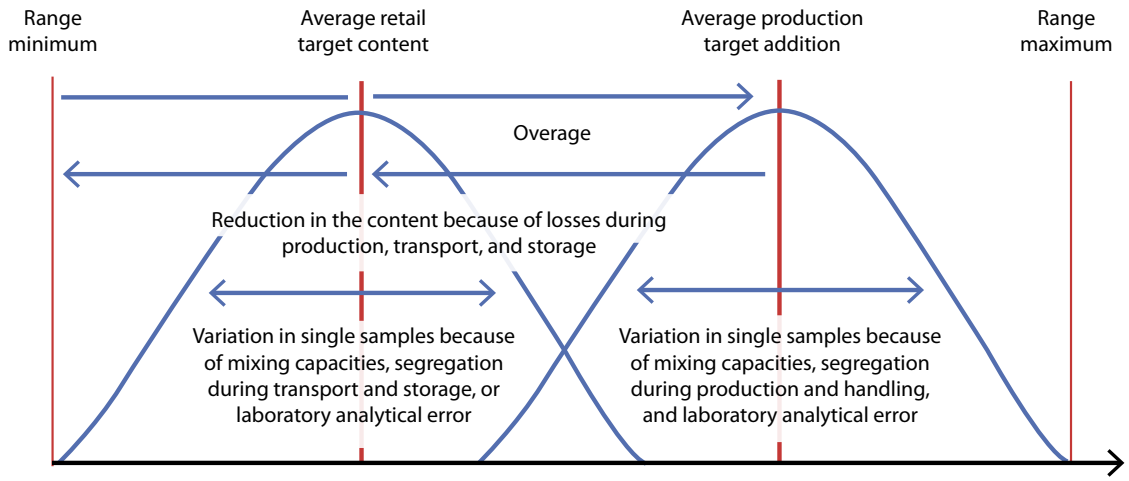


Fig. 1. illustrates that the standard range needs to include the target content of the flour when reaching the consumer target (**retail target**) as well as the **target addition at the factory/production**. Variation of the content around these targets needs to be considered. There can be several sources of variation, such as differing mixing capacities or segregation during transport and storage.

The micronutrient content will be measured using analytical assays, which estimate the true content and are therefore subject to variation. The standard should indicate whether the applied range includes chemical assay variations and, if so, what analytical method and acceptable analytical error are considered.

If measurement uncertainty of laboratories varies, it is best to define the expected true average target content and acceptable variation in the standard without considering the variation of the chemical assay. The actual measurement uncertainty is applied by the laboratory around the measured estimate when chemical assay results are compared with the standard.

The standard range is limited by the **legal minimum** at the lower end and can be limited by a **legal maximum** if upper safety levels of the micronutrient are an issue. If a country only indicates one target and/or range, then that target content and range pertain to the content that should be seen in samples of flour taken at retail. The standard should clarify whether the legal minimum: (i) is expected to be attained by all sampling units (i.e. legal minimum = range minimum); or (ii) is the average content that the flour is to contain at the retail level, with a defined acceptable variation that can be demonstrated with a defined number of samples (i.e. legal minimum = retail target). The latter approach (legal minimum = retail target) is recommended and this should be stated in conjunction with the minimum sampling requirements for verification.

4.3.1 Comparison of micronutrient content of flour to fortification standard

When analysing samples, the laboratory may analyse one or two micronutrients to assess compliance (marker or indicator micronutrient). The other micronutrients are expected to be proportionate in the tested sample based on the premix composition. This should be periodically confirmed through verification of the premix quality.

If flour samples are collected during inspection at the production site, the target content will be the production target addition (retail target plus the overage) and the average content of samples taken should be close to the target addition, above the legal minimum, and below the legal maximum (if indicated).

For imported flour the average content indicated on the CoC/A (analysed at production) should be close to the production target addition (retail or legal target plus overage). The average content of samples taken at the import site should be close to or in between the retail target and the production target addition, above the legal minimum, and (if indicated) below the legal maximum.

The average of flour samples collected at the retail level meets the standard if it is above the legal minimum and below the legal maximum (if indicated). The content should be close to, or above, the retail target.

Inspectors need to communicate the results to the mill or supplier.

Inferences based on the sample results will be different depending on: where the samples were collected; the difference between the results and the standard; and the confidence level of the sampling method.

If the sample results fall outside the legal range, inspectors can opt for additional sample collection and encourage additional audit/inspection at the production or import site or investigation in the supply chain if sampling took place at the retail level. The authorities should define the action required based on the results of audits/inspections and the sampling plans applied.

A thorough review of the production process and records should be the approach to ensure that the flour is produced according to the specifications. Ultimately, the mill must demonstrate that corrections have been made to ensure satisfactory flour quality, or fines and penalties may be imposed.

4.3.2 Critical issues to consider when reviewing analytical results of micronutrients

Although external, import, and commercial monitoring includes a government audit (or review) of the QA procedures, results of quantitative testing from samples taken during inspection to confirm compliance (or noncompliance) have a strong impact on legal actions. It is important that inspection exercises are conducted with skill and adequate care to obtain reliable results.

Many factors can influence the test results and, if they are not considered, may cause unfair judgement of the quality of the fortified flour and create unnecessary conflicts between the industry and the food control authorities *(14)*. A good understanding of those key factors and how they influence inspection must be established through adequate training of inspectors. To draw appropriate conclusions and request pertinent follow-up actions, the variation of the true content of the flour samples or flour-based products needs to be considered, together with the analytical measurement uncertainty. The major issues to consider are discussed below.

4.3.2.1 The average is more robust than minimum content when assessing performance of food fortification

Currently, many countries have standards that set a minimum content of micronutrients for regulatory purposes. This practice originated from the assumption that all producers have the same blending capacity, and that all micronutrients and fortification vehicles behave in the same way. In reality, this is not the case. In the example in **Fig. 2**, the minimum content changed drastically with different nutrient variations. This is evidenced by the coefficient of variation. As a consequence, in an effort to satisfy the minimum content requirement, mills can sometimes add more premix than necessary, which can then have adverse effects on the organoleptic properties of the flour or provide excess nutrients to the population.

Fig. 2. **Average target addition with varying coefficient of variation**

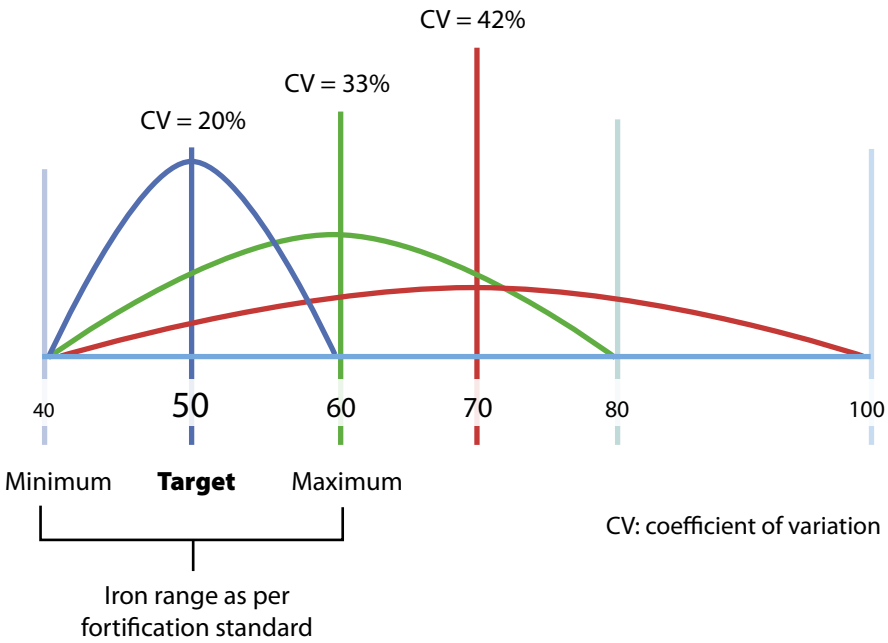


Fig. 2 shows that to satisfy the minimum content of 40 mg/kg, a mill with a 20% variation would target addition of 50 mg/kg, whereas a mill with a larger variation of 33% would have a higher target at 60 mg/kg. A mill with a variation of 42% would target an additional average of 70 mg/kg to satisfy the minimum of 40 mg/kg. All three mills satisfy the minimum, but only one satisfies the requirements for targeting 50 mg/kg with an acceptable coefficient of variation of 20%.

Reports from a mill in Chile showed that, with the same target addition of iron, but different coefficients of variation, compliance with the minimum content changed drastically (**Box 3**).

Box 3. **Examples of difficulties with use of minimum content in fortification standards**

The following examples from Chile illustrate that satisfying a stipulation for minimum content is related to the variation of mixing.

Iron fortification: experience from a mill

The standard required the addition of 22 mg/kg iron to flour, and the intrinsic content was 15 mg/kg. The expected average was therefore 37 mg/kg. In 2011, the average was 40 mg/kg and the minimum was 28.5 mg/kg when the coefficient of variation of the mill was 22.8%. These conditions indicated the mill was compliant. However, the following year, similar additions resulted in an average of 38 mg/kg but, owing to a poorer mixing performance, the coefficient of variation increased to 36.6% and the minimum was reduced to 20.5 mg/kg. Under this second set of conditions, the mill was considered noncompliant.

Folic acid fortification

When the food control authorities tried to enforce a minimum value of 1.3 mg/kg for folic acid, the average content rose to 7.2 mg/kg, which was much higher than the 2.2 mg/kg selected as the target content to provide the appropriate additional intake of folic acid to the population. As a consequence of the minimum content policy, the population of Chile was at risk of excessive folic acid intake.

In conclusion, the adoption of a minimum content in fortification standards is not only cumbersome and unfair to apply, but it also does not correspond to the nutritional goals of the programme. It is preferable to include an average target content with a range of variation for each fortificant listed in the fortification standards. The expected average content should always be close to the target value and not just above minimum range.

4.3.2.2 The use of an acceptable range of variation around the average is useful for promoting homogeneity

It is advisable to define an acceptable range around the target content to account for variations in the amount of fortificant observed. This is needed to ensure that millers maintain reasonable homogeneity in the fortified flour *(15)*[11]. Variation can be caused by:

- inadequate or non-homogeneous mixing of the premix into the flour;
- physical separation of micronutrients (segregation);
- loss of micronutrients over time (decay);
- variations in the intrinsic content;
- inadequate sample quantity (because of the low concentration of micronutrients in the food matrix, small samples could show high variation);
- analytical variation of the chemical assay.

The magnitude of the variation or range around the average should be experimentally determined by each mill for each sampling framework, food matrix, and micronutrient. The variations determined by each mill should be considered when defining the acceptable variation around the target fortification content in the fortification standard. The variations will also allow determination of an appropriate sampling plan in the QA/QC protocol for the mill. The experiment involves determining the spread in nutrient content for single samples collected over a defined short time period around an average value. This is repeated on different days and an average variation determined and compared against the standard. The mill must make efforts to minimize high variation values by improving processes, such as mixing capabilities, to attain a variation that is determined as achievable.

The standards should describe the nature of the sampling framework when testing dry, solid fortified food

[11] The Canadian government for example has defined the acceptable range when assessing fortified flour samples as 80–175% of all nutrient values currently specified in the flour standard. This range is considered achievable based on current industry and laboratory practices.

samples for micronutrients: number, frequency, and size of single samples; preparation of composite samples; and quantity of each sample dissolved for analytical determination.

In summary, the target content should always be the focus of the standard and not a value above the minimum range. It is therefore preferable to use composite samples instead of single samples, since this saves resources and time invested in analytical work and better reflects the average micronutrient content of the batch.

Where a range has been set and, despite the mills' efforts, variation cannot be reduced to this level, the mill should approach the standard institute of the country. A request should be made to modify the standard such that it reflects the reality of an acceptable fortification process and the recommended sampling framework. A standard that does not take into account the inevitable variation in results owing to different factors may result in mills being unfairly condemned for poor compliance.

4.3.2.3 The effect of the food matrix on the micronutrient content of fortified products

For samples of liquid fortified foods (e.g. oils or milk), the distribution of micronutrients is highly homogeneous and therefore single samples could represent the content of a large amount of the fortified product. This is not the case for dry food, such as fortified wheat flour. Furthermore, the dilution factor for micronutrient premix is typically in the order of 1:1000 to 1:10 000 in flour. Therefore, even after mixing a bag of wheat flour well, the micronutrient content variation could be significant among different locations of the same package. This variation is likely to become apparent when single samples from the same batch/lot undergo quantitative testing, especially if the sample quantity is small. **Table 3** shows the results from single samples taken from batches of various fortified foods in Malawi and Uganda. The coefficient of variation is related not only to the food matrix, but also to the mixing capacity of the producer and the precision of the chemical assays used for micronutrient analysis.

Table 3. **Variation of micronutrient content in solid and liquid foods**

Food vehicle	**Oil (batch 1)**	**Oil (batch 2)**	**Sugar (batch 1)**	**Sugar (batch 2)**	**Wheat flour (batch 1)**
Micronutrient	Vitamin A (mg/kg)	Vitamin A (mg/kg)	Vitamin A (mg/kg)	Vitamin A (mg/kg)	Total iron (mg/kg)
Sample 1	28	38	14	16	68
Sample 2	22	36	12	21	66
Sample 3	22	33	17	20	55
Sample 4	20	41	16	22	57
Sample 5	22	–	19	26	41
Sample 6	26	–	15	21	42
Sample 7	–	–	16	19	35
Sample 8	–	–	16	19	35
Sample 9	–	–	19	11	60
Sample 10	–	–	19	15	60
Average/mean	**23**	**37**	**16**	**19**	**52**
CV%	**14**	**9**	**14**	**22**	**24**

CV%: coefficient of variation expressed as a percentage.

4.3.2.4 Segregation and decay of micronutrients along the flour product-marketing chain

Nutrient segregation (separation) and decay are primarily relevant for inspections that take place in the market. By the time flour reaches the commercial level, it has been subjected to various environmental factors during transportation, handling, and storage. Time alone can also be relevant. The heterogeneity of micronutrient contents in the flour can be because of segregation (for example of iron) caused by shaking of bags during transport or differential decays (for example of light- or oxygen-sensitive micronutrients) caused by environmental exposure. Accordingly, each bag of flour should be mixed very well prior to taking single samples or by taking samples (ideally three) from different locations (e.g. top, middle, bottom) of the bag.

4.3.2.5 Variation of analytical assays

Quantitative assay results are estimates of the true content and the true content lies within a range around the measured estimate. The validation of a certain method and determination of the measurement uncertainty for a specified analyte and sample matrix is done by conducting repeated measurements of a reference standard or a sample with a known amount of the analyte (true content).

The measurement uncertainty or total error is the sum of the bias or trueness (systematic error or difference between the mean estimate of repeated measurements and the true value of the sample) and the imprecision (random error or the spread of the repeated measurement results) expressed as the standard deviation of the mean value or as the coefficient of variation (**Fig. 3**).

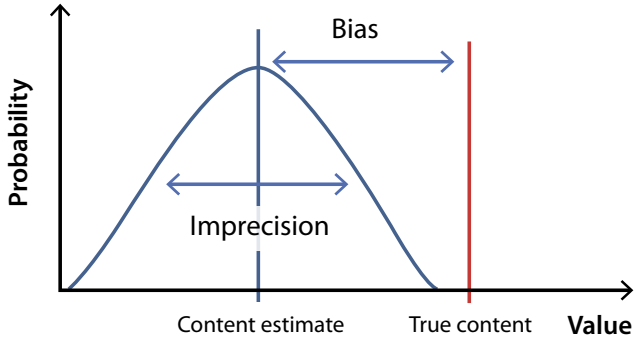
If the bias/systematic error is known, the results can be corrected to reduce the measurement uncertainty, for example, by recalibration or application of a correction factor *(16)*.

The more standard deviations we include in the range, the more confident we are that the true content lies within the range around the measured content. How confident we are is stated by the confidence level. The calculation of the measurement uncertainty or range around the measured content with a 95% confidence level is as follows.

measurement uncertainty = bias ± 1.96 x imprecision.

The true content of the sample is within the range of measured content ± measurement uncertainty.

Fig. 3. Measurement uncertainty



In analytical chemistry, variations will occur depending on the analytical methods and laboratories used, but they should ideally be low. Many countries have adopted a micronutrient variation of +/-10% into the fortification standard, including the chemical assay variation. This variation will most probably not correspond to the actual variation of the chemical assay used, nor will take into account other factors that cause variations, such as differing mixing capacities at the mills etc. As a consequence, millers will have extreme difficulty complying with the standards and are set up for failure. If this is the case then the country needs to revise their fortification standards to ensure they provide a target that is appropriate for the population need and an achievable range that allows for acceptable variation (**Fig. 1**).

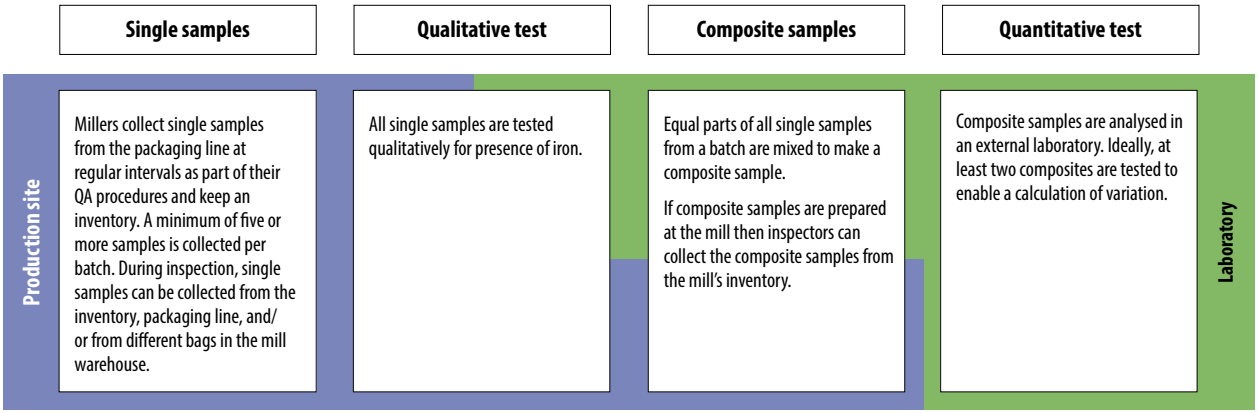
Table 4 shows how the variation is measured through repeated analysis of a well-homogenized sample with a known amount of iron. The coefficient of variation of the quantitative determination of iron using ultraviolet-visible spectrophotometry in the same flour sample is 10.3% with a bias of 4.4%. Based on these results the measurement uncertainty with 95% confidence is: 24.4% = 4.4% + 1.96 x 10.2%.

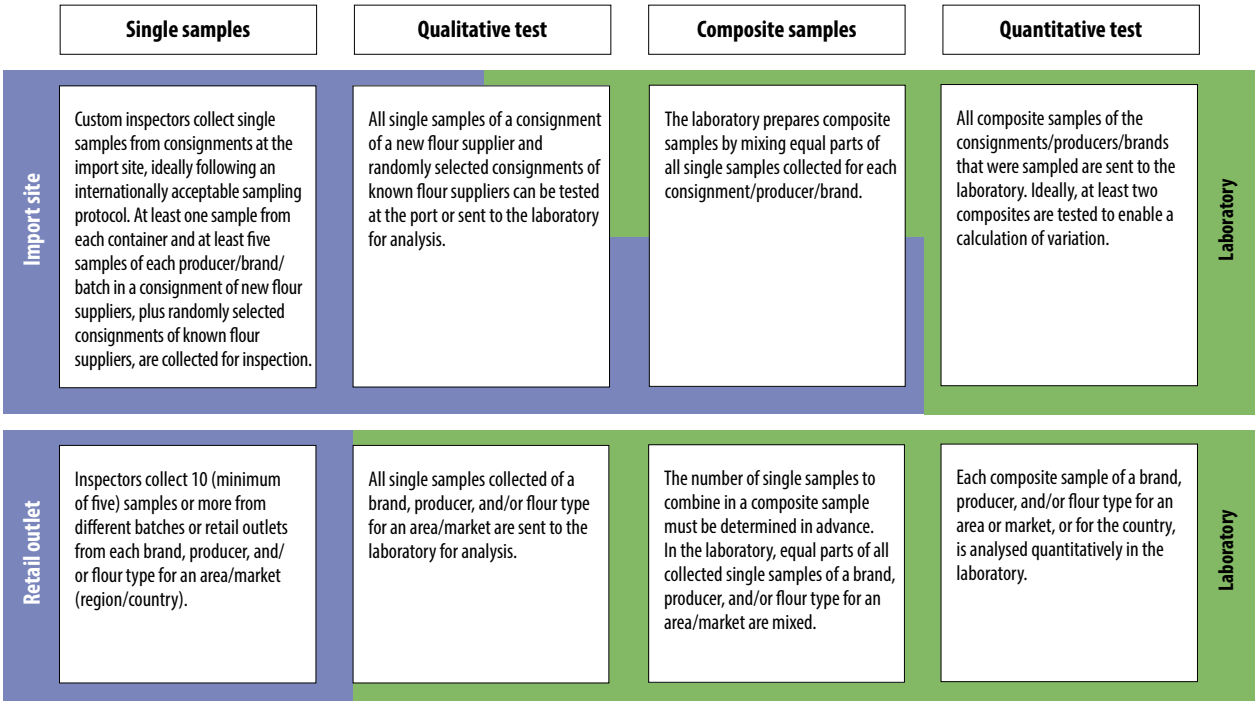
If measurement uncertainty of laboratories varies, it is best to define the range of the true content in the standard without considering the variation related to analytical assay. In that case the respective measurement uncertainty around the measured content is applied when chemical assay results are compared with the standard range.

Table 4. Variation in results of analyses of a single sample of flour spiked with iron at 50 mg/kg

Test number	Iron (mg/kg)
Test 1	50.3
Test 2	51.2
Test 3	42.4
Test 4	43.5
Test 5	58.4
Test 6	55.8
Test 7	57.9
Test 8	59.4
Test 9	51.7
Test 10	52.2
Test 11	51.8
Test 12	50.7
Average	**52.1**
Standard deviation	**5.3**
Coefficient of variation (%)	**10.2**
Difference to true content	**2.4**
Bias (%)	**4.4**

4.4 Overview of sample collection, preparation, and analysis for regulatory monitoring





4.5 Import monitoring

4.5.1 Sample of import monitoring form *(8)*

Date:	Border post/district:
Inspector name:	Country of origin:
Importer name:	Importer address:
Shipping record ID:	Lot numbers and size (tonnes):

FORTIFIED FLOUR EXAMINATION: LABELLING INFORMATION		
	Adequate (Yes/No)	Comments
Brand name		
Flour type		
Manufacturer		
Nutrient claims		SPECIFY NUTRIENTS:
Expiry date		
Lot number		
CoC/A		
Presence of nutrient[a]		

Action:	Signature:

[a] Based on qualitative test on at least one sample per brand and per container/truck of a consignment.

4.5.2 Sample report of import inspection *(8)*

Date	Importer	Flour producer	Flour type	Brand	Country of origin	Amount (tonnes)	CoC/A ok?	Tested micronutrient	Qualitative test result (+ or -)	Action taken

4.5.3 Verifying flour and premix consignments at an import site

4.5.3.1 Verifying flour consignments at importation site

On receipt of a flour consignment at an importation site, the batches/lots are inspected by verifying the points in the flour checklist.

- A CoC/A is provided for all the batch/lot numbers that form part of the consignment (see **Annex 4.5.3.2** for an example of a CoC/A).
- Packaging is intact, and the flour has not been exposed to any contamination.
- The information on the label corresponds to the CoC/A.
- The label on the packaging has not been tampered with and key information – such as product name, lot number, date of manufacture or expiry date/best before date, and name of supplier – is present.
- The flour should be traceable to the original producer, despite the involvement of many traders in the supply chain.
- The type and quantity of micronutrient content, labelling, and instructions for use satisfy the fortification standards of the country.

If any of the above is not satisfactory, the flour should not be accepted.

4.5.3.2 Example of a certificate of conformity/analysis for flour

Certificate of analysis

Premier Millers, 20 Industrial Street, New City, Nutriland +777-314-220-0000

Lot number	PFA23022014
Lot size	500 kg
Batch number	LN45015
Date of manufacture	November 2014
Best before date	May 2015

Product: fortified wheat flour

Test	Specification	Result
Moisture	Maximum 14%	12.20%
Protein	Minimum 10%	13.00%
Colour	White	Complies
Vitamin A (ppm)	0.6–1.8 ppm	1.4
Iron (ppm)	15–30 ppm	20

Storage recommendation

Protect from light and keep in dry places

This is to certify that the lot number **PFA23022014** was manufactured in accordance with the requirements of ISO 22000-2005 and confirmed with the above specification when dispatched from our warehouse.

Premier Millers	20 Industrial Street	Tel +777-314-220-0000

Date of analysis: 15 November 2019

ppm: parts per million.

4.5.3.3 Verifying premix consignments at the importation site

On receipt of a premix consignment at an importation site, the batches/lots are inspected by verifying the points in the premix checklist.

- A CoC/A is provided for every batch/lot number that forms part of the consignment (see **Annex 3.2.1.1** for an example of a CoC/A).
- All CoC/A parameters should be within the purchase specification limits.
- Boxes are intact and, where damage is present, the content is checked to ensure that the plastic lining is not broken and that the premix has not been exposed to any contamination.
- The information on the label corresponds to the CoC/A and the list of nutrients. The content and type corresponds to the requirements of the fortification standard (see **Checklist 4** for a CoC/A in, **Annex 3.2.1.2**).
- Labels on boxes have not been tampered with and key information – such as product name, lot number, date of manufacture or expiry date/best before date, and name of supplier – is present.
- The premix should be traceable to the original producer, despite the involvement of many traders in the supply chain.

If any of the above is not satisfactory, the premix should not be accepted.

4.6 Commercial monitoring

4.6.1 Market overview

Determining the market volume share of each producer/flour type/brand in the market.

Producer/ production site	Flour type	Brand name	Import or local	Market share by brand by region (R)								Market share by brand
				R1	R2	R3	R4	R5	R6	R7	R8	
Producer A	Bread wheat flour	Brand A	Local	30%	50%	25%	50%	30%	30%	45%	25%	40%
Producer A	Bread wheat flour	Brand B	Local	20%	50%	25%	50%	30%	30%	–	–	20%
Producer B	Cake flour	Brand C	Local	15%	–	40%		5%	30%	5%	25%	12%
Producer C	Bread wheat flour	Brand D	Import	35%	–	10%	–	35%	10%	45%	50%	28%
Market share by region				26.5%	7%	17.5%	8%	17%	14%	5%	5%	100%

4.6.2 Sampling plan

4.6.2.1 Same sample size (single samples) per stratum (producer/flour type/brand/region) to form one composite

Producer/ production site	Flour type	Brand name	Import or local	R1	R2	R3	R4	R5	R6	R7	R8	Total
Producer A	Bread wheat flour	Brand A	Local	10	10	10	10	10	10	10	10	80
Producer A	Bread wheat flour	Brand B	Local	10	10	10	10	10	10	–	–	60
Producer B	Cake flour	Brand C	Local	10	–	–	–	10	10	10	10	50
Producer C	Bread wheat flour	Brand D	Import	10	–	10	–	10	10	10	10	60
Samples at the factory level[a]				40	20	30	20	40	40	30	30	250

[a] Assuming 10 single samples per brand/product, one sample per producer, or two composite samples.

4.6.2.2 Same sample size (single samples) per stratum (producer/flour type/brand/country) to form one composite at the country level

Producer/production site	Flour type	Brand name	Import or local	Total
Producer A	Bread wheat flour	Brand A	Local	10
Producer A	Bread wheat flour	Brand B	Local	10
Producer B	Cake flour	Brand C	Local	10
Producer C	Bread wheat flour	Brand D	Import	10
Total				**40**

4.6.3 Sample collection form for commercial monitoring

This information is logged by the inspector collecting wheat flour samples at the market level. This sample collection form is based on the ECSA-HC *Manual for commercial inspection of fortified foods (1)* and the *Fortification assessment coverage toolkit manual (9)*. Please consult these references for more detailed templates and guidance. In addition, mobile applications are available that can facilitate data and sample collection.

Inspector:												
Region/district:						**Food:**						
						LABELLING INFORMATION						
Place[a]	**Date**	**Retail outlet type**	**Brand name with product description**	**Flour type**	**Unique sample code**	**Labelled as fortified?[b]**	**Producer name and location[c]**	**Lot number**	**Production date**	**Expiry/ best before date**	**Original packaging type**	**Original packaging size**

[a] City/town/village/neighbourhood.
[b] Mention of added micronutrients or fortification logo?
[c] Additional columns are recommended to capture information on the packer/distributer/exporter/importer and thereby distinguish the various suppliers that may be indicated as the responsible party on the packaging.

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5

CONSUMPTION MONITORING

INTRODUCTION

Monitoring the performance of a flour fortification programme at the household or individual consumption level is needed to ensure that (i) the coverage of fortified flour and intake of nutrients from fortified flour is as expected based on the design of the programme, and (ii) the expected nutrition and health benefits are likely to accrue. Formerly known as household/individual monitoring *(1)*, in this manual this concept is called **consumption monitoring.** The overarching aim of consumption monitoring is to periodically assess the additional micronutrient content provided to a population via the consumption of flour that, by law or standards, should be fortified.

The additional nutrients delivered by fortified flour are a function of the additional content of those nutrients in the flour (i.e. micronutrient content of fortified flour) and the typical intake of the flour by consumers (i.e. fortified flour intake) (**Table 1**). Through the combination of these parameters, the additional intake of micronutrients delivered to the target population by means of the flour (i.e. micronutrient intake from fortified flour) can be estimated. Another important parameter in consumption monitoring is the percentage of the surveyed population consuming fortified flour (i.e. fortified flour coverage). This chapter gives a detailed description of these four consumption-related indicators and the annexes provide details of their measurement.

Fortified flour refers to a flour that is confirmed to be fortified, while **fortifiable flour** refers to a flour that should be fortified based on legislative mandate. For all the indicators described, both fortified and fortifiable can apply. For example, consumption of flour that is confirmed to be fortified can be described as **fortified flour intake**. If the flour is supposed to be fortified based on legislative decree but that is not confirmed, then consumption of that flour can be noted as **fortifiable flour intake**. For convenience, all the indicators are referred to as "fortified" in this chapter and corresponding annexes.

Table 1. Indicators for consumption monitoring[a]

Assessment purpose	Key indicators
Fortified flour coverage	**WHO/CDC indicator:** Households consuming fortified flour (fortified flour coverage)
Micronutrient content of fortified flour	**WHO/CDC indicator:** Average additional content of micronutrients in fortified flours (micronutrient provision)
Fortified flour intake	**WHO/CDC indicator:** Average daily intake of fortified flour (fortified flour consumption)
Micronutrient intake from fortified flour	**WHO/CDC indicator:** Average additional amount of micronutrients delivered daily by consumption of fortified flour

[a] The full list of indicators can be found in the WHO/CDC *eCatalogue of indicators for micronutrient programmes (2)*.

5.1.1. Considerations for assessing consumption monitoring

In general, consumption monitoring should be initiated when the external, import, and commercial monitoring data (see **Chapter 4**) suggest that there is fortified flour available in the country. In practice, available resources will influence how frequently or whether consumption monitoring activities are conducted. Ideally, some degree of consumption monitoring will occur regularly. One way to minimize costs is by adding fortified flour consumption monitoring questions (**Annex 5.1** and **Annex 5.2**) to surveys that are regularly conducted in the country. These can be, for example, household income and expenditure surveys *(3)*, ongoing health or nutrition surveillance systems *(4)* or periodic health surveys *(5)*, food basket surveys *(6)*, STEPwise approach to surveillance (STEPS) surveys *(7)*, dietary surveys *(8)*, or nutrition surveys *(9)*.

In some countries, people purchase prepared foods such as bread loaves, naan, rotis, or tortillas that are made with flour. However, in other countries, it is common to find households that largely purchase flour to make foods

from scratch at home. The food acquisition and consumption patterns of households in the target region will influence the survey questions. It may be necessary to ask about the use of flour, the consumption of foods made with flour (i.e. flour-based foods), or both (**Annex 5.1**). This chapter focuses on assessing consumption monitoring of flour; for flour-based foods, certain adjustments must be made to the methodology. See **Annex 5.3** for an example of a survey focused on flour-based foods and **Annex 5.4** for a description of the necessary adjustments.

If the results of consumption monitoring indicate that a high percentage of the target population is receiving a significant amount of nutrients from fortified flour, an impact evaluation of the fortification programme can be considered. In such evaluation, the impact of fortification is assessed on nutrition and health outcomes, such as the prevalence of zinc deficiency or the prevalence of anaemia. Tools are available to guide the design and implementation of impact evaluations *(10, 11)*; this manual does not address the topic.

The following decisions need to be made before any aspect of consumption monitoring is assessed. Guidance on answering these questions is provided in **Annex 5.5.**

- What target populations will be surveyed?
- Will this be a stand-alone survey, or will the questions be integrated into another survey?
- How many households and/or individuals need to be surveyed?
- What types of food will be assessed (e.g. flour and/or flour-based foods)?
- Will food samples be collected and analysed? If so, how many samples and how will the sampling take place?
- What nutrients will be measured in food samples?
- Which laboratories will measure the nutrients in food samples?

In most countries, consumption monitoring is conducted as often as resources allow (**Box 1**) by those in charge of household surveys, such as national and local nutrition departments, government agencies or nutrition research institutes.

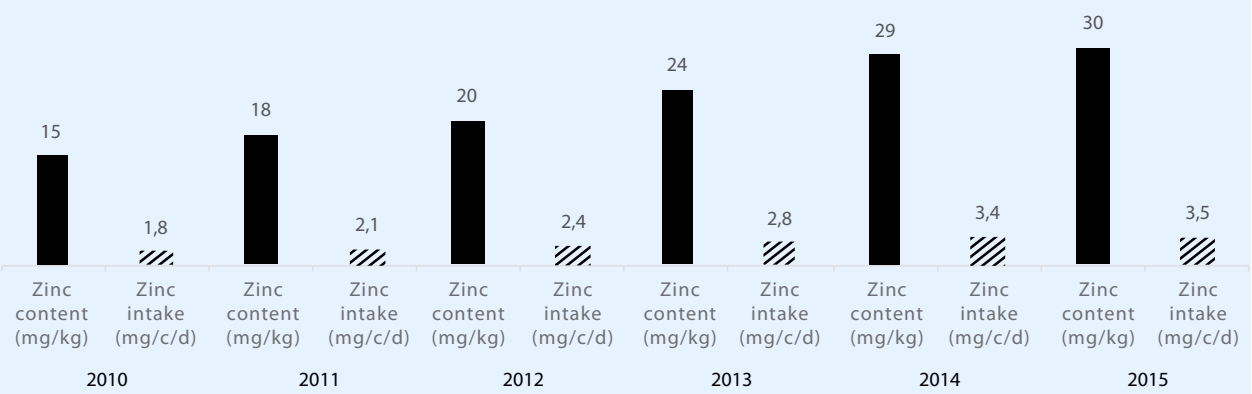
Box 1. Example of the use of fortified flour intake data (collected at one time) with data on the micronutrient content of fortified flour (collected annually) to estimate micronutrient intake from fortified flour over time

Obtaining fortified flour intake information requires conducting a survey of household or individual flour consumption. If dietary patterns do not change frequently, the same intake information can be used over many years. When a fortification programme has been implemented for several years, the average additional content of micronutrients in fortified flour may eventually stabilize near programme goals. These figures can be provided by food control authorities (**Chapter 4**). Fortified flour intake data can be combined with annual data on the average additional content of micronutrients in fortified flour to estimate micronutrient intake from fortified flour by individuals or households.

In this example, apparent intake of fortified maize flour per capita was estimated from a household income and expenditure survey conducted by the ministry of finance in 2010. For the household in the example, average intake was 118 g per capita per day.

The maize flour fortification programme started in 2010 and, although all mills fortified their flour, only 25% of the mills fortified to standards (i.e. 30 mg/kg zinc). External monitoring by food control authorities revealed that, during the following 5 years, more mills were adequately fortifying maize flour (micronutrient content of fortified flour increased; as shown as solid bars in the graph), and thus more of the maize flour available to the population was adequately fortified (micronutrient intake from fortified flour increased; as shown as hatched bars in the graph).

The graph shows data for a fictitious household. Zinc intake in mg per capita per day (mg/c/d) from fortified flour[a] was estimated using data on fortified flour intake from the 2010 household income and expenditure survey (118 g/capita per day) and information on the zinc content of fortified flour during 2010–2015 from government monitoring.



Abbreviations used: mg/kg, milligrams per kilogram; mg/c/d, milligrams per capita per day.

[a] Calculation: "fortified flour intake in grams per capita per day" multiplied by "zinc content of fortified flour in milligrams per kilogram" and divided by 1000.

5.2 Indicator: fortified flour coverage

WHO/CDC indicator: Households consuming fortified flour (fortified flour coverage)

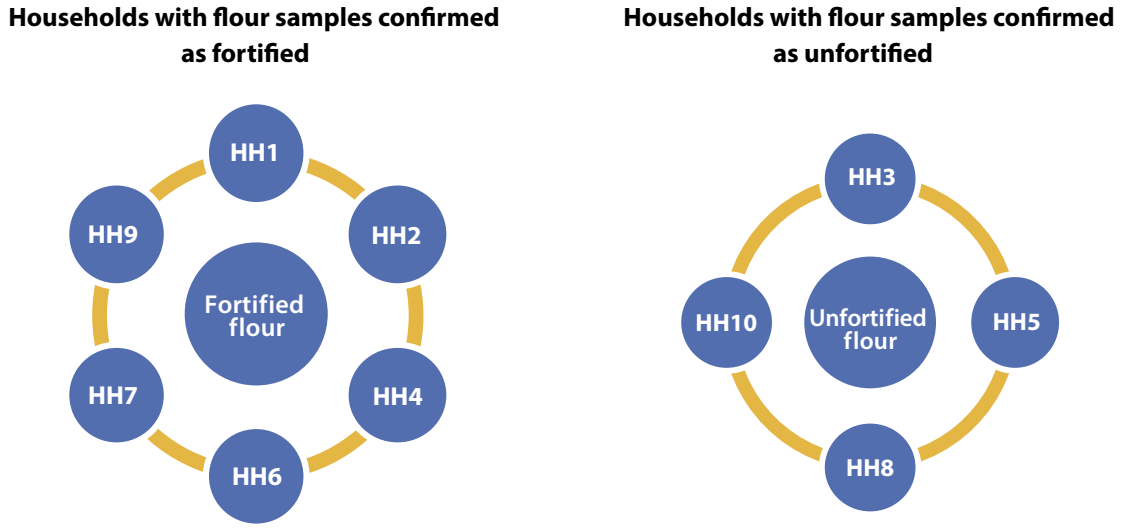
Since the primary goal of fortification programmes is to ensure that populations consume adequate amounts of critical micronutrients to prevent and help overcome deficiencies, it is important to specify the proportion of the population that is likely to be reached by the flour fortification programme, including the population most at risk. This is known as **fortified flour coverage**. Coverage can be approximated through surveys applied to households where the target population lives (assuming the flour acquired by the household has been consumed by all family members) *(12)*; see sample questionnaires to assess fortified flour coverage in **Annex 5.1** and **Annex 5.2**). If **flour-based foods** (e.g. bread, naan, tortillas) are predominantly used by households instead of flour, **Annex 5.4** lists the adjustments that need to be made to the survey. **Annex 5.6** details the steps to follow for measurement.

This indicator can be directly estimated using information about the flour used by targeted consumers together with a rapid, qualitative assessment of whether that flour is fortified. Fortified flour coverage is expressed as a percentage of the population consuming flour that is confirmed to be fortified by an assay (**Fig. 1**). This information indicates the proportion of the population that benefits from the programme and can be compared with programme goals. For example, if the programme goal is to reach 70% of women of childbearing age, a fortified flour coverage of 20% among that population group is too low. A high percentage of households consuming fortified flour is not enough to predict impact without information on the additional nutrient intake provided by flour or its products to consumers (see **Chapter 5.5** on the indicator for micronutrient intake from fortified flour).

Fig. 1. **Estimating fortified flour coverage: a visual representation**

In a survey, a sample of wheat flour is collected from each of 10 households (HH). The qualitative iron spot test (*13*) is applied to each sample. The samples from HH 1, 2, 4, 6, 7, and 9 are determined to be fortified; those from HH 3, 5, 8, and 10 are determined to be unfortified.

The household coverage of fortified flour is the total number of household samples confirmed to be fortified divided by the total number of household samples collected, multiplied by 100: 6/10 x 100 = 60%.



Limitations of calculating fortified flour coverage as described in this manual include the following.

There may be households that are unwilling or unable to provide a flour sample; they are excluded from the calculations of coverage. If a large proportion of households do not provide samples, then the validity of the coverage estimate is questionable. In these cases, the percentage of households that provided a sample should be reported along with the coverage estimate.

If the culinary practice of a population does not include using flour in the household to prepare foods, it will be impossible to gather household flour samples. In these cases, consider other methods for estimating crude coverage such as the percentage of flour domestically produced or imported that is fortified. Food control authorities, millers, and importers could provide the information for this estimate. Alternatively, the coverage of fortified flour-based food (e.g. bread) can be determined.

During household surveys, it is possible that flour is not found in a branded package or that the flour was never in a branded package. In these cases, it will be challenging to determine whether the household's flour should be fortified in the country. For example, if flour produced in small-scale mills is exempt from fortification, inquiring about the source of the flour (e.g. "Was it milled locally?") may help determine whether it is required to be fortified and thus whether it should be assessed during the survey.

Finally, interpretation of the coverage results may require further information that is not described in this manual (e.g. geographical region of those surveyed). Discussions with fortification stakeholders will ensure that necessary information to interpret the results is included in the survey or is taken into consideration during the report-writing phase.

5.3 Indicator: micronutrient content of fortified flour

WHO/CDC indicator: Average additional content of micronutrients in fortified flours (micronutrient provision)

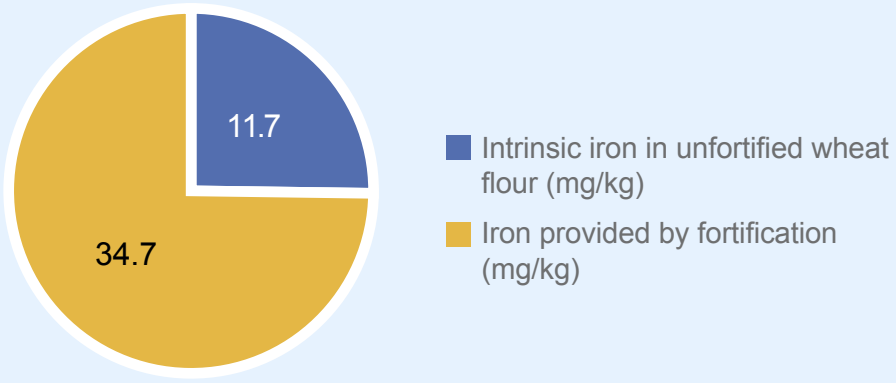
All flour has micronutrients that are inherently present, meaning that they are naturally found in the flour; these nutrients are also known as native or intrinsic nutrients. Fortification adds an additional amount of those micronutrients to the flour via fortificant premix. In some instances, micronutrients that are not inherently found in flour are also added through fortification.

The goal of assessing the micronutrient content of fortified flour is to estimate the **average additional amount** of each micronutrient that is available to the population through fortified flour (**Box 2**).

Box 2. Calculating micronutrient content of fortified flour: a visual representation

In this example, the iron intrinsic/native/inherent to unfortified wheat flour is 11.7 mg/kg.

The total amount of iron in a sample of wheat flour after fortification is 46.4 mg/kg. The added iron provided in fortified flour is calculated by subtracting native iron from total iron; this yields 34.7 mg/kg iron.



To calculate the micronutrient content of fortified flour, several steps are followed. First, a decision is made on how the micronutrient content of flour will be estimated: from monitoring by the government data, including external, import, or commercial monitoring data or from flour samples collected at households. Then, nutrient levels are obtained from both fortified and unfortified versions of the same food. Subtracting the micronutrient amounts of unfortified flour from fortified flour yields the micronutrient amount provided through fortification.

Annex 5.7 lists the steps to follow for its measurement. If **flour-based foods** (e.g. bread, naan, tortillas) are predominantly used by households instead of flour, see **Annex 5.4** for the adjustments that need to be made to the survey. In addition, **Annex 5.5** has guidance on several aspects that should be considered in advance of implementing surveys.

Whether external, import, or commercial monitoring information is used, or samples are analysed, the intrinsic nutrient content of unfortified flour must be subtracted from the nutrient content of analysed flour to calculate the average additional content of micronutrients delivered by fortified flour. There are several options for obtaining the intrinsic content of unfortified flour. One option is to contact the producer and request the nutrition information for unfortified flour or an unfortified sample that can then be sent to a laboratory for nutrient analysis. Another option is to use the nutrient values for unfortified flour from the country's food composition table.

As described in this manual, there are limitations to the calculation of micronutrient provision, which include the following.

- It may not be possible to analyse samples of fortified and unfortified flour for all the nutrients of interest because of lack of laboratory capacity or financial constraints. In these cases the following alternatives may be used.
  - Use the values of one **marker nutrient** (e.g. iron) to serve as a proxy for all nutrients added to flour via the premix (e.g. iron, zinc, thiamin, riboflavin, niacin, folic acid) (see **Annex 5.4.1**). Since the nutrients are combined in the premix, an appropriate concentration of one nutrient suggests that the levels of all nutrients in the premix comply with the fortification standards.
  - Explore alternative sources of nutrition information, such as food control authorities, mills, and food composition tables.
- It may be challenging to access information on the micronutrient content of fortified flour that is gathered as part of monitoring by the control authorities. It may be helpful to establish a protocol for information sharing among relevant stakeholders.
- The intrinsic value of a nutrient in flour may change from year to year or season to season, depending on factors such as fertilization practices, milling processes, and the variety of wheat or maize that is milled. It may be desirable to assess the intrinsic value of marker nutrients in flour on a yearly basis.

5.4 Indicator: fortified flour intake

WHO/CDC indicator: Average daily intake of fortified flour (fortified flour consumption)

The potential dietary impact of a flour fortification programme depends on how much of the fortified flour is eaten by consumers. **Fortified flour intake** is the estimation of the amount of fortified flour that is consumed by the target populations. **Table 2** shows an example of households surveyed about how much flour they used over a specific time period and how many individuals ate in the household during that time. Then, the amount of flour consumed per household is calculated on a daily basis. For example, if the survey asks about flour use over a 14-day period, the amount of flour is divided by 14 to estimate the daily intake. Then, the average amount of fortified flour consumed by individuals is estimated.

Table 2. Estimating daily per capita fortified flour intake

In a household survey, heads of households were asked how much industrially milled and packaged flour (i.e. the type of flour that should be fortified in that country) they used in the last 7 days, and how many people ate in the household in the same period. This information was used to estimate the amount of flour consumed per household in grams per capita per day (g/c/d) as 104.5.

Household	Flour used in household in the last 7 days (g)	Individuals who ate in household in the last 7 days (number)	Apparent daily amount of flour consumed per household per capita (g/c/d)[a]
1	5047	7	103
2	2660	4	95
3	1827	3	87
4	1890	2	135
5	3885	5	111
6	658	1	94
7	4305	5	123

Household	Flour used in household in the last 7 days (g)	Individuals who ate in household in the last 7 days (number)	Apparent daily amount of flour consumed per household per capita (g/c/d)[a]
8	5110	5	146
9	1722	6	41
10	4620	6	110
Total			**1045**
Average household per capita consumption			**104.5**

[a] Calculation: "flour used in HH in 7-day period in grams" divided by "individuals who ate in HH in 7-day period" divided by 7.

Annex 5.8 lists the steps to follow for its measurement. If **flour-based foods** (e.g. bread, naan, tortillas) are predominantly used by households instead of flour, Annex 5.4 describes the adjustments that need to be made to the survey. Additionally, Annex 5.5 has guidance on aspects that should be considered in advance of implementing surveys.

As described in this manual, there are limitations to consider in calculating fortified flour intake, which include the following.

- In some settings, individuals or households do not keep flour in the house; instead, they use flour-based products such as tortillas, roti and bread. In these instances, it will be necessary to determine what percentage of the food that is made with flour. Annex 5.5 provides guidance for these cases, so that the fortified flour intake can be calculated for flour-based foods.
- Surveys that ask about amounts **purchased for the household** assume that this amount is consumed by all household members. Since this assumption is not usually confirmed, any estimates of fortified flour intake and micronutrient intake from fortified flour from these surveys are usually referred to as **apparent consumption**. Methods used to estimate consumption should be clearly specified in reports.

5.5 Indicator: micronutrient intake from fortified flour

WHO/CDC indicator: Average additional amount of micronutrients delivered daily by consumption of fortified flour

The potential impact of a flour fortification programme does not only depend on the additional micronutrient content provided by the flour, it also depends on how much of the flour the target populations consume. The **micronutrient intake from fortified flour** is an estimation of the additional amounts of micronutrients delivered daily by the consumption of fortified flour. Annex 5.9 provides detailed information on calculating the indicator.

Micronutrient intake from fortified flour is derived by multiplying the additional micronutrient content provided by the fortified **flour** with the amount of fortified **flour** the target populations consume. **Box 3** describes the calculation, using the example data from **Box 1**.

Box 3. Calculating micronutrient intake from fortified flour: an example

From the example in **Box 1**, for 2010 the information available is:

- Fortified maize flour intake: 118 grams/capita/day
- Zinc content of fortified flour: 15 mg/kg

To calculate zinc intake from fortified flour, these two values are multiplied and divided by 1000:

(118 grams/capita/day x 15 mg/kg)/1000 = 1.8 mg/capita/day

For the example household, fortified flour contributed 1.8 mg of zinc per capita per day. Micronutrient intake can also be calculated for flour-based foods such as bread, if micronutrient content and flour intake are available for that specific food (see **Annex 5.4**). **Annex 5.5** also has guidance on several aspects that should be considered in advance of implementing surveys.

As described in this manual, the calculation of micronutrient intake from fortified flour has several limitations. This is mainly because this indicator is the product of the micronutrient content of fortified flour and fortified flour intake, and limitations in the calculation of those indicators will also affect the calculation of micronutrient intake from fortified flour.

5.6 Reporting

Programme decision-making can be aided by summarizing the results of consumption monitoring activities and analyses on a regular basis (e.g. every completed year) and making them publicly available (e.g. *14*). Sample tables with results for each consumption monitoring indicator are noted in **Annex 5.6**, **Annex 5.7**, **Annex 5.8** and **Annex 5.9**. A sample report outline for the totality of the consumption monitoring activities is shown in **Annex 5.10.**

The following general points may help with interpreting the results of consumption monitoring and with making recommendations.

1. If fortified flour intake is low or very heterogeneous in the target population, this suggests that the flour fortification programme is unlikely to have the desired public health impact and that flour may not be the optimum or only fortification vehicle needed. In this case, other fortification vehicles could be considered. The reasons for low or heterogeneous fortified flour intake could be explored. Possible reasons are that the supply is limited or that the price of the flour may be unaffordable for the target population.

2. If fortified flour coverage is high and the micronutrient content of fortified flour is low, this suggests that the distribution channels for fortified flour are adequate, but the additional content of micronutrients in the flour is insufficient. The focus could be on ensuring that the flour produced in-country and imported is fortified according to standards.

3. If fortified flour coverage is low and the micronutrient content of fortified flour is high, this suggests that the quality of fortified flour is adequate but that most households in the target population are not purchasing or receiving the well-fortified flour. The focus could be on understanding and addressing the causes of low coverage, sustaining compliance by flour producers and importers, improving flour distribution channels, and considering other food vehicles.

4. If micronutrient intake from fortified flour is low, this suggests that the intervention is not producing a dietary impact. The source of low micronutrient intake could be investigated: is it because of (i) low fortifiable flour intake or (ii) insufficient amounts of micronutrients in the flour? If the main source is (i), focus on the activities noted in point 1. If the main source is (ii), focus on those activities noted in point 2.

5. If micronutrient intake from fortified flour is very high, for example close to or exceeding tolerable upper intake levels *(15)*, this may indicate that the nutrient levels in the fortification standards are too high, or that millers of domestic and imported flour are adding significant overages to the flour. The focus could be on understanding the causes of the high intake. An estimation of the nutrient intake from the rest of the diet could help determine whether the fortification standards should be changed. The results can be compared with programme goals for fortified flour coverage, micronutrient content of fortified flour, fortified flour intake, or micronutrient intake from fortified flour. For any results that are far from achieving goals, potential causes can be identified and remedial actions recommended. For any results that are at or above goals, consider whether any activities need to be (i) strengthened to sustain those results and ensure the goals are met in the coming year or (ii) scaled back to ensure the population is not at risk of excessive micronutrient intakes *(16, 17)*.

5.7 Conclusions

Through consumption monitoring, programme implementers and decision-makers will have a better understanding of the potential dietary impact that fortified flour will have on the target population. Such information can be used to strengthen or modify the programme such that safe and maximum benefits from fortification can be obtained.

CHAPTER 5 ANNEXES

5.1 Sample consumption monitoring questions that can be added to surveys

Table 3 lists questions that can be adapted for use in different countries to assess fortified flour coverage, micronutrient content of fortified flour, fortified flour intake, and micronutrient intake from fortified flour. Adaptations to assess consumption monitoring for households are listed as footnotes.

Table 3. Sample of the minimum questions needed to assess consumption monitoring of flour and flour-based foods for an individual *(18–22)*

Question[a]	Consumption monitoring domain(s)
Section A	
1. What type(s) of flour[b] do **you** most use in your home?[c] If the answer is "No flour is used in the home", skip to section B.	• Fortified flour coverage • Fortified flour intake • Micronutrient content of fortified flour • Micronutrient intake from fortified flour
2. For [the type of flour you most consume], how much do **you** typically use in a day?[d]	• Fortified flour intake • Micronutrient intake from fortified flour
3. May we take a sample of this flour? (yes/no/none is available)	• Fortified flour coverage • Micronutrient content of fortified flour
Section B	
4. Do **you** consume [flour-based food][e] in your home?[f] (Yes/No) If the answer is no, end the survey.	• Fortified flour coverage • Fortified flour intake • Micronutrient intake from fortified flour
5. For [flour-based food][e], what is the brand and producer name of the food **you** typically consume in a day?[g]	• Micronutrient content of fortified flour
6. For [flour-based food][e], how much do **you** typically consume in a day?[h]	• Fortified flour intake • Micronutrient intake from fortified flour
7. May we take a sample of this food?[i] (yes/no/none is available)	• Fortified flour coverage • Micronutrient content of fortified flour

[a] These illustrative questions are aimed at the main beneficiary of a flour fortification programme. For example, this can be a woman of childbearing age in a household. If the questions are adapted for household consumption monitoring, note that the person who is most knowledgeable about a household's use of flour may not be the same as the main beneficiary.

[b] Ask for the brand, producer, flour type (e.g. maida, atta), and source (e.g. store, kiosk, World Food Programme).

[c] This question is about an individual's use. To ask about a household's use, the question can be reworded as follows. "What type/types of flour is/are most used in this household?"

[d] This question is about an individual's use. To ask about a household's use, the question can be reworded as follows. "For [the type of flour the household most consumes], how much is typically used in a day in the household?"

[e] This refers to foods predominantly made with flour such as roti, naan, tortillas, and bread. This question can be repeated for all the flour-based foods that form an important market share in the country.

[f] This question is about an individual's use. To ask about a household's use, the question can be reworded as follows. "Is/are [flour-based food/foods] consumed in this household?"

[g] This question is about an individual's use. To ask about a household's use, the question can be reworded as follows. "For [flour-based food], what is the brand and producer name of the food typically consumed in a day in this household?"

[h] This question is about an individual's use. To ask about a household's use, the question can be reworded as follows. "For [flour-based food], how much is typically consumed in a day in this household?"

[i] If there are resources and the capacity to quantify one or several nutrients in a flour-based food, ask this question and collect food samples.

Some comments and recommendations for the use of these questions follow.

1. The questions are organized into two sections: flour (section A) and foods made from flour (section B). Depending on whether targeted fortification beneficiaries are more likely to have flour in their homes or foods made from flour (such as store-bought bread), you may choose to ask both sections A and B or only one (**Annex 5.4**).

2. The questions ask about a person's use or intake of flour and foods made with flours. The footnotes offer suggestions for adjusting these questions to ask about a household's use of the flour and foods.

3. If multiple types of flour should be fortified according to national legislation and standards, respondents can be asked in section A about (i) the flour types, (ii) those that make up the largest market share, or (iii) only the most commonly used/consumed flour. All reports written on the topic of consumption monitoring should clearly state the types of flour targeted.

4. If consumption monitoring activities are going to focus on flour-based foods instead of flour, it will be important to focus on just a few products. While countries might have legislation and standards for a few types of flour, that flour then becomes an ingredient in numerous flour-based products. Thus, the survey should assess (in section B) only a few products that form a large, consumer-driven market share and use them as a proxy. See **Annex 5.4** for more guidance.

5. All questions can be reworded as needed; those that are inside square brackets ([ ]) require the insertion of local terms, such as brand names, flour producers, and flour-based foods.

6. The intake questions are worded as "typically consume" (e.g. questions 2 and 6). As described in **Annex 5.8**, there are multiple ways in which intake can be assessed, such as individual consumption in the previous day or household purchase in the previous week. The wording can be modified as needed.

7. Samples taken (questions 3 and 7) can be analysed quantitatively for micronutrient content of fortified flour. However, information on the micronutrient content of fortified flour can also come from regulatory monitoring data that is gathered regularly by food control authorities (see **Chapter 4**). **Annex 5.7** describes the options available for estimating the micronutrient content of fortified flour.

8. If information on the micronutrient content of fortified flour is to come from monitoring data provided by food control authorities, it will be important for the survey to include questions on the brand and producer information for the flour and flour-based foods used by households (e.g. questions 1 and 5).

5.2 Sample consumption monitoring questionnaire applied in South Africa for maize meal

Below is the section on maize meal from a questionnaire that was administered to heads of households in South Africa as part of a food fortification coverage survey *(19)*. In this survey, many more questions were asked than the minimum required to measure the recommended indicators for consumption monitoring (**Annex 5.1**). The following points should be noted.

- The survey inquires about maize meal, a type of maize flour that is consumed throughout South Africa.
- The survey requires collection of complementary information before the survey form can be completed, such as the types of maize meal that are required to be fortified (question 3).
- The survey focuses on the **main** type of maize meal used in the home (question 2).
- The survey asks about the source of the maize meal (question 4). Since maize that is ground at home is not mandated to be fortified in South Africa, this question allows exclusion of this type of flour from the survey results.
- The survey asks about the quantity purchased and how long that amount lasts in the household (questions 6 and 7, respectively). Under the assumption that all maize meal purchased is eventually consumed, this is an indirect way to assess maize meal consumption.

- The survey inquires about the brand and producer of maize meal (questions 8 and 9, respectively). This can be used to link with regulatory monitoring data (**Chapter 4**) to obtain the micronutrient content of fortified flour information without having to analyse samples.
- The survey assesses whether a fortification logo is affixed to the maize meal package (question 10). If regulatory monitoring (**Chapter 4**) indicates that all maize meal producers using the fortification logo on their packaging are indeed producing high-quality fortified maize meal, it can be indirectly assumed that the maize meal is fortified.
- The survey requests permission to take a maize meal sample from the home (question 11). This sample can be assessed qualitatively for the presence of a marker nutrient that indicates the sample is fortified (to calculate fortified flour coverage) and/or quantitatively to measure one or more nutrients of interest in the sample (to calculate micronutrient content of fortified flour). **Chapter 3** describes the testing methods that can be applied to the samples.
- The survey does not ask questions about purchased foods made with maize meal. This survey is appropriate in contexts where most households purchase maize meal that is then used to prepare foods in the home. In other settings, where most households purchase foods made with maize meal and bring them into the home, it would be more appropriate for a survey to ask about foods made with maize meal (see **Annex 4**).
- The questions related to each consumption monitoring indicator are:
  - flour fortification coverage – questions 1, 2, 4, and 11;
  - micronutrient content of fortified flour – questions 8, 9, and 11;
  - fortified flour intake – questions 1, 2, 4, 6, and 7;
  - micronutrient intake from fortified flour – 1, 2, 4, 6, 7, 8, 9, and 11.

MAIZE MEAL FORTIFICATION QUESTIONNAIRE

Number	Questions	Answers		Skips	Consumption monitoring indicators assessed
	Now, I would like to talk with you about maize meal.				
1	Does your household prepare foods using maize meal (e.g. porridge, pap)? (CIRCLE ONLY ONE ANSWER)	Yes, regularly Yes, sometimes No, never	1 2 3	If **3,** end survey.	• Flour fortification coverage • Fortified flour intake • Micronutrient intake from fortified flour
2	What is the main type of maize meal that is used in your household? (CIRCLE ONLY ONE ANSWER)	Sifted Supersifted Coarse/Braaipap Instant/quick cooking Other:	1 2 3 4 99		• Flour fortification coverage • Fortified flour intake • Micronutrient intake from fortified flour
3	Can you show me this main maize meal? (CIRCLE ONLY ONE ANSWER)	Yes No	1 2		
4	(IF MAIZE MEAL IS AVAILABLE) When your household got this maize meal, where did you get it from? (IF MAIZE MEAL IS NOT AVAILABLE) The last time your household got maize meal, where did you get it from? (CIRCLE ONLY ONE ANSWER)	Purchased Ground at home Received from food aid Don't know/don't remember Other:	1 2 3 88 99	If **2,** end survey.	• Flour fortification coverage • Fortified flour intake • Micronutrient intake from fortified flour

MAIZE MEAL FORTIFICATION QUESTIONNAIRE				
Number	**Questions**	**Answers**	**Skips**	**Consumption monitoring indicators assessed**
5	*(IF MAIZE MEAL IS AVAILABLE)* When you household got this maize meal, how was it packaged? *(IF MAIZE MEAL IS NOT AVAILABLE)* The last time your household got maize meal, how was it packaged? (READ **ALL** RESPONSES) (CIRCLE ONLY **ONE** ANSWER)	Original package 1 Re-packaged 2 My own container 3 Don't know 88 Other: 99		
6	*(IF MAIZE MEAL IS AVAILABLE)* When you household got this maize meal, how much did you get? *(IF MAIZE MEAL IS NOT AVAILABLE)* The last time your household got maize meal, how much did you get? (SHOW EXAMPLES OF COMMONLY USED CONTAINERS AND MEASURES) (A. WRITE IN THE NUMBER) (B. CIRCLE THE UNIT)	A. B. kg 1 g 2		• Fortified flour intake • Micronutrient intake from fortified flour
7	How long does this amount usually last in your household? (A. WRITE IN THE NUMBER) (B. CIRCLE THE UNIT)	A. Duration B. Day(s) 1 Month(s 2		• Fortified flour intake • Micronutrient intake from fortified flour
8	(IF MAIZE MEAL IS AVAILABLE) **OBSERVE BRAND** (IF MAIZE MEAL IS NOT AVAILABLE, **ASK THE RESPONDENT** "What is the brand of this maize meal?) (WRITE IN ONLY **ONE** ANSWER)	Brand name (write in) (Code assigned) Don't know 88 Other: 99		• Micronutrient content of fortified flour • Micronutrient intake from fortified flour
9	(IF MAIZE MEAL IS AVAILABLE) **OBSERVE PRODUCER** (IF MAIZE MEAL IS NOT AVAILABLE, **ASK THE RESPONDENT** Who is the producer of this maize meal?) (WRITE IN ONLY **ONE** ANSWER)	Producer name (write in) (Code assigned) Don't know 88 Other: 99	If maize meal is not available, end survey.	• Micronutrient content of fortified flour • Micronutrient intake from fortified flour
10	LOOK FOR FORTIFICATION LOGO (CIRCLE ONLY **ONE** ANSWER)	Logo not observed (labelled) 1 Logo not observed (no label) 2 Logo observed 3		
11	May I take a small sample? (IF "YES", TAKE SAMPLE AND STICK MAIZE MEAL LABEL ON SAMPLE CONTAINER)	Sample taken 1 No sample taken 2		• Flour fortification coverage • Micronutrient content of fortified flour • Micronutrient intake from fortified flour

5.3 Sample consumption monitoring questionnaire applied in Nigeria to assess fortified flour intake of flour-based foods

To estimate fortified flour intake, the following questionnaire excerpt was administered to all women of childbearing age in households from two states in Nigeria as part of a food fortification coverage survey *(21)*. In this survey, women were asked the following two questions about 27 food items that contain either wheat flour or maize flour and that, by law, should be fortified.

1. In the last 7 days, how many times did you eat products made from wheat flour or maize flour, such as [FOOD ITEM]?

2. Usually how much of [FOOD ITEM] did you eat at one sitting?

For the second question, women were shown photographs of different portion sizes (**Box 4**); the amount of wheat flour or maize flour that these food items contain was ascertained in advance of the survey (see **Box 5** for an example for one food).

The following points should be noted.

- The survey inquires about foods containing either wheat flour or maize flour that are mandated to be fortified.
- The survey requires collection of complementary information before the survey form can be completed, specifically the food items, the portion sizes (see **Box 4**), and the amount of flour in each portion size (**Box 5**).
- The frequency and portion size questions of survey permit estimation of fortified flour intake.

INDIVIDUAL WHEAT AND MAIZE FLOUR CONSUMPTION

In the last 7 days, how many times did you eat products made from wheat flour or maize flour, such as [FOOD ITEM]?
(IF FREQUENCY = 00, DON'T ASK THE PORTION SIZE)
Usually how much of [FOOD ITEM] did you eat at one sitting? (SHOW PICTURES OF PORTIONS!)
(REPEAT QUESTIONS FOR EACH FOOD ITEM LISTED BELOW)

Number	Items	1. Frequency (number of times)	2. Portion size
wmfc1	Noodles		
wmfc2	Spaghetti		
wmfc3	White bread loaf		
wmfc4	Sliced bread		
wmfc5	Tuwo masara		
wmfc6	Semolina meal		
wmfc7	Whole wheat meal		
wmfc8	Plain puff puff		
wmfc9	Sausage roll		
wmfc10	Beef burger with egg		
wmfc11	Chicken pie		
wmfc12	Round doughnut		
wmfc13	Fried fish roll		
wmfc14	Scotch egg		
wmfc15	Buns		

INDIVIDUAL WHEAT AND MAIZE FLOUR CONSUMPTION			
In the last 7 days, how many times did you eat products made from wheat flour or maize flour, such as [FOOD ITEM]? (IF FREQUENCY = 00, DON'T ASK THE PORTION SIZE) Usually how much of [FOOD ITEM] did you eat at one sitting? (SHOW PICTURES OF PORTIONS!) (REPEAT QUESTIONS FOR EACH FOOD ITEM LISTED BELOW)			
Number	**Items**	**1. Frequency (number of times)**	**2. Portion size**
wmfc16	Cup cake		
wmfc17	Egg roll		
wmfc18	Pepper puff puff		
wmfc19	Ring doughnut		
wmfc20	Samosa		
wmfc21	Spring roll		
wmfc22	Fruit cake		
wmfc23	Plain cake		
wmfc24	Baked fish roll		
wmfc25	Vegetable burger		
wmfc26	Vegetable burger with egg		
wmfc27	Meat pie		

Box 4. Photographs of portion sizes for food item "plain puff puff" to aid Nigerian women recall the portion size they typically eat at one sitting *(21)*

PLAIN PUFF PUFF

1

2

PLAIN PUFF PUFF

3

4

5

6

7

Box 5. The amount of wheat flour in each portion size of foods included in a survey in Nigeria *(21)*: an example for "plain puff puff"

Plain puff puff, as prepared in Nigeria, contains wheat flour. The amount of wheat flour in each of the seven portion sizes depicted in **Box 4**, was estimated from recipes.

Portion size number	Amount of flour in portion size (g)
1	6
2	12
3	24
4	48
5	72
6	96
7	120

5.4 Adjustments to consumption monitoring survey where the focus is on flour-based foods

In some settings, it may be appropriate to estimate consumption monitoring indicators for flour-based foods (such as bread and tortillas) instead of flour. This occurs where target populations do not use flour in their homes to prepare foods; instead they consume prepared flour-based porridges, tortillas, naan, etc. that have been made outside of the home. However, using flour-based foods introduces many challenges to consumption monitoring assessments. They include the following.

- **Determining fortified flour coverage** There may not be validated methods available to qualitatively test whether vitamins and minerals have been added to the flour-based food. Such tests are used to rapidly and inexpensively determine whether a food is fortified, a key factor in calculating coverage. In addition, there are so many foods made with flour on the market that it could be challenging to select a limited few for a survey.
- **Determining micronutrient content of fortified flour** It may be difficult to obtain unfortified flour-based food samples (analysis of these samples is one way of estimating the nutrient content of unfortified foods) or information for these unfortified foods in food composition tables (another way of estimating nutrient content). For the micronutrient content of fortified flour, calculation of the amount of each nutrient added by fortification requires subtraction of the amount of each nutrient naturally found in unfortified foods from the amount of each nutrient as measured in fortified foods.
- **Determining fortified flour intake** It may be difficult to obtain (i) the list of the most commonly consumed flour-based foods, (ii) common portion sizes consumed by the target population, and (ii) the percentage of flour that these foods contain. The first is necessary for generating the food list that will be included in the survey and the second and third are needed to calculate the grams of flour consumed from these foods.
- **Determining micronutrient intake from fortified flour** Challenges include all those noted for fortified flour intake and micronutrient content of fortified flour (which are used to calculate micronutrient intake from fortified flour).

This manual has been written with an emphasis on flour rather than on flour-based foods. If flour-based foods are more widely used by households in your setting, options for proceeding are as follows.

1. Adjust the collection of consumption monitoring indicators from flour to flour-based foods using the guidelines described below.

2. Eliminate some of the consumption monitoring indicators for which it will be difficult to gather information on flour-based foods. For example, to determine the micronutrient content of fortified flour used to make flour-based food, the amount of flour used to make the foods is necessary. In settings where dozens or hundreds of food products containing fortified flour are consumed, it may be difficult to obtain this information.

3. Meet with fortification stakeholders (see **Chapter 6**) to discuss alternative ways to estimate consumption monitoring indicators, such as dividing the **total amount of fortified flour produced in (and imported into) the country** by the **total amount of flour produced in (and imported into) the country** for a crude estimate of fortification coverage.

Note that a big challenge to assessing consumption monitoring indicators for flour-based foods will be selecting the limited number of foods that will be inquired about in the survey (**Box 6**).

Box 6. Sample method for selecting foods containing wheat flour for a monitoring survey of fortification consumption

Selecting foods that contain wheat flour for a fortification consumption monitoring survey includes three steps: identifying flour-containing foods and the amount of flour they have, estimating the daily intake of these foods by the target population, and selecting the survey foods. A fictitious example from the United States of America is provided to illustrate these steps.

Identifying flour-containing foods and their amount of flour

The United States Department of Agriculture National Nutrient Database is searched for foods that contain wheat flour *(23)*. For example, a search for "**bread wheat**" yields 18 foods, including "bread, wheat, white wheat", "bread, paratha (Indian bread), whole wheat, frozen", and "bread, reduced-calorie, wheat". A search for "**cracker wheat**" results in 20 foods, such as "crackers, wheat, low salt" and "crackers, wheat, sandwich, with peanut butter filling". Searching for "**tortilla wheat**" results in two foods: "wheat flour, white, tortilla mix, enriched" and "tortillas, ready-to-bake or -fry, whole". The amount of wheat flour in these 40 foods and others that contain substantial amounts of wheat flour is determined by contacting the food producers directly or reviewing their websites. From this step, those containing the most amount of wheat flour per 100 grams of food are identified.

Estimating the daily intake of these foods by the target population

The National Health and Nutrition Examination Survey *(24)* is then analysed to determine how much of foods containing wheat flour are consumed daily by women of childbearing age. From this step, the foods consumed by the most women and the foods consumed in the highest amount are identified.

Selecting wheat flour-containing foods for a fortification consumption monitoring survey

After reviewing the information from the first two steps, the group decides to include in the survey foods that meet all these criteria: foods containing more than 50 g of wheat flour per 100 g, foods consumed by the highest percentage of women, and foods whose consumption by women is at least 75 g per day. Because of resource limitations, the group decides to restrict the list to the top 20 foods that meet their criteria.

5.4.1 Adjustments to assess fortified flour coverage using flour-based foods instead of flour

As described in **Annex 5.6**, when possible, fortified flour coverage is based on a simple, rapid, qualitative analysis of flour to determine whether it is fortified. If such tests do not exist for the flour-based foods of interest, the following three options are available.

1. Quantitatively test samples of foods to measure the content of one marker nutrient.
2. Use the fortification logo to determine whether the food is fortified.
3. Do not assess coverage.

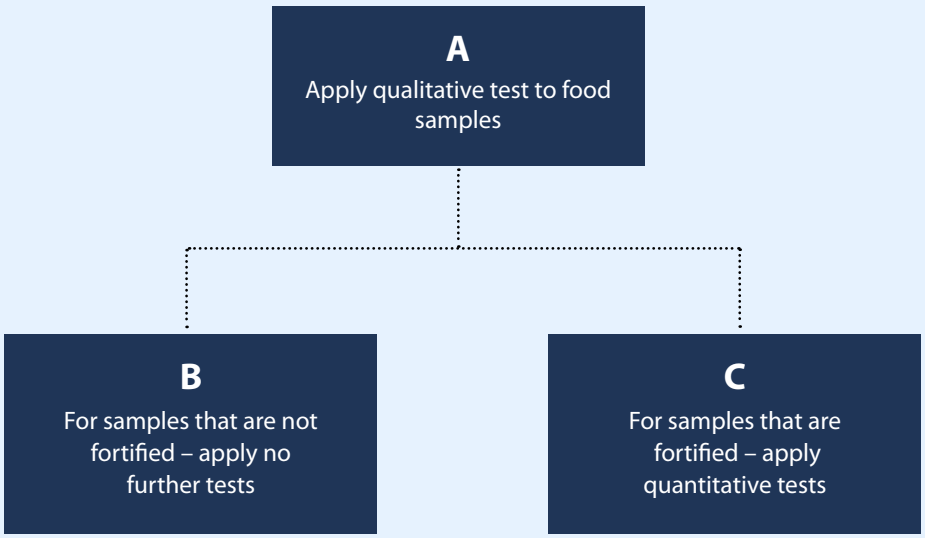
Option 1 requires sampling of foods and taking them to a central location for analysis. The same care should be taken in the collection, transportation, and storage of food samples as for flour samples. Guidelines used to collect bread samples, for example, are noted in a nutrition toolkit *(11)*.

Option 1. Quantitatively test samples of foods to measure the content of one marker nutrient

Quantitative tests are generally more expensive than qualitative tests. If that is the case for testing the nutrient of interest in the food of interest, testing all samples quantitatively will likely be more expensive than testing all samples qualitatively first, and then applying the quantitative test only to those samples deemed fortified by qualitative testing (**Box 7**). However, in the absence of a validated qualitative method for the nutrient and food of interest, quantitative measurement of a nutrient in the food will be the only way to confirm whether it has been fortified.

Box 7. How qualitative tests can be used in combination with quantitative tests to measure the micronutrient content of fortified flour

The micronutrient content of fortified flour is calculated using the quantitative information obtained from the samples in group C (see **Annex 5.7**).



Option 2. Use the fortification logo to determine whether the food is fortified

Regulatory monitoring officials may know if food producers use: (i) fortified flour in their formulations (because the fortified flour was observed to be present in the food-production plant) and (ii) a fortification logo on their products

made with fortified flour (or note fortified flour in the list of ingredients). Officials may have this information for specific food producers, specific products, and specific brands made with those products. If officials have this information, it may be possible to estimate coverage indirectly. Specifically, a survey can be conducted of consumers' use of products. During the survey, enumerators note the producer, product, and brand, as well as whether the fortification logo is present (or fortified flour is noted in the ingredient list). This consumer information is merged with regulatory monitoring information to determine what percentage of brands (or products) consumed are considered fortified by monitoring officials.

Option 3. Do not assess coverage

The final option is to not assess coverage as described in this manual. Alternatives include using information provided by industry, food control authorities, and customs officials to estimate coverage in other ways.

5.4.2 Adjustments to assess the micronutrient content of fortified flour using flour-based foods instead of flour

The micronutrient content of fortified flour summarizes the amount of additional nutrients provided by a food that should be made with fortified flour, compared with the amount in its unfortified counterpart (**Annex 5.7**). For flour-based foods, this requires comparing the nutrient content of the unfortified food with that of the fortified food. A challenge to this approach is selecting the limited number of foods that will be the basis for consumption monitoring.

The options for determining the nutrient content of fortified and unfortified flour-based foods are as follows.

1. Request the information from food manufacturers, food control authorities, and customs officials.
2. Use a food composition table that is accepted by the country (for unfortified food only).
3. Measure nutrient levels in fortified and unfortified food in a laboratory.

Option 1. Request the information from food manufacturers, food control authorities, and customs officials

Food manufacturers have their food products analysed nutritionally. This is done as a minimum for the nutrition label information, and perhaps more frequently as part of QA and QC protocols. Contact them and request information on the nutritional profile of the fortified and unfortified foods of interest.

Alternatively, nutrient profiles for fortified flour-based foods can be obtained from samples that are measured for external, import, or commercial monitoring (see **Chapter 4**). Assuming samples are sent to laboratories for quantitative analysis as part of the monitoring activities, the food control authority will have such nutrient data. It will be necessary to get values for specific **brands** of fortified food (e.g. Brand A, Brand B); if the brand names are not available, then values can be obtained for fortified food made by different **producers** (e.g. Producer A, Producer B).

If regulatory authorities have the nutrient values for fortified foods from monitoring data, it will only be necessary to get nutrient values for **unfortified** foods, ideally from the same brand or producer. The easiest way to get an unfortified sample is by making a request to the producer. This may be difficult for flour-based foods because regulations might require manufacturers to make these foods with fortified flour. An alternative can be to obtain the recipe for the food (e.g. 100 g of fortified flour, 20 g of sugar, etc.) and to use a food composition table to estimate the nutrient contribution of all ingredients, being careful to use the **unfortified** flour values in the calculation (**Box 8**).

Box 8. Example of using recipe information to estimate the nutrient content in an unfortified flour-based food

Producer A sells brown sugar shortbread made with fortified wheat flour. Based on the producer's analysis, one serving contains 1.4 mg of iron.

Producer A is unable to provide a sample of shortbread made with unfortified flour; however they provide the recipe to make 24 servings: 500 g butter, 250 g brown sugar, and 675 g of wheat flour.

The United States National Nutrient Database *(23)* was used to determine the iron content in one serving of shortbread (0.4 mg) using unfortified flour.

Food number	Food name	Iron in food (mg/kg)	Amount in recipe (g)	Iron in recipe (mg)[a]
01142	Butter, without salt	0.2	500	0.1
19334	Sugars, brown	7.1	250	1.8
20481	Wheat flour, white, all-purpose, unenriched (i.e. unfortified)	11.7	675	7.9
Total iron in recipe (using unfortified flour)[b]				9.8
Total iron per serving (using unfortified flour)[c]				0.4

[a] Calculation: "Iron in food" multiplied by "amount in recipe" and divided by 1000.

[b] Calculation: The sum of "iron in recipe (mg)" for each ingredient.

[c] Calculation: "Total in recipe" divided by 24 (the number of servings the recipe makes).

Option 2. Use the food composition table (for unfortified food only)

As noted in the example in **Box 8**, at times the food composition table is the only option available for estimating the nutrient profile of unfortified flour-based foods. If your country does not have a food composition table, or it does not have the unfortified version of the food you are looking for, use the table from a neighbouring country. To find these tables, visit the International Network of Food Data Systems of the Food and Agriculture Organization of the United Nations, which links to food composition tables from around the world *(25)*.

Option 3. Measure nutrient levels in fortified and unfortified food in a laboratory

As described in **Annex 5.7**, a final option can be to measure nutrient levels in fortified and unfortified versions of the same food. The same steps are followed, only that flour-based foods are analysed instead of flour. There may be difficulties in creating homogeneous mixtures of solid foods, such as biscuits; however, a laboratory experienced with measuring nutrients in such foods can take care of this step.

For options 1, 2, or 3 calculate the micronutrient content of fortified flour (**Box 9**).

Box 9. An example of calculating the amount of a nutrient added by fortification to a flour-based food using Option 2 as the source of information

One serving of brown sugar shortbread made with **fortified** wheat flour contains 1.4 mg of iron. One serving of the same shortbread made with **unfortified** wheat flour contains 0.4 mg of iron (see **Box 8**).

The amount of iron that is contributed by fortification is calculated by subtracting the iron amount in unfortified shortbread from the iron amount in fortified shortbread. The iron provision of fortified shortbread is:

1.4 mg/serving – 0.4 mg/serving = 1.0 mg/serving

5.4.3 Adjustments to assess fortified flour intake using flour-based foods instead of flour

Fortified flour intake refers to the amount of fortified flour consumed by individuals or households (**Annex 5.8**). When flour-based foods are used to estimate consumption instead of flour, an additional step is required: the amount of flour in flour-based foods must be estimated. Other than this new step, there are no differences in the methods used to estimate fortified flour intake.

5.4.4 Additional step: Estimate the amount of flour in flour-based foods

The amount of flour in flour-based foods is often expressed as grams of flour in 100 g of flour-based foods. The easiest and most direct way to get this information is to make a request to the producers. Another option is to request the recipe for the food to help calculate the amount of flour (**Box 10**).

Box 10. Example of calculating the amount of flour in flour-based foods using a recipe

In Nigeria, women of childbearing age were asked about their intake of foods containing wheat flour or maize flour. To estimate the amount of flour in these foods, recipes were compiled *(21)*.

For example, the danwake recipe contains 125 g wheat flour, 125 g bean flour, 125 g cassava flour, 15 g dried baobab leaves, 6 g dried pepper, 28 g onion, 2 g salt, and 8 g bouillon cubes. The total weight of these ingredients is 434 g. The amount of wheat flour in 100 g of danwake is calculated:

Wheat flour in 100 g danwake = 125 g / 434 g x 100 g = 28.8 g

Alternatively, this information can be expressed as 28.8% of danwake is wheat flour.

With information on the amount of flour in flour-based foods, the amount of fortified flour consumed from flour-based foods can be estimated (**Box 11**).

Box 11. Example of how to calculate the fortified flour intake from flour-based foods of an individual in a day

In country X, instant noodles made with wheat flour are an important source of fortified flour intake. A survey of 500 women of childbearing age asked about the amount of instant noodles they consumed in the previous 7 days. During the planning stages of the survey, noodle producers were contacted, and it was found that on average there are 76 g of wheat flour in every 100 g of instant noodles.

One of the surveyed women reported consuming two different brands of instant noodles over the past 7 days: Brand A whose single-sized portions contain 85 g of instant noodles and Brand B whose family sized portions contain 210 g of instant noodles. Regulatory monitoring information from food control authorities confirmed that both brands were consistently fortified in the previous year.

The woman reported she ate a single-sized portion of Brand A every day for lunch at work (Monday–Saturday) and shared a family-sized portion of Brand B equally with her mother on Sunday. Her intake of fortified flour over the 7 days was calculated as 467.4 g and per day as 66.8 g.

Day	Brand	Amount of fortified noodles consumed (g)	Amount of fortified flour consumed (g)[a]
Monday	A	85	64.6
Tuesday	A	85	64.6
Wednesday	A	85	64.6
Thursday	A	85	64.6

Day	Brand	Amount of fortified noodles consumed (g)	Amount of fortified flour consumed (g)[a]
Friday	A	85	64.6
Saturday	A	85	64.6
Sunday	B	105	79.8
Total over 7 days[b]			467.4
Average per day[c]			66.8

[a] Calculation: "Amount of fortified noodles consumed (g)" multiplied by the amount of wheat flour in 100 g of noodles (76 g)" divided by 100.

[b] Calculation: Sum of "amount of fortified flour consumed (g)".

[c] Calculation: "Total over 7 days" divided by 7.

5.4.5 Adjustments to assess micronutrient intake from fortified flour using flour-based foods instead of flour

Micronutrient intake from fortified flour summarizes the additional nutrients delivered by fortified flour to an individual or household. It is estimated by multiplying fortified flour intake with the micronutrient content of fortified flour. Micronutrient intake from fortified flour can be calculated for any flour-based food only if **fortified flour intake** and **micronutrient content of fortified flour** are available for that specific food.

5.5 Planning for consumption monitoring

Undertaking a survey to assess consumption monitoring requires planning. The following planning considerations are common to evaluating any of the consumption monitoring indicators; they should be discussed and resolved before proceeding with indicator estimates.

1. What target populations will be surveyed?
2. Will this be a stand-alone survey or will the questions be integrated into another survey? How many households or individuals need to be surveyed?
3. What types of food will be assessed (e.g. flour(s) and/or flour-based foods)?
4. Will food samples be collected and analysed? If so where, how many, and how will the sampling take place?
5. What nutrients will be measured in food samples?
6. Which laboratories will measure the nutrients in food samples?

PLANNING CONSIDERATION 1. WHAT TARGET POPULATIONS WILL BE SURVEYED?

Fortification programmes may target specific beneficiaries, such as women of childbearing age. If these beneficiaries are specified in programme documentation (such as legislation), they should be the focus of the survey. Resources are often insufficient for all population groups (e.g. older people, women of childbearing age, adult men, adolescents, school-age children, preschool-age children, and infants) to be assessed in one survey. If beneficiaries have not been written into programme documentation, target groups may need to be specified for the survey.

Consumption patterns may dictate whether individual-level or household-level questions are asked. For example, if it is customary to use flour in the household to prepare foods, then it may be easier to ask about flour purchased or used by **households**. Conversely, if the target population consumes flour-based food outside the home, then it may be easier to ask about flour-based foods consumed by **individuals** from the target population.

PLANNING CONSIDERATION 2. WILL THIS BE A STAND-ALONE SURVEY, OR WILL THE QUESTIONS BE INTEGRATED INTO ANOTHER SURVEY? HOW MANY HOUSEHOLDS OR INDIVIDUALS NEED TO BE SURVEYED?

Consumption monitoring questions can be asked as part of a stand-alone fortification survey (e.g. *20)*. An alternative and less costly option is to integrate the questions into surveys that are periodically conducted in the country. These can be, for example, household income and expenditure surveys *(3)*, ongoing health or nutrition surveillance *(4)* or periodic health surveys *(5)*, food basket surveys *(6)*, STEPwise approach to surveillance (STEPS) surveys *(7)*, dietary surveys *(8)*, or nutrition surveys *(9)*.

Regardless of whether the survey will be stand-alone or integrated, a certain number of individuals or households need to be surveyed to assess consumption monitoring indicators. A sample size calculation will determine the minimum number of individuals or households that need to be surveyed for the representativeness desired (e.g. national, urban/rural, by province, by ethnic group). **Box 12** shares an example of the considerations used to determine the number of **households** that would be surveyed in one Nigerian state in a stand-alone survey. The goal was to have **state-representative** information on fortified food coverage, fortified food intake, and micronutrient intake from fortified food. Guidance on sample size calculations for the number of individuals or households to be surveyed can be obtained elsewhere *(10, 11)*.

Box 12. Example of a sample size calculation to determine the number of households to visit in one state in Nigeria to ensure state-representative results *(26)*

A food fortification coverage survey was completed in 2015 *(21)*. This was a cross-sectional, two-stage, cluster-sampling household survey. It was designed to be representative at the state level.

For the first stage of sampling, census enumeration areas served as the primary sampling units (clusters) and 30 were selected within the state.

The second sampling stage was the selection of households within the primary sampling units (clusters).

Calculation of the household sample size was as follows. The target number of households that completed the survey was based on estimating food fortification coverage (i.e. prevalence). Assuming a 95% confidence interval, 50% prevalence, a precision of 0.05, and a design effect of 2 (because of the use of cluster sampling), a target sample size of 856 households was calculated. Assuming a 10% non-response rate, the sample was increased to 942 households. In each of the 30 selected clusters, 32 households (i.e. a total of 960 households) were invited to participate in the survey to ensure the desired sample size of 942 households in the state was reached.

PLANNING CONSIDERATION 3. WHAT TYPES OF FOOD WILL BE ASSESSED (E.G. FLOUR AND/OR FLOUR-BASED FOODS)?

There are two types of food that can be assessed in consumption monitoring: flour and flour-based foods. If most of the target population obtains (via purchase, donation, or barter) **flour for use in the home**, then it is preferable to assess flour in the survey. Note that in some countries, legislation and standards may specify that only some of the flour types need to be fortified (**Box 13**). Prior to conducting the survey, each country's legislation and standards need to be reviewed so all relevant parties agree on the type of flour or flours that will be assessed.

Box 13. Example of rationale for deciding which flours will be the focus of consumption monitoring

Three types of wheat flour are popularly consumed in India: atta, maida, and sooji. In one state of the country, both atta and maida flours must be fortified; however sooji flour does not need to be fortified. When a household survey was undertaken, interviewers asked each person in charge of purchasing food for their household how much atta and maida flour was bought in the last 2 weeks. The survey did not ask about sooji flour because it was not relevant for the fortification programme monitoring efforts.

If most of the target population generally consumes **flour-based foods that are prepared outside the home**, such as bread, chapatis, rotis, instant noodles, or tortillas, then it is preferable to assess these foods. It may become prohibitively expensive to sample numerous types of flour-based foods and analyse their nutrition content. In these cases, consider assessing the **most commonly consumed** flour-based foods. Other flour-based foods that are not assessed can be noted in the final report (see **Annex 5.10**). If flour-based foods will be assessed in the survey, some adjustments need to be made in the way consumption monitoring indicators are calculated (see **Annex 5.4**).

PLANNING CONSIDERATION 4. WILL FOOD SAMPLES BE COLLECTED AND ANALYSED? IF SO WHERE, HOW MANY, AND HOW WILL THE SAMPLING TAKE PLACE?

Will food samples be collected and analysed?

In consumption monitoring, the flour and/or foods **consumed** by individuals or households are ascertained through a survey. If the micronutrient content of fortified flour and the micronutrient intake from fortified flour are to be estimated, the nutrient profile of these flours and foods can be determined by using existing regulatory monitoring information (see **Chapter 4**). Alternatively, samples from households or retail outlets can be collected and analysed for their nutrition content.

There are costs associated with obtaining the nutrient profile of flours and flour-based foods through existing external, import, and commercial monitoring data or laboratory analyses of samples. To obtain monitoring information from food control authorities requires personnel time. Properly gathering, storing, transporting, preparing, and analysing samples incurs costs related to personnel time, materials, supplies, and laboratory testing.

From where will existing nutrient information of foods be obtained?

It is possible that nutrient information obtained from external, import, or commercial monitoring activities (see **Chapter 4**) is available and can be used instead of collecting samples; for an example see reference *(14)*. This option will be significantly less costly than laboratory testing of samples collected at households. The challenges include accessing and collating the data, since they may not be organized in a central location, and then filling in gaps for any foods reported as being consumed by households but for which monitoring information is not available.

From where will food samples be collected?

The most common place to collect flour and food samples for consumption monitoring activities is households *(19–20,27)*. Alternatives include gathering flour and food samples from retail outlets based on household reports of the most commonly consumed foods *(28–30)*. This manual focuses on household sampling.

How many food samples need to be collected?

Most surveys are designed to collect one sample per household. In practice, some households may not have the flour or food available, or they may not wish to provide it to the enumerators. Each sample is analysed for one or several nutrients to generate an estimate of the nutrient(s) provided by fortified flour or food.

The nutrient values measured in the sample (i.e. micronutrient content of fortified flour) can be linked with the amount of food reported as consumed (i.e. fortified flour intake) in the household, to calculate the additional nutrients delivered by fortified flour (i.e. micronutrient intake from fortified flour). In cases where 100% of households did not provide a sample, the average micronutrient content of fortified flour for a neighbourhood or region can be used to calculate micronutrient intake from fortified flour *(20)*.

How will food sampling take place?

Enumerators need to be well trained in the collection of samples from households and need to be given the appropriate tools to do so (e.g. plastic gloves, plastic bags, labels for bags). Guidance on flour collection, storage, and transportation is available in a nutrition survey toolkit *(11)*. **Box 14** describes a modification to the protocol enumerators were asked to follow when collecting maize meal and wheat flour samples from households as part of food fortification coverage surveys completed in several African countries *(18–21)*.

Box 14. **Adaptation of the guidance provided to enumerators gathering maize meal and wheat flour samples from households as part of food fortification coverage surveys** ***(18–21)***

Collection of dry maize meal and wheat flour

Amount of sample to take in each household: 100 g (about 12 tablespoons). The following steps are for collecting a sample of maize meal.

1. Prepare a small sachet bag, take out the label for the maize meal; prepare a larger sachet bag.
2. Mix the maize meal, take a sample, fill the small sachet bag with 100 g (about 12 tablespoons) of maize meal and close the bag.
3. Stick the label with the unique number assigned to the household on the maize meal small sachet bag.
4. Place the maize meal small sachet bag into the larger sachet bag. (This gives an extra protection layer and ensures that, even if the sample label should fall off the small sachet bad, it will not be lost.)
5. Circle the response "sample was taken" on the household questionnaire.

PLANNING CONSIDERATION 5. WHAT NUTRIENTS WILL BE MEASURED IN FOOD SAMPLES?

In an ideal setting, all nutrients that are added to flour during the fortification process (i.e. via the premix) are quantified. However, owing to resource limitations, it may be necessary to compromise. At a minimum, aim to measure one marker nutrient in the food samples gathered (**Box 15**). When choosing the nutrients to analyse, consider the laboratory capacity available to measure the nutrients of interest accurately and precisely, as noted in planning consideration 6.

Box 15. Example of using a marker nutrient to determine the nutrient profile of wheat flour

In Iran, wheat flour must be fortified with a premix containing 30 mg/kg iron and 1.5 mg/kg folic acid. It is less expensive to measure **iron** content than folic acid content in flour samples. Since millers add the premix (not the nutrients individually) to flour, the flour should contain iron and folic acid in the same proportions as in the premix. Therefore, if the iron content in a sample of flour is within the range stipulated in national standards, it is assumed that the folic acid will also be in the standards range. By using iron as the indicator nutrient, Iran can assess the iron profile of wheat flour at low cost and use that value to determine whether the flour is fortified at expected levels with both iron and folic acid.

PLANNING CONSIDERATION 6. WHAT LABORATORIES WILL MEASURE THE NUTRIENTS IN FOOD SAMPLES?

Ideally, laboratories designated to analyse flour or flour-based food samples will have two qualifications. First, the laboratory will be ISO 17025 certified for the analysis of all nutrients of interest (for example, a laboratory certified for the quantification of iodine but not zinc would not be suitable). Second, the laboratory will have experience measuring nutrients in the types of food samples to be collected (e.g. maize flour, bread, crackers, biscuits, tortillas). If certified laboratories are not available, select a laboratory that follows rigorous QC and QA procedures, such as standardizing their analysts, adhering to detailed analytical protocols, and participating in international round-robin tests, such as *Fapas proficiency testing*. To identify laboratories, consult with government laboratories that are responsible for testing samples obtained through regulatory monitoring. Laboratories should also be registered in the WHO *Global laboratory directory for the assessment of micronutrient status*.

5.6 How to measure the recommended fortified flour coverage indicator

Measuring the percentage of households consuming fortified flour, the recommended fortified flour coverage indicator, requires the following steps.

1. Apply fortified flour coverage questions in survey and collect samples at household level.
2. Administer qualitative (or quantitative) test to flour samples.
3. Calculate fortified flour coverage results.
4. If the programme has coverage goals, compare results to goals.
5. Prepare a report with results.

If either of the following conditions is met, the fortified flour coverage indicator as described in this manual cannot be calculated.

- Flour samples will be taken from retail outlets instead of households.
- Neither of the following tests can be applied: (i) a rapid, qualitative method for assessing the presence of nutrients in flour; (ii) a quantitative method for assessing the amount of nutrients in flour.

STEP 1. APPLY FORTIFIED FLOUR COVERAGE QUESTIONS IN SURVEY AND COLLECT SAMPLES AT HOUSEHOLD LEVEL

Sample coverage questions appear in **Annex 5.1** and **Annex 5.2.** The final questions should be inserted into a survey and applied to households. As part of the survey, a sample of flour should be taken.

STEP 2. ADMINISTER QUALITATIVE OR QUANTITATIVE TEST TO FLOUR SAMPLES

As described in **Chapter 3**, the iron spot test is a rapid, qualitative test to determine whether wheat or maize flour is fortified with iron *(13, 27, 31)*. Flour samples obtained from households are taken to a central location where a person trained in administering the qualitative test does so for each sample. **Box 16** gives an example of the information registered from the testing. If quantitative methods are used, a target average and an acceptable range of variation must be established to determine the level at which a sample is considered to be fortified.

Box 16. Example of the minimum information to register after applying the qualitative iron spot test to wheat flour samples taken from households

A positive result means the sample is fortified; a negative result means the sample is not fortified.

Household number	Test result
1	Positive
2	Negative
2	Negative

STEP 3. CALCULATE FORTIFIED FLOUR COVERAGE RESULTS

Fortified flour coverage from household surveys is calculated using two values: the number of households using flour confirmed to be fortified by a qualitative or quantitative test (X) and the number of households surveyed that had flour samples tested (Y). Household fortified flour coverage is calculated by dividing X by Y and multiplying by 100 (**Box 17**).

Box 17. An example of calculating fortified flour coverage

550 households were surveyed and a sample of the flour type that should be fortified in the country (e.g. refined, low-extraction wheat flour) was obtained from each home. The qualitative iron spot test was applied to each sample to determine whether it had been fortified. In 385 of those households, the test determined that the flour was fortified. Household coverage was calculated as:

Fortified flour coverage = 385 / 550 x 100 = 70%

STEP 4. IF THE PROGRAMME HAS COVERAGE GOALS, COMPARE RESULTS TO GOALS

The percentage of households consuming fortified flour can be compared with previously set programme goals. If the survey results indicate that the country is far from reaching its coverage goal for the fortification programme, an option is to identify barriers to millers producing fortified flour and barriers to consumers accessing and using fortified flour. If coverage results meet or exceed goals, it may be appropriate to revisit the goals and decide whether an increase is necessary. Fortified flour coverage could also be disaggregated, for example by region or by socioeconomic status, to identify variabilities in coverage. This may identify the population groups with low access to fortified flour. Also, if the programme is continuously monitoring, it may lead to continued benefits of fortification for the target population.

STEP 5. PREPARE A REPORT WITH RESULTS

An illustrative example that can be used to present the main findings for the fortified flour coverage indicator is presented in **Table 4**. The values are fictitious and theoretically come from the inclusion of coverage questions and wheat flour sampling among a subsample in a national demographic and health survey. In this example, one wheat flour sample was successfully obtained from every household selected for flour specimen collection, and the fortified flour coverage was 70%. It may be desirable to present results disaggregated by characteristics such as geographical region or socioeconomic status of households.

Table 4. Results for the fortified flour coverage indicator from a household survey

Item	Number (%)
Households where samples were taken[a]	550 (100%)
Households consuming fortified flour[b]	385 (70%)

[a] One wheat flour sample was obtained from each household.

[b] As determined by the iron spot test *(13)*.

5.7 How to measure the recommended indicator for micronutrient content of fortified flour

Several steps are required to appropriately measure the micronutrient content of fortified flour. The first step is to determine the source of the information: if monitoring data from regulatory authorities will be used to estimate the micronutrient content of fortified flour, follow steps 2RA–8RA. If flour samples will be collected instead from households, follow steps 2H–7H.

- **Step 1** Determine the information source for micronutrient content of fortified flour: monitoring data from regulatory authorities or household sampling.
- If the monitoring data are from regulatory authorities (RA)
  - **Step 2RA** Identify and collate monitoring information gathered by food control authorities for flour.
  - **Step 3RA** Apply questions on the micronutrient content of fortified flour in a survey.
  - **Step 4RA** Obtain nutrient levels in fortified and unfortified flour contained in reports from regulatory authorities.
  - **Step 5RA** Calculate the amount of each nutrient added via fortification by subtracting the values of the unfortified flour from the values of the fortified flour.
  - **Step 6RA** Calculate the average additional content of micronutrients in fortified flour.
  - **Step 7RA** If the programme has goals for the micronutrient content of fortified flour, compare results with goals.
  - **Step 8RA** Prepare a report with results.
- If flour samples will be collected from households (H)
  - **Step 2H** Apply questions on the micronutrient content of fortified flour in a survey and include collection of flour samples.
  - **Step 3H** Obtain nutrient levels in fortified and unfortified flour by laboratory analysis.
  - **Step 4H** Calculate the amount of each nutrient added via fortification by subtracting the values of the unfortified flour from the values of the fortified flour.
  - **Step 5H** Calculate the average additional content of micronutrients in fortified flour.
  - **Step 6H** If the programme has goals for the micronutrient content of fortified flour, compare results with goals.
  - **Step 7H** Prepare a report with results.

STEP 1. DETERMINE THE INFORMATION SOURCE FOR MICRONUTRIENT CONTENT OF FORTIFIED FLOUR: MONITORING DATA FROM REGULATORY AUTHORITIES OR HOUSEHOLD SAMPLING

There are several sources of information on the micronutrient content of fortified flour. The monitoring information habitually gathered by food control authorities (see **Chapter 4**) is one example. The advantage is that the data are already available and, if recently collected, can represent the flour that the population is currently consuming. The disadvantage is that it may be difficult to gain timely access to this information and the data may not be disaggregated (e.g. by flour type, brand, producer, region). A second option is to collect samples from selected households as part of a survey and have them analysed in a laboratory. The advantage is that this represents the flour that people have in their homes. The disadvantages are that there may not be any or enough flour in the home to sample and that laboratory testing for nutrients may be expensive.

STEPS 2RA TO 8RA. USING MONITORING DATA FROM REGULATORY AUTHORITIES

Step 2RA. Identify and collate monitoring information gathered by control authorities for flour

Before conducting the survey, meet with the food control authority in the country to explain the purpose of the work and the monitoring information needed. Since the monitoring information needs to be linked with the

household information, come to an agreement on the information that needs to be collected from surveys to make this linkage (e.g. flour type, brand and producer; region where household is located).

After the survey is concluded, share the survey results with the food control authority and identify any gaps where monitoring information is missing for fortified flour consumed by survey respondents. Develop and execute a plan to obtain the missing information (e.g. the food control authority will gather the information in the near future; the survey team will collect food samples from markets and have them analysed in a laboratory).

Step 3RA. Apply questions on the micronutrient content of fortified flour in a survey

Sample questions to assess micronutrient content of fortified flour appear in **Annex 5.1** and **Annex 5.2**. Since monitoring information will be used to estimate the micronutrient content of fortified flour, no samples of flour need to be taken from households. However, the survey should inquire about the flour **brand** and **producer** since this information will be needed to link fortified flour intake information (collected at the household) with the micronutrient content of fortified flour information (obtained from monitoring data from regulatory authorities). The final questions should be inserted into a survey and applied to individuals or households.

Step 4RA. Obtain nutrient levels in fortified and unfortified flour included in reports from regulatory authorities

To calculate the amount of each nutrient added by fortification, it is necessary to subtract the amount of each nutrient naturally found in flour (i.e. prior to fortification) from the amount of each nutrient as measured in fortified flour. The nutrient content of fortified flour is identified in Step 1. The information on the nutrient profile of unfortified flour may already be known by millers, food control authorities, or be reported in the country's food composition table. Consult with these experts and documents.

Step 5RA. Calculate the amount of each nutrient added via fortification by subtracting the values of the unfortified flour from the values of the fortified flour

To calculate the amount of each nutrient added by the fortification process, the intrinsic nutrient levels in **unfortified** flour should be subtracted from the nutrient levels in samples of **fortified** flour. This procedure can be repeated for all nutrients of interest. An example of how to complete this calculation using monitoring information from regulatory authorities is provided in **Box 18**.

Box 18. Example of calculating the amount of a nutrient added by fortification using monitoring information obtained from food control authorities

In the past year, food control authorities made four visits to a mill that produces Brand A of wheat flour. Following external monitoring guidelines (see **Chapter 4**) at each visit, the inspectors collected four samples during a 1.5 hour period when **fortified** wheat flour was produced. They also asked the millers for the nutrient profile of **unfortified** wheat flour.

The four samples from the first visit were mixed to form a composite sample. The same was done with the samples collected during the subsequent visits. The four composite samples of fortified flour were sent to a food control laboratory for analysis of riboflavin levels.

Visit number	Sample type	Riboflavin (mg/kg flour)
1	Composite of four samples, fortified	3.9
2	Composite of four samples, fortified	3.9
3	Composite of four samples, fortified	4.6
4	Composite of four samples, fortified	4.5

Millers reported that unfortified Brand A wheat flour had 0.4 mg/kg riboflavin. The riboflavin value for **unfortified** wheat flour was subtracted from the riboflavin value of the **fortified** composite samples; this was done separately for the samples from each of the visits. The amount of riboflavin contributed by fortification ranged from 3.5 mg/kg to 4.2 mg/kg.

- For visit 1: 3.9 mg/kg – 0.4 mg/kg = 3.5 mg/kg
- For visit 2: 3.9 mg/kg – 0.4 mg/kg = 3.5 mg/kg
- For visit 3: 4.6 mg/kg – 0.4 mg/kg = 4.2 mg/kg
- For visit 4: 4.5 mg/kg – 0.4 mg/kg = 4.1 mg/kg

Step 6RA. Calculate the average additional content of micronutrients in fortified flour

The average additional content of each micronutrient provided by fortification can be estimated from monitoring information gathered by food control authorities. This calculation requires adding the additional content values for all **fortified** samples and dividing that total by the number of **fortified** samples. It may be desirable to calculate averages for groups, such as by brand and by producer. An example of monitoring information from regulatory authorities is noted in **Box 19**.

Box 19. Example of calculating the average additional content of micronutrients from fortificants using monitoring information gathered by food control authorities

A fortification survey was applied in 875 households. Household representatives were asked what brand of maize meal they use in their home and the amount they purchased in the past 2 weeks. No maize meal samples were obtained from the homes. Instead, external monitoring records from food control authorities were used to estimate the nutrient contribution provided by the maize meal.

In the survey, 173 households reported producing their own maize meal at home; this maize meal is not required to be fortified and was excluded. The remaining 702 households reported purchasing Brand A of maize meal from the country's largest producer. None of the households reported purchasing imported maize meal. From Step 5RA, the amount of niacin added as a fortificant to Brand A maize meal was 47 mg/kg for samples obtained during a first external monitoring visit and 60 mg/kg for samples obtained during a second external monitoring visit. The average additional content of niacin contributed by fortification for Brand A maize meal was calculated by summing the niacin values and dividing by two.

(47 mg/kg + 60 mg/kg) / 2 = 53.5 mg/kg

Step 7RA. If the programme has goals for the micronutrient content of fortified flour, compare results with goals

The average amount of nutrients provided by fortified flour can be compared with previously set programme goals. If the survey results indicate that the country is far from reaching its goals for the fortification programme, an emphasis should be placed on identifying barriers to producing adequately fortified flour. If the micronutrient content of fortified flour results meets the programme goals, it will be important to remain vigilant so that success is maintained. If results indicate that a specific brand of flour is regularly overfortified, which is less common, it will be important for regulatory authorities to investigate the reason(s) and address the situation with the millers to ensure programme safety.

Step 8RA. Prepare a report with results

Table 5 can be used as example to present the main findings for the indicator micronutrient content of fortified flour. This table has fictitious values for the micronutrient content of fortified flour using information obtained through commercial monitoring by regulatory authorities (see **Chapter 4**).

In this example, during 1 month, food control inspectors gathered samples of maize flour from Province X, which borders a country that does not require fortification of maize flour. They visited 25 retail outlets and gathered four samples for each of 10 brands. They formed 10 composite samples (one for each of brand) by thoroughly mixing about 100 g each from samples 1–4 of each brand. The 10 composite samples were quantitatively analysed for one marker nutrient: iron. The average micronutrient content of fortified flour of the 10 brands was 28.1 mg iron per kg flour.

Table 5. Results for the indicator micronutrient content of fortified flour for maize flour samples taken by food control authorities from retail outlets in Province X as part of regulatory monitoring procedures

Item	Value
Number (%) of retail outlets visited	25 (100%)
Number (%) of samples taken	40 (100%)
Number (%) of brands assessed	10 (100%)
Average/mean (standard deviation) additional iron content of all composite samples (mg/kg)	28.1 (4.4)
Average/mean (standard deviation) additional iron content of each composite sample/brand (mg/kg)	
Brand 1	32[a]
Brand 2	25[a]
Brand 3	23[a]
Brand 4	26[a]
Brand 5	25[a]
Brand 6	30[a]
Brand 7	29[a]
Brand 8	23[a]
Brand 9	36[a]
Brand 10	32[a]

[a] Only one composite sample was analysed per brand, therefore a standard deviation cannot be calculated.

STEPS 2H TO 7H. USING FLOUR SAMPLES COLLECTED FROM HOUSEHOLDS

Step 2H. Apply questions on the micronutrient content of fortified flour in a survey that includes collection of flour samples

If samples will be used to estimate the micronutrient content of fortified flour, then a sample of flour should be taken from randomly selected households, as described in **Annex 5, Planning consideration 4** (will food samples be collected and analysed?). Sample questions for assessing the micronutrient content of fortified flour appear in **Annex 5.1** and **Annex 5.2**. The final questions should be inserted into a survey and applied to individuals and households.

Step 3H. Obtain nutrient levels in fortified and unfortified flour

To calculate the amount of each nutrient added by fortification, it is necessary to subtract the amount of each nutrient naturally found in flour (i.e. prior to fortification) from the amount of each nutrient measured in fortified flour. The samples gathered through the survey are quantitatively analysed for all nutrients of interest, or just

the marker nutrient. This generates the nutrient profile of the **fortified** flour. It may not be necessary to measure unfortified flour samples; the information on the nutrient profile of unfortified flour may already be known by millers, food control authorities, or be reported in the country's food composition table. Consult with these experts and documents.

Step 4H. Calculate the amount of each nutrient added via fortification by subtracting the values of the unfortified flour from the values of the fortified flour

To calculate the amount of each nutrient added by the fortification process, the intrinsic nutrient levels in **unfortified** flour should be subtracted from the nutrient levels in **fortified** flour. This procedure can be repeated for all nutrients of interest. An example of how to complete this calculation using household samples is detailed in **Box 20.**

Box 20. Example of calculating the amount of a nutrient added by fortification in individual samples obtained from households

The country's food composition table notes that zinc content of unfortified maize meal is 5.5 mg/kg. A survey was applied to five regions (150 households; 30 households per region). All households were requested to provide a maize meal sample and most did. The zinc levels in maize meal samples from five households from Region A are shown below.

Region	Household number	Zinc (mg/kg flour)
A	1	22.3
A	2	20.8
A	3	18.1
A	4	26.7
A	5	23.8

The zinc value from the unfortified maize meal is subtracted from the zinc value of each household sample obtained. Thus, the **amount of zinc contributed by fortification** is:

- For household 1: 22.3 mg/kg – 5.5 mg/kg = 16.8 mg/kg
- For household 2: 20.8 mg/kg – 5.5 mg/kg = 15.3 mg/kg
- For household 3: 18.1 mg/kg – 5.5 mg/kg = 12.6 mg/kg
- For household 4: 26.7 mg/kg – 5.5 mg/kg = 21.2 mg/kg
- For household 5: 23.8 mg/kg – 5.5 mg/kg = 18.3 mg/kg

Step 5H. Calculate the average additional content of micronutrients in fortified flour

The average additional content of each micronutrient provided by fortification can be estimated from household samples. This calculation requires adding the values of the same nutrient for all **fortified** samples and dividing that total by the number of samples tested. It may be desirable to calculate averages for groups, such as by geographical region. Examples from household samples are noted in **Box 21.**

Box 21. Examples of calculating the average additional content of micronutrients provided by fortification using data from household samples

Maize meal samples were obtained from 150 households, as described in **Box 20**. The amount of zinc contributed by fortification for each household was calculated, as described in **Box 20**. The table shows the amount of zinc contributed by fortification for each of the five regions. For example, the average amount of zinc contributed by fortification of the maize meal in Region A is 16.8 mg/kg.

Region	Amount of zinc (mg/kg flour) contributed by fortification[a]
A	16.8
B	17.4
C	17.5
D	9.5
E	17.4

[a] Calculation: The sum of "amount of zinc (mg/kg) contributed by fortification" of all households sampled from the region divided by the number of households sampled from region.

Step 6H. If the programme has goals for the micronutrient content of fortified flour, compare results with goals

The average amount of nutrients provided by fortified flour can be compared with previously set programme goals. If the survey results indicate that the country is far from reaching its goals for the fortification programme, an emphasis should be placed on identifying barriers to producing adequately fortified flour. If the micronutrient content of fortified flour results meets the programme goals, it will be important to remain vigilant to ensure success is maintained. Though unlikely, if micronutrient content of fortified flour results indicate that a specific brand of flour is regularly overfortified, it will be important for regulatory authorities to investigate the reason(s) and address the situation with the millers to ensure programme safety.

Step 7H. Prepare a report with results

Table 6 can be used to present the main findings for the indicator **micronutrient content of fortified flour**. This example has fictitious values for the micronutrient content of fortified flour based on the inclusion of related questions and household sampling into a national demographic and health survey. In this example, wheat flour samples were obtained from 1200 households. At the national level, the micronutrient content of fortified wheat flour was calculated to be 44 mg/kg for iron, 52 mg/kg for zinc, and 69 mg/kg for niacin.

Table 6. Results for the indicator micronutrient content of fortified flour for wheat flour samples taken from households in the survey

Item	Value
Households from which samples were taken	1200
Average/mean (standard deviation) additional iron content in fortified samples (mg/kg flour)	44 (3)
Average/mean (standard deviation) additional zinc content in fortified samples (mg/kg flour)	52 (7)
Average/mean (standard deviation) additional niacin content in fortified samples (mg/kg flour)	69 (9)

5.8 How to measure the recommended fortified flour intake indicator

Measuring the fortified flour intake indicator requires the steps described below. This is in addition to those steps common to all consumption monitoring indicators, which are described in the annexes of this chapter.

1. Apply fortified flour intake questions in survey.
2. Estimate fortified flour intake for target populations.
3. If the programme has goals for fortified flour intake, compare results to goals.
4. Prepare a report with results.

STEP 1. APPLY FORTIFIED FLOUR INTAKE QUESTIONS IN SURVEY

Sample fortified flour intake questions appear in **Annex 5.1** and **Annex 5.2**. Questions about how much flour was used by the individual or household must be asked. If the micronutrient content of fortified flour information from monitoring by food control authorities will be used with fortified flour intake to estimate the micronutrient intake from fortified flour, the household survey should inquire about the brand and producer of flour used by households. The final questions should be inserted into a survey and applied.

STEP 2. ESTIMATE FORTIFIED FLOUR INTAKE FOR TARGET POPULATIONS

The goal of the fortified flour intake indicator is to estimate the amount of **fortified flour** consumed by the target groups. First, the enumerator must try to determine whether the flour used by households must be fortified by law. For example, in South Africa, maize meal produced at home does not need to be fortified; it was therefore excluded from a fortification survey (see **Annex 5.2**).

Several methods are available to estimate the intake of fortified flour by individuals or households. These include: (i) 24-hour dietary recall *(32)*; semiquantitative food frequency questionnaire *(33)*; weighed food record *(34)*; and (iv) household income and expenditure survey *(35)*.

With closed-ended methodologies (i.e. where the interviewee selects from predefined answers), such as the semiquantitative food frequency questionnaire and household income and expenditure survey, care must be taken to inquire only about flours that are expected to be fortified in the country (e.g. because of a legislative mandate). This is because in closed-ended methodologies, consumers are asked to report intake or acquisition of specific foods (e.g. maize flour). If flours that are not required to be fortified are included in the list of predefined answers, then the intake of fortified flour will be overestimated. Conversely, if flours that are required to be fortified are excluded, then the intake of fortified flour will be underestimated.

There are different ways to estimate intake of fortified flour. In some nutrition surveys, the interviewee is asked to recall the amount of specified foods s/he ate during a particular period of time (e.g. the previous day or week). If the amount consumed is for a period greater than 1 day, the amount is divided by the number of recall days to give a daily intake (**Box 22**).

Box 22. **Example of how to calculate the daily fortified flour intake of an individual**

In a survey of 550 households, one woman of reproductive age was selected to participate per household. Women were asked: "What amount of flour did you use in the past 7-day period?"

One of the surveyed women from one of the households reported using a specific wheat flour type daily during the previous work week (Sunday–Thursday) and none during the weekend (Friday and Saturday). The enumerator visually confirmed that the flour should have been fortified because it was refined, a flour type that should be fortified by law, and it was in a package from a large industrial mill.

The woman prepared buns for her lunchtime meal during the work week. She showed the enumerator the container she filled with flour each day to make the buns. The enumerator estimated the container held 250 g of flour. Each day, the woman baked four buns; she ate two buns and her father ate the other two buns. Thus, her daily intake of fortified flour from the buns was calculated as:

250 g / 2 = 125 g

Her intake of fortified flour was calculated as 625 g over the 7-day period and 89.3 g per day.

Day	Amount of fortified flour consumed (g)
Sunday	125
Monday	125
Wednesday	125
Thursday	125
Friday	0
Saturday	0
Total over 7 days[a]	625
Average per day[b]	89.3

[a] Calculation: Sum of "amount of fortified flour consumed (g)".

[b] Calculation: "Total over 7 days" divided by 7.

In other nutrition surveys, the interviewee is asked to recall the amount of specified foods the **household** ate during a particular period (e.g. previous day or week). To convert that information into flour intake for the household, the same steps noted in **Box 22** can be taken. Household-level flour intake can then be converted into individual-level intake. For example, if the household contains multiple people, the **household daily intake of flour** can be divided by the total number of household members to generate daily flour intake per capita. An alternative is to express household-level intake per adult male equivalents; this methodology is described elsewhere *(36)*. With either methodology, children (including infants) and adults of all ages are included in the denominator.

In economic surveys, the interviewee is asked to recall how much fortified flour or foods prepared with fortified flour they **acquired** (through purchase, harvest, as a gift, food aid, barter) for their household in a particular period (e.g. previous week, 2 weeks, or month). Such information can be used to estimate **apparent consumption** using the steps described previously. **Box 23** has an example of using household food purchase information to estimate the apparent consumption of fortified flour for individuals in the home.

Box 23. **Example of using household food purchase information to estimate the apparent consumption of fortified flour per capita in the home**

A household income and expenditure survey was applied to 6000 households in a country. As part of the survey, households were asked how many individuals (from newborns to older adults) consumed meals from the family pot in the previous 14-day period and how much fortified maize flour was purchased in the same period. The 2-week apparent consumption of flour per individual was the amount of flour purchased divided by the number of people who ate from the family pot. Dividing this figure by 14 days yielded the daily apparent consumption of flour per capita. The table shows the information from 4 households.

Household identifier	Number of individuals who ate from family pot	Amount of fortified maize flour purchased in previous 14 days (kg)	Amount of fortified maize flour apparently consumed per capita per day (g)[a]
1	7	7	71
2	5	10	143
3	6	3	35
4	2	3	107

[a] Calculation: "Amount of maize purchased (kg)" multiplied by 1000, divided by the "number of individuals who ate from family pot", divided by 14.

STEP 3. IF THE PROGRAMME HAS GOALS FOR FORTIFIED FLOUR INTAKE, COMPARE RESULTS TO GOALS

The average amount of fortified flour consumed by individuals or households can be compared with previously set programme goals. If the survey results indicate that the country is far from reaching its goal, reasons should be explored (e.g. consumption habits have changed, and people are eating less flour than expected, or there are barriers to the target population accessing fortified flour). If fortified flour intake results meet or exceed goals, it may be appropriate to revisit the goals and decide whether they should be changed. If fortified flour intake is higher than when the programme was initiated, the levels of additional nutrients required for flour could be revisited and modified if needed.

STEP 4. PREPARE A REPORT WITH RESULTS

Table 7 illustrates how the main findings for the fortified flour intake indicator can be presented. The fortified flour intake values are fictitious but theoretically come from the inclusion of questions into a national demographic and health survey. It may be desirable to present results disaggregated by characteristics, such as geographical region or socioeconomic status of households.

In this example, women of childbearing age were asked the amount of flour they used over a 7-day period. The average daily fortified flour intake was estimated at 152 g.

Table 7. **Results for the fortified flour intake indicator for women of childbearing age whose households were surveyed**

Number of households visited	1139
Fortified flour intake in grams per day (average/mean (standard deviation))	152 (37)

5.9 How to measure the recommended indicator for micronutrient intake from fortified flour

The measurement of the micronutrient intake from fortified flour indicator requires combining the results from the micronutrient content of fortified flour and fortified flour intake. Micronutrient intake from fortified flour summarizes the additional nutrients delivered by fortified flour to the target population. The measurement of the indicator involves the steps described below. This is in addition to those steps common to all consumption monitoring indicators, which are described in **Annex 5.5**.

1. Apply questions for micronutrient content of fortified flour and fortified flour intake in a survey.
2. Estimate the additional micronutrients delivered by fortified flour to the target population, using the results from micronutrient content of fortified flour and fortified flour intake.
3. If the programme has goals for the micronutrient intake from fortified flour, compare results to goals.
4. Prepare a report with results.

STEP 1. APPLY QUESTIONS FOR MICRONUTRIENT CONTENT OF FORTIFIED FLOUR AND FORTIFIED FLOUR INTAKE IN A SURVEY

Questions on the micronutrient content of fortified flour and fortified flour intake must be asked in a survey for the micronutrient intake from fortified flour to be calculated. Sample questions appear in **Annex 5.1** and **Annex 5.2**. The final questions should be inserted into a survey and applied to individuals or households.

STEP 2. ESTIMATE THE ADDITIONAL MICRONUTRIENTS DELIVERED BY FORTIFIED FLOUR TO THE TARGET POPULATION, USING THE RESULTS FROM THE MICRONUTRIENT CONTENT OF FORTIFIED FLOUR AND FORTIFIED FLOUR INTAKE

Micronutrient intake from fortified flour summarizes the additional nutrients delivered by fortified flour. The micronutrient content of fortified flour and fortified flour intake information is combined to calculate the micronutrient intake from fortified flour. One way to facilitate combining the information is to create an electronic database with the following information for every individual or household surveyed (**Box 24**).

- Identification: the unique number assigned to the targeted individual or household.
- Micronutrient content of fortified flour: the average additional nutrient content in the type of fortified flour targeted for the survey. The micronutrient content of fortified flour may be available for multiple nutrients. The unit used should be consistent with how the nutrient is presented in food composition tables (e.g. mg for iron, µg for vitamin B_{12}) and expressed per kg of flour, per 100 g of flour, or per another consistent amount of flour.
- Fortified flour intake: the average amount of fortified flour consumed by each individual or household targeted for the survey. This value should be expressed in grams of flour per day for the individual or the household.
- Micronutrient intake from fortified flour: the additional nutrient amount delivered by consumption of fortified flour. Micronutrient intake from fortified flour may be available for multiple nutrients; the unit used should be consistent with how the nutrient is presented in food composition tables (e.g. mg for iron, µg for vitamin B_{12}) and expressed per day.

Micronutrient intake from fortified flour can then be calculated by multiplying the **additional nutrient content in fortified flour** by the **amount of fortified flour consumed**. If the first value is expressed per kg and the second value is expressed per gram, this product needs to be divided by 1000 to generate the amount in grams. **Box 24** shows an example of this calculation.

Box 24. **Example database generated to calculate the micronutrient intake from fortified wheat flour in women of childbearing age**

In a survey of 550 households, one woman of childbearing age was selected to participate per household. Women were asked the amount of flour they used over a 7-day period. Import monitoring information was used to estimate the amount of nutrients in the flour consumed.

An eight-column database was created with the unique number assigned to the household [1]; micronutrient content of fortified flour [2–4]; fortified flour intake [5]; and micronutrient intake from fortified flour [6–8]. The information for one woman from one household is summarized in the table.

[1]	[2]	[3]	[4]	[5]	[6]	[7]	[8]
Household number	Additional iron content in fortified wheat flour (mg/kg)	Additional zinc content in fortified wheat flour (mg/kg)	Additional niacin content in fortified wheat flour (mg/kg)	Amount of fortified flour consumed (g/day)	Additional iron delivered by consumption of fortified wheat flour (mg/day)[a]	Additional zinc delivered by consumption of fortified wheat flour (mg/day)[b]	Additional niacin delivered by consumption of fortified wheat flour (mg/day)[c]
1	47	50	64	75	3.5	3.8	4.8

[a] Micronutrient intake from fortified flour for iron (column [6]) = column [2] x column [5] / 1000.
[b] Micronutrient intake from fortified flour for zinc (column [7]) = column [3] x column [5] / 1000.
[c] Micronutrient intake from fortified flour for niacin (column [8]) = column [4] x column [5] / 1000.

STEP 3. IF THE PROGRAMME HAS GOALS FOR THE MICRONUTRIENT INTAKE FROM FORTIFIED FLOUR, COMPARE THE RESULTS TO THE GOALS

The average amount of nutrients provided by the consumption of fortified flour can be compared with previously set programme goals. If the survey results indicate that the country is far from reaching its goal, an emphasis should be placed on identifying barriers to millers producing adequately fortified flour and to consumers accessing this flour. If the micronutrient intake from fortified flour results exceeds that of the goals, it may be appropriate to revisit the programme and decide whether changes to the nutrient standards are warranted.

STEP 4. PREPARE A REPORT WITH RESULTS

Table 8 can be used to present the main findings for the micronutrient intake from fortified flour indicator. The values are fictitious but theoretically come from the inclusion of fortified flour intake questions into a national demographic and health survey and the use of import monitoring data on the micronutrient content of fortified flour. It may be desirable to present results disaggregated by characteristics, such as geographical region or socioeconomic status of households. The average additional iron, zinc, and niacin delivered by fortified flour were 3.5 mg/day, 4.2 mg/day, and 5.5 mg/day, respectively, for women of childbearing age.

Table 8. **Results for the micronutrient intake from fortified flour indicator for women of childbearing age whose households were surveyed**

Item	Value
Number of households visited	1139
Average/mean (standard deviation) additional iron delivered by fortified flour (mg/day)	3.5 (1.1)
Average/mean (standard deviation) additional zinc delivered by fortified flour (mg/day)	4.2 (1.4)
Average/mean (standard deviation) additional niacin delivered by fortified flour (mg/day)	5.5 (1.8)

5.10 Sample outline for a report summarizing consumption monitoring results

In crafting a report with findings, consider who the target readers are and how they are expected to use the information.

I. Executive summary

II. Background and history of the national fortification programme

III. Objectives of the report

IV. Methods used to gather information for the report

V. Main results

- a. Fortified flour coverage
- b. Micronutrient content of fortified flour
- c. Fortified flour intake
- d. Micronutrient intake from fortified flour
- e. Other sources of information (if applicable)

VI. Analysis and interpretation of the results

- a. Achievements of the fortification programme
- b. Challenges of the fortification programme

VII. Recommendations, conclusions, and priority areas for corrective action

VIII. Bibliography cited

IX. Annexes

REFERENCES

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REVIEW AND SYNTHESIS OF MONITORING INFORMATION

INTRODUCTION

Monitoring activities are essential to measuring the success of a flour fortification programme. A comprehensive monitoring system will have the following objectives: oversee and promote the fortification programme, collect relevant data, review results, report/share results to inform of stakeholders and other interested actors, guide future fortification efforts, and recommend changes to the programme if issues arise.

At the programme development stage, several issues should be addressed. Will monitoring roles be divided among stakeholders? What monitoring resources are needed? What arrangements will be made for reporting and sharing monitoring results? As described in other chapters of the manual, the primary types of programme monitoring include: internal (**Chapter 3**); external, import, commercial (**Chapter 4**); and consumption (**Chapter 5**) monitoring. This chapter will focus on the review and synthesis of programme monitoring information.

Monitoring information is usually reviewed and synthesized by a multisector alliance (or a committee within that alliance) that oversees the flour fortification programme. For further information about this alliance, see **Chapter 2**.

Ideally, the alliance will have a mandate for recommending or even instituting programme changes based on the results of monitoring or on inputs from public entities. Throughout the world, national legislation frameworks give authority for flour fortification programmes and flour fortification monitoring. They may also authorize the creation of a fortification multisector alliance under a government ministry or other government institution (see **Annex 6.1**). **Box 1** highlights the Guatemala experience.

Box 1. Legislation that created a National Food Fortification Commission to oversee food fortification in Guatemala *(1)*

Legislation was passed in Guatemala in 1992 to create the National Food Fortification Commission (Comisión Nacional para la Fortificación, Enriquecimiento y/o Equiparación de Alimentos, CONAFOR). The purpose of CONAFOR is to "coordinate and supervise the adequate execution of the food fortification programmes" in the country. CONAFOR is composed of public sector, industry, and consumer-protection group representatives, with technical support provided by academia and United Nations agencies *(2)*.

6.2 Implementation of flour fortification monitoring programme

To appropriately meet its objectives, the multisector alliance needs timely access to programme monitoring data and information, which can come from multiple sources including: regulatory monitoring activities (see **Chapter 3** and **Chapter 4**) and consumption monitoring activities (see **Chapter 5**). The following are examples of stakeholders that, as part of the multisector alliance, would provide useful information generated through monitoring activities. Note that these stakeholders should be independently using and acting on data in real time without waiting for discussions among the alliance.

- **Millers** As part of internal monitoring, millers undertake QA and QC to ensure that the fortified flour is of a consistent quality. The data generated as part of QA/QC activities can be used to estimate the overall quality and quantity of fortified flour produced in the country.
- **Inspectors** Government inspectors carry out external, import, and/or commercial monitoring activities per national guidelines. Through audits, inspections, and flour sample analyses, inspectors determine whether adequately fortified flour is being produced, imported, and marketed in the country.

- **Consumer groups** Consumer groups can conduct their own form of commercial monitoring in the marketplace to verify the quality of flour available to consumers. This activity could entail sample collection and analysis (if resources permit) or simply scanning the shelves for products labelled as fortified. These findings document the performance of the domestic and foreign milling industry.
- **Research institutions** Research institutions can be an important partner for flour fortification programmes because their staff will often conduct household surveys or market assessments to evaluate whether consumers are using fortified flour or flour-based products and benefiting from the programme. They may also have the capacity to conduct laboratory analyses of samples.
- **Other** There are multiple sources, related to or independent from the fortification programme, of useful information for the multisector alliance to review. For example, real-time monitoring of duties paid on imported vitamin and mineral premix can be utilized to estimate the amount of premix used in a country during a particular period. Sensory studies, consumer acceptability surveys, and dietary intake research may also yield insights for adjusting the fortification programme.

To meet its responsibilities, the multisector alliance may choose to form subcommittees with authorization to monitor and report back on range of activities. Sample subcommittees that could be formed include: information aggregation and interpretation and report writing; policy and coordination; industry and production; standards enforcement; social marketing; and advocacy.

6.2.1 Information aggregation and interpretation and report writing

Many entities have a stake in monitoring the flour fortification programme, thus data will be made available through a variety of sources. The role of the multisector alliance will be to gather, collate, aggregate, and review those data on a regular basis (e.g. annually) to ascertain progress. Organizing the programme monitoring data by monitoring domain and indicator (**Annex 6.2**) is a meaningful way to keep track of the information. This system will also help the multisector alliance to present the findings in a clear and consistent manner to all stakeholders. For example, mills will regularly send flour samples to a third-party laboratory for independent verification of nutrient levels (see **Chapter 3.3**). Inspectors verify the adequacy of QA/QC procedures and may also collect food samples during external monitoring visits as well as in the market. The inspectors, or other persons in their agency, aggregate the collected information for all mills visited and products in the market during a particular period (e.g. 1 year). This consolidated, national-level information can be shared with the multisector alliance or with a subgroup.

To enhance data tracking and reporting, a database can be used to collate information. **Box 2** provides an example from Egypt. Project Healthy Children and GAIN developed a similar automated system for use globally, the *FortifyMIS (management information system) for online fortification monitoring*. *FortifyMIS* is designed to supplement current government monitoring efforts by enabling the coordination, aggregation, digitalization, reporting, and use of regulatory monitoring data to improve evidence-based decisions *(3,4)*. The system enables programmes to track product compliance efficiently and effectively in real time. This allows countries to act on identified gaps to improve programme outcomes in a timely, cost–effective, and sustainable manner (**Box 3**).

Box 2. Creation of a database for monitoring flour fortification activities in Egypt *(5)*

An automated system was developed in Egypt for monitoring the country's flour fortification programme. It allows millers, external laboratory staff, and food control authority inspectors to enter relevant data and make them available to other stakeholders. Millers enter their premix usage and flour production into the system and send flour samples to a laboratory. The food control authority personnel input the inspection results and collect flour samples from each mill, which are sent to a laboratory. Laboratories receive flour samples from the mills and regulators. After the sample analyses are completed, laboratory personnel enter the results directly into the database to report back to the mills and the food control authority.

Box 3: Use of FortifyMIS – an online management information system – to track product compliance data in real time *(3)*

FortifyMIS users in a country include those who routinely collect and use data on the quality and quantity of fortified foods including food producers, government inspectors, laboratory staff, and central government staff. Direct, decentralized data entry occurs through use of any computer or hand-held smart device (e.g. smartphone or tablet). This arrangement means staff no longer need to solicit and consolidate information from multiple sources that is often conflicting and in paper format.

Each user of the system has a unique login and password linked with a role, access rights, and viewing privileges as defined by a country's monitoring framework. Only users with the correct permissions and roles can access the data. Dashboard reports allow results to be quickly summarized. Data can also be disaggregated, for example, by quarter, customs station, market, importer, or producer. Automatic graphical displays of the data allow easy reporting and quick action to be taken to adjust programme needs in real time.

FortifyMIS can be adapted to any country-specific situation, used online and offline, translated into any language, and used for any fortified flour. The goals of *FortifyMIS* are improving how compliance is tracked and how process data are acted upon. To obtain the data needed for country-specific use of this system, programme managers must review and streamline their inspection processes and data flows, reduce duplication of efforts, agree on roles and responsibilities, which would result in significant savings in time and resources. The system can also be integrated into other platforms that a country may use (e.g. the health management information system, such as *District health information software 2*).

FortifyMIS was used in Malawi and was found to display results in a rapid, informative, and visually powerful format, enabling managers to correct programme shortcomings *(6)*.

If the multisector alliance feels that the flour fortification programme is not functioning as expected, the group can and should encourage necessary changes for improvement as was done in South Africa (**Box 4**).

Box 4: Utilizing data to improve the fortification programme in South Africa

The prevalence of neural tube defects was reduced in South Africa following fortification of wheat and maize flour with folic acid *(7)*. However, there was no improvement in iron status following fortification of wheat and maize flour with electrolytic iron *(8)*. These data suggested that the fortified flour was reaching beneficiaries, but the iron compound and level of iron needed to be modified. Discussions among government, industry, and other stakeholders led to an agreement to amend regulations in favour of use of a more bioavailable compound, and trials are underway to confirm that this change will not affect consumer acceptance *(9)*.

The regular review of the country's fortification programme can culminate with an annual report that the multisector alliance generates or commissions. The report should be widely shared with all fortification stakeholders through meetings, press conferences, social media, and public postings. The report can summarize statistics, progress to date, milestone achievements, and challenges to the fortification programme. For some years, the Ministry of Health of Chile published annual reports of external monitoring results from the flour fortification programme *(10)*. An example of the results presented can be found in **Annex 6.3**. A sample outline for a comprehensive national report is shown in **Annex 6.4**.

6.3 Conclusion

A strong monitoring system is an essential component of any flour fortification programme and one that must be committed to and upheld by all stakeholders. Monitoring data are collected from a variety of sources and are analysed and stored by additional entities. Thus, it is important to have a multisector alliance that is charged with gathering, reviewing, reporting, and disseminating the consolidated monitoring findings to all stakeholders and the public. If the multisector alliance feels that programme objectives are not being realized, it may recommend changes or lead efforts to alter the programme.

CHAPTER 6 ANNEXES

6.1 Examples of legislation framework that give authority for flour fortification programme and flour fortification monitoring

The enabling legal framework for flour fortification and flour fortification monitoring is often based on a country's **Food Act or Law**. This act generally lays the overall foundation for government food policy and regulation, with implementation the responsibility of the ministry of health or an autonomous authority answerable to the minister of health. The legislation empowers the authority to monitor the compliance of flour fortification activities in the country with the national regulation and standards.

National regulations and standards are the most common legislative instruments applied to flour fortification and include technical specifications of flour such as quality, safety, and fortification parameters. Standards might include considerations on: (i) recommended nutrients, target fortification levels, minimum and maximum levels, and fortification compounds; (ii) provisions on labelling, claims and advertising; procedures for regulatory monitoring and product sampling; and (iii) enforcement measures to ensure compliance.

Several standards of the *Codex alimentarius* provide general guidance on flour, such as those on composition, quality, and food safety factors that may be used by the regulators or food control authorities *(11)*. A code of practice for food premix operations was created by the Pan American Health Organization to ensure premix quality for fortification programmes, such as adequate types and levels of nutrients added *(12)*.

An important feature of some national legislation is the creation of a fortification multisector alliance *(13, 14)*.

Typically, the legislation mandating large-scale flour fortification authorizes the monitoring activities of fortified flour and premixes that are imported into a country. This is done to ensure that imported flour supplies comply with the same standards as domestically produced flour. Furthermore, World Trade Organization agreements and *Codex alimentarius* standards are also considered by regulators when establishing provision for flour fortification monitoring within a national regulatory framework, if the country is member of these organizations *(15, 16)*.

6.2 Indicators for programme monitoring

This is a minimum set of indicators that can be used to monitor a national fortification programme. Other indicators from the WHO/CDC *eCatalogue of indicators for micronutrient programmes* can be added *(17)*. It is recommended that any indicators originally reported at the local level (e.g. mill, region) should also be reported at the national level (e.g. all mills in the country, all regions in the country).

Monitoring domain	WHO/CDC indicator title	Indicator definition	Additional considerations
External monitoring (see **Chapter 4**)	Quality-assurance and quality-control procedures in place at large-scale flour mills	Documentation of internal quality assurance and quality control procedures for fortification in place among the mills participating in the flour fortification programme. This is verified during inspections.	Not all mills may be required to fortify flour; this is for each country to decide. The denominator in this calculation should include those mills that are expected to fortify and that have been visited by regulatory authorities.

Monitoring domain	WHO/CDC indicator title	Indicator definition	Additional considerations
External monitoring (see **Chapter 4**)	Samples of flour from mills meet fortification specifications according to country standards	Mills where the flour samples meet the required content as required by national regulations. This indicator is calculated among large industrial mills (>20 tonnes/day) in the country.	Not all mills may be required to fortify flour. The denominator in this calculation should include those mills that are expected to fortify and from which samples were taken by regulatory authorities.
Import monitoring (see **Chapter 4**)	Certificate of Conformity for imported fortified flour	Imported fortified flour must have phytosanitary documentation that certifies the nutrient content. Often called a Certificate of Conformity or Certificate of Analysis, this document certifies that imported fortified flour follows the specifications within the national regulations of the importing country.	Consider disaggregating the national results by flour producer (i.e. for every producer, the percentage of consignments that have a Certificate of Conformity (or Analysis) for the imported wheat flour and food made of wheat flour).
Import monitoring (see **Chapter 4**)	Samples of imported fortified flour tested meet fortification specifications	Imported flour samples that adhere to the nutrient content as specified by regulations. This indicator is calculated from among all samples of imported flour from the same source (producer/supplier/brand) that are taken for quantitative testing and is part of regulatory monitoring procedures.	Consider disaggregating the national results by flour producer
Commercial monitoring (see **Chapter 4**)	Retail and market samples of flour and products made from flour meet fortification specifications	This indicator monitors the nutrient content of retail samples of flour from the same source (producer/supplier/brand) that regulations state should be fortified and whether the samples meet the required fortification content.	Consider disaggregating the national results by flour producer.
Consumption monitoring (see **Chapter 5**)	Households consuming fortified flour (fortified flour coverage)	This indicator refers to the proportion of the population that is likely to be reached by the flour fortification programme, including the population most at risk. This indicator can be approximated through surveys applied to households coupled with a rapid, qualitative assessment of whether household flour is fortified.	Consider disaggregating the national results by the lowest geographical region that the survey design permits (e.g. for every province, the percentage of households consuming fortified flour or its products).

Monitoring domain	WHO/CDC indicator title	Indicator definition	Additional considerations
Consumption monitoring (see **Chapter 5**)	Average additional content of micronutrients in fortified flours (micronutrient provision)	The purpose is to estimate the average additional amount of each micronutrient that is available to the population through fortified flour. Data sources to measure this indicator include monitoring information gathered by food control authorities and analysis of flour samples.	Consider disaggregating the national results by flour producer (e.g. for every producer, the average additional content of micronutrients from fortificants determined in samples) and by flour type (e.g. maida, atta).
Consumption monitoring (see **Chapter 5**)	Average daily intake of fortified flour (fortified flour consumption)	Estimation of the amount of fortified flour that is consumed by the target populations. There are several ways to estimate intake by individuals.	Consider disaggregating the national results by the lowest geographical region that the survey design permits (e.g. for every province, the average daily intake of fortified flour among those surveyed) and for different groups of interest (e.g. the average daily intake of fortified flour among women of childbearing age).
Consumption monitoring (see **Chapter 5**)	Average additional amount of micronutrients delivered daily by consumption of fortified flour	This indicator provides an estimation of the additional amounts of micronutrients delivered daily by the consumption of fortified flour. It is derived by multiplying the additional micronutrient content provided by the fortified flour with the amount of fortified flour the target populations consume.	Consider disaggregating the national results by the lowest geographical region that the survey design permits (e.g. for every province, estimated additional micronutrients delivered by fortified flour) and for different groups of interest (e.g. estimated additional micronutrients delivered by fortified flour to women of childbearing age).

6.3. External monitoring results in a national report on flour fortification from Chile *(10)*

Table 1. Percentage of flour samples that conform to national standards, by nutrient and sample origin

		Thiamin		Riboflavin		Folic acid		Iron	
Origin of flour	Total samples	Number of samples tested	Number (%) meeting standards	Number of samples tested	Number (%) meeting standards	Number of samples tested	Number (%) meeting standards	Number of samples tested	Number (%) meeting standards
Domestic production	193	193	166 (86%)	193	174 (90.2%)	193	20 (10.4%)	193	159 (82.4%)
Imported	19	19	18 (94.7%)	19	17 (89.5%)	18	1 (5.5%)	19	16 (84.2%)
Total	212	212	184 (86.8%)	212	191 (90.1%)	211	21 (10%)	212	175 (82.5%)

6.4 Sample outline for a comprehensive, annual national report on flour fortification

I. Executive summary

II. Background, history, and objectives of the national flour fortification programme

III. Objectives of the report

IV. Methods used to gather information for the report

V. Main results

- a. Internal monitoring
- b. External monitoring
- c. Import monitoring
- d. Commercial monitoring
- e. Consumption monitoring
- f. Flour production and premix volumes
- g. Other sources of information
- h. Comparison with programme objectives

VI. Analysis and interpretation of the results

- a. Achievements of the fortification programme
- b. Challenges to the fortification programme

VII. Recommendations, conclusions, and priority areas for corrective action

VIII. Bibliography cited

IX. Annexes

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