

REGULATORY MONITORING OF FORTIFIED WHEAT FLOUR

Guidelines for Millers & Food Control Agencies

FOOD AND DRUGS BOARD

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PART I. INTRODUCTION

- 1.1 What is Regulatory Monitoring?
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The fortification of commonly eaten food stuffs such as salt, flour, sugar, rice and milk are an effective and economical way to consistently ensure that nations' populations are provided with the essential micronutrients to prevent and eliminate nutritional deficiencies and other related health problems. Since 1996, Ghana has enacted a law that called for fortification of salt with potassium iodate. This has been successful. This has necessitated the need to fortify other foods that are widely consumed in the country as vehicles for addressing certain nutritional deficiencies. The consumption of wheat flour based foods and vegetable oil is common to every household thereby making these two product the choice for the fortification program.

The fortification of wheat flour will make available to over 18 million people by supplying them with a variety of micronutrients, including iron, folic acid, other B vitamins - vitamin B1 (thiamin), vitamin B2 (riboflavin), niacin and vitamin B12 – among others. Although flour millers continue to compete based on type of flour and price in the market place, the level of fortification is standardized at the national level.

The Ghana government recognizes the value and importance of wheat flour fortified with iron and other micronutrients as a public health measure, particularly to combat iron deficiency and anemia, and most have implemented national wheat flour fortification programs. Flour producers are also in strong support of these programs, demonstrated by their signing of a Memorandum of Understanding (MOU) in September 2006. This gesture gave support to the promotion and assistance to develop the necessary legislation for mandatory fortification of wheat flour according to the recommendations of the WHO.

However, it is also recognized that it is not sufficient to simply have a wheat flour fortification program *per se*. It is essential to ensure that the fortified wheat flour is available and accessible to consumers in sufficient amounts and with uniform high quality. This goal can only be accomplished through the execution of individual actions and close cooperation of the actors involved in wheat flour fortification, i.e., the flour producers, food control agencies and other governmental entities, along with the support of consumers, researchers and the academia. In particular, flour producers must consistently provide fortified wheat flour of good quality in accordance with the national standards, and the government must ensure that all wheat flour available in the market adequately meets the standards.

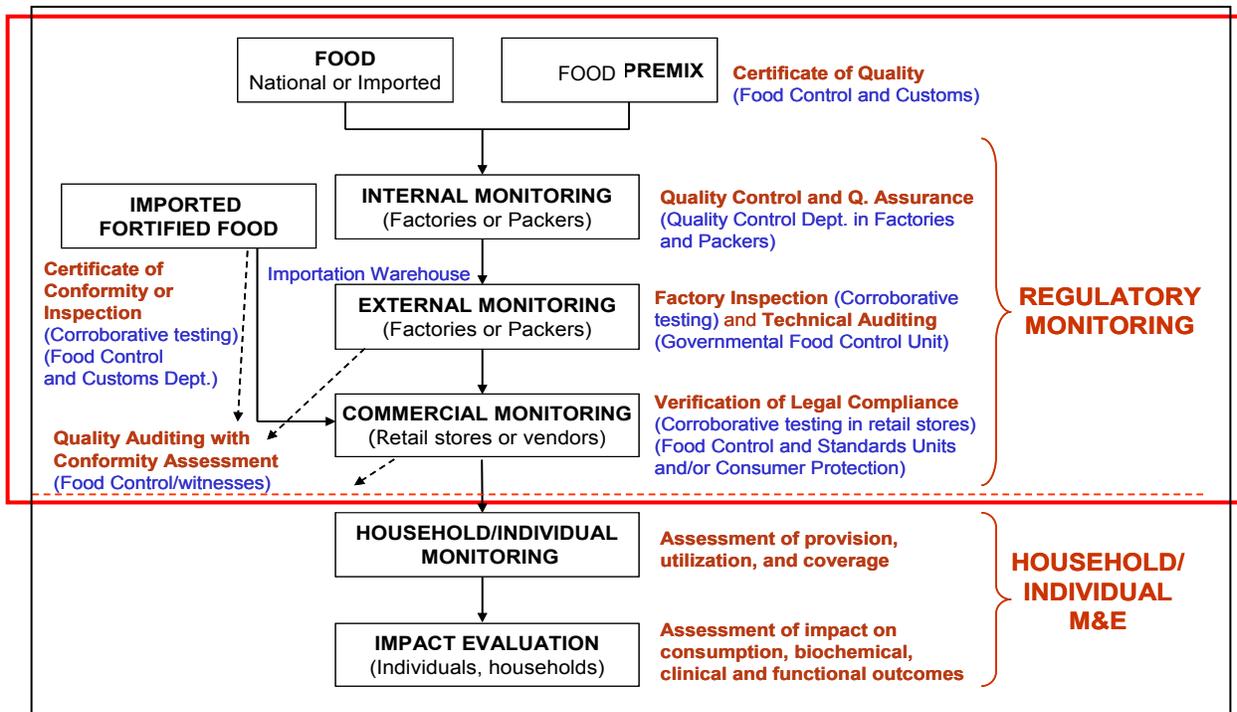
Meeting national regulations and standards for optimal wheat flour fortification with multiple micronutrients is of paramount importance for an effective program. To this end, continuous and active monitoring systems to identify problems and take corrective actions in order to fulfill program objectives must be put in place.

1.1 What is Regulatory Monitoring?

In order to achieve its expected impact, a program’s operational performance must be monitored through continuous data collection at key delivery points. When bottlenecks or operational inefficiencies are identified, information must be directed to the appropriate program entity responsible for implementing corrective measures and for redirecting the program as necessary. This set of actions constitutes the overall *monitoring* of the program.

Figure 1 presents the framework used to describe the different steps involved in the monitoring of a food fortification program. (Although the framework includes the entirety of the monitoring and evaluation system, the “Household/Individual Monitoring and Evaluation” component will not be addressed in this manual.)

Figure 1. Flowchart of the Monitoring and Evaluation System for Food Fortification



Source: WHO

Regulatory Monitoring recognizes the utmost importance of the fortified product maintaining its expected quality, from factory to retail stores. The Executing Agency will operate is a system of monitoring and control that will ensure that fortified foods meet nutrient quality and safety standards.

As seen in **Figure 1**, regulatory monitoring will be conducted in of three stages:

- (1) Internal Monitoring: refers to the quality assurance and quality control (QA/QC) practices conducted by producers, importers, and packers;

- (2) External Monitoring: refers to the inspection and auditing activities at production centers (factories and packaging units) and importation custom sites. Governmental authorities or regulatory agencies are responsible for external monitoring, which is implemented as a mechanism to assure compliance with national regulations and standards; and
- (3) Commercial Monitoring: it is also under the responsibility of the government, but conducted at the level of retail stores, also to verify that the fortified products comply with national standards.

An effective monitoring system requires a set of established procedures, methodologies, distribution of responsibilities, and reporting requirements to ensure continuous assessment of functionality, and an efficient feedback mechanism, which facilitates the establishment and implementation of corrective measures when operational problems arise. Success criteria will be established at each stage of monitoring process as exemplified in **Table 1**.

Table 1. Example of success criteria used for regulatory monitoring of food fortification programs (% of samples that must comply with levels)

Monitoring Stage	Minimum Levels (Indicators)		Maximum Tolerable Level
	Production	Retail (Legal)	
Internal (QA/QC)	≥80%	100%	<20%
External (Inspection and auditing)	≥80%	≥80%	<20%
Commercial	---	≥80%	<20%

Adapted from: WHO, in press.

Inasmuch as regulatory monitoring addresses the assurance of fortified foods in meeting nutrient quality and safety standards, it is important that clearly defined regulations and standards are in place to provide a legal framework for the overall monitoring system.

- Examples of aspects to be considered in regulations and standards that regulate wheat flour fortification:
- Identification of the entities responsible for production, quality control and quality assurance, and external and commercial monitoring of fortification programs.
 - The type of fortificant to be used, the level of fortification, and the permitted range or minimum and maximum levels of fortificants in fortified wheat flour at the mill.
 - Consideration of Codex Alimentarius specifications, including Codex food standards and Food Chemicals Codex (FCC) specifications, regulating world trade.
 - Consideration to specifications in neighboring countries to harmonize standards to the extent possible.
 - Defined precautions and food-safety conditions to be observed during production, transportation, storage, and sale of wheat flour.
 - Specification of information to be included on the label for fortified wheat flour and stipulate that misleading advertising ascribing healing properties to the consumption of fortified wheat flour is not permitted.
 - Procedures and corrective actions for non-compliance with the specified regulations.
 - Procedures to be followed for the release of any imported wheat flour for sale or distribution in the

country.

- Procedures for changing regulations and incorporating new knowledge and technology when they become available.

1.2 Public-Private Shared Responsibility

Inasmuch as the food fortification program is a public health intervention, the government of Ghana, through the Food and Drugs Board in collaboration with other agencies will exercise responsibility to assure the safety and adequacy of the fortified food. The food control agencies will ensure compliance to the national regulations, standards and norms. The formation of a National Food Fortification Alliance which includes industry has been formed and are partners in the fortification program. Since industry was party to drafting of the regulations and standards regulating the fortification program, it is anticipated that this cooperation will ensure commercial feasibility of meeting the regulatory requirements. The alliance also provides a clear definition of program objectives, basic activities, and the role of each of the sectors involved. This positive approach has promoted cooperation between the milling sector and the different government bodies.

Hitherto, the main activities of external monitoring by food control or regulatory agencies have been the inspection and technical auditing of wheat mills and packing and distribution centers with a focus on testing food samples for their various micronutrient constituents. The results of the laboratory analyses are then compared to the standards, and corresponding actions are taken. However, sample testing has two main drawbacks: (1) samples reflect on product quality after the production process and usually when products are well on their way in the distribution system, and (2) the time lapse for lab results, their interpretation, and feedback is compounded by the cost of sampling and analysis. Over-reliance on sample testing, therefore, can lead to high costs and slow response time in addition to producing results after-the-fact.

This Guideline encourages the minimized use of sample testing, particularly at the production level, and increased use of a more proactive, speedy and inexpensive approach of process monitoring and consistent data recording on production rate and premix flow. This emphasis on process control ensures that process controls are implemented with only few minor modifications to the existing production process or procedures. In most cases, the control points are already being observed, and it is just a matter of reorienting the assembly, analysis and interpretation of data. It is proactive because deviations or non-compliance can usually be identified in real time and the conditions causing them can be corrected immediately. Process monitoring will reduce sample testing considerably, although not eliminate it altogether. However random sample testing, will be conducted to assure the physiological aspects of a monitoring system. Furthermore, it is important that flour producers know that they can be inspected and verified at any time, to ensure compliance to regulations and standards at all times.

Since Process control requires a reorientation of approach, attitude and thinking towards regulatory monitoring, the commitment of producers, importers and retailers will be formalized so as to secure law effective enforcement and systematized monitoring. Furthermore, as data generated mainly by the flour producers is shared and assessed by the food control agencies, confidentiality, trust and mutual respect shall be established and maintained to enable these

activities to take place. Regulatory procedures, including sanctions and penalties, will always be applied in a transparent and fair manner recognizing that the provision of high quality products in compliance with national regulations and standards is in the interests of both government and the food producers.

In addition to the roles of these two principle actors, there will opportunity for feedback from consumer interests and shared knowledge and technology from the academic and research institutions. The Food and Drugs Board which is the Executing Agency, will ensure maintenance of clear understanding and respect of roles and responsibilities of each entity in the fortification process, good relations built on clear and timely communication and team work are required to achieve the standards and program objectives in an efficient and cost-effective manner.

1.3 Purpose and Structure Guidelines

This Guideline is developed for flour millers and food control agencies, for the purpose of establishing and implementing a comprehensive regulatory monitoring system for fortified wheat flour. It attempts to provide clear guidelines and instructions on setting up each component of the system (internal, external and commercial monitoring) required to assure and verify the quality of fortified wheat flour at the flour mill, packing center and customs site, as well as at the retail level.

This Guideline incorporates and adapts concepts and information from other previous publications, in order to remain in line with WHO guidelines and other authoritative documents on this topic.

The scope of Guidelines covers:

Part I. INTRODUCTION describes the overall regulatory monitoring system and the need for public-private shared responsibility in its sustained successful implementation.

Part II. ASSURANCE OF PREMIX QUALITY provides a guideline for assuring the quality of food premixes.

Part III. IN-PLANT QUALITY ASSURANCE SCHEME, directed to wheat flour producers, describes the QA/QC of flour fortification at production. It points out the necessity of ensuring proper premix handling to proper and consistent control of operations during the fortification and distribution process.

Part IV. INSPECTION AND AUDITING, directed to food control agencies, is a guide for inspection and technical auditing at production and packing centers and importation custom sites. It also provides a compendium of sampling and analytical methods for measuring the micronutrient content levels in fortified wheat flour.

Part V. POST MARKET SURVEILLANCE, also directed to food control agencies, is a guide for inspection and sampling at retail sites.

PART II. ASSURANCE OF PREMIX QUALITY

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| <ol style="list-style-type: none">2.1 Verification of Certificate of Quality and Batch Records2.2 Quantitative Analysis of Micronutrient Content2.3 Dissemination of Performance Reports |
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The growing number of commercial premix suppliers, has necessitated the need for both the public health authorities and food producers to recognize the need to assure premix quality in terms of hygiene, food safety, and good manufacturing practices, thereby assuring that the premix meets the minimum requirements for human consumption, as well as in relation to adequate types and levels of nutrients added. This need is based on CODEX *Code of Practice for Food Premix Operation* which incorporates the principles of quality management and food safety as well as HACCP principles, as a guideline for establishing industry standard on reducing risk related to adulterated food premixes entering into the food chain. Furthermore, the requirements of Food Chemicals Codex (FCC) provides standards of quality and purity for many food chemicals used in foods, including micronutrient fortificants have been considered. Therefore the manufacturer should ensure that the premix contains ingredients and fortificants that meet FCC specification and/or any national regulations.

This guidelines addresses quality control procedures for premix control at individual mills, as part of the overall quality assurance/quality control system, are described in detail in **Part III**.

The EA will carry out annual evaluation of premix quality with the industry and collaborating agencies. The following will be used for the assessment:

1. verification of certificate of quality and batch records
2. quantitative analysis of micronutrient content
3. dissemination of performance reports

2.1 Verification of Certificate of Quality and Batch Records

In general, problems with quality are rare when the premix is purchased from a reliable company that issues a Certificate of Quality (CoQ) or Certificate of Analysis (CoA) with the shipment, demonstrating that the shipment meets the relevant standards and specifications. Since commercial premix producers have better access to raw materials and analytical capabilities than producers of individual vitamins and minerals, it is more preferable and strongly recommended that food premixes be obtained from reputable suppliers instead of purchasing individual ingredients and preparing premixes *in-situ*.

It is therefore required that a list of approved suppliers of premixes shall be maintained both at each flour mill and a copy at the office of the Food and Drugs Board. The information on the list shall include the following:

- the name of the supplier,
- the contact information (name and address of manufacturer etc),
- the name of the principal officers of the company (PM, QAM and PM)
- the name of the sales associate or main contact person in country.
- and the brand of premixes carried by the supplier.
- ISO certification status
- HACCP accreditation status

It shall be the responsibility of the EA to review the CoQs or COAs issued by each manufacturer for the following quality indicators:

- grade,
- particle size,
- concentration of nutrients,
- in addition to premix batch records.

The CoQ or CoA provided should be reviewed for the following specifications:

- Chemical assay of the premix batch;
- Batch number and the date of manufacture;
- Date of packaging if different from date of manufacture;
- Expiry date; and
- Certification that the premix is food grade.

The *batch records* are the detailed records of the premix manufacture process and show the weights of each ingredient that are added to constitute the particular premix. Analysis of these records will confirm that the correct ingredients are present in the premix.

Packaging of the food premixes is especially important for maintaining their integrity, packaging specifications should be specified and also later verified. Premixes shall be packaged using air and watertight containers well protected from exposure to light. Typically, this should include an inner polyethylene bag containing the premix, which is placed inside an outer heavy cardboard box or barrel, or outer plastic pail. The inner bag should be re-sealable, and the outer containers should be re-closable. Packaging in this manner is important to avoid absorption of moisture, contamination, or degradation due to light.

All of these observations along with any corrective actions taken when the required specifications are not met must be properly recorded as part of the performance records of Supplier Quality Assurance scheme.

2.2 Quantitative Analysis of Micronutrient Content

The EA will collect samples of premix selected at random from all the available supplier brands for laboratory analysis to confirm that the premix composition meets specifications. One sample testing should be conducted at regular intervals, or annually, and the results on the conformity of the sample should be shared with all the millers relevant manufacturers.

The *nutrient content* of the premix should take into account the extent to which it is diluted when added to wheat flour at the mill. An overage is usually added to compensate for any variation in the natural levels of nutrients in wheat flour, to make up for any processing losses, and to ensure that the final level will be minimally achieved. The premix samples analyzed must show the fortificant content within the permitted range or minimum and maximum levels of fortificants as specified by regulation.

For the determination of the micronutrient contents in samples sent to the designated laboratory, a routine of complete analysis utilizing quantitative methods should be conducted to verify the premix vitamin and mineral levels.

The laboratory shall prepare a report of the results within 15 days after receiving the premix samples, and this report sent to the regulatory agency which will be responsible for feedback to the premix suppliers and the mills.

2.3 Dissemination of Performance Reports

The report of the laboratory results and results of the verification of CoQ and Batch records should be filed and used to update the list of approved suppliers. The executing agency shall be responsible for providing feedback within 15 days on the premix performance reports to the respective suppliers and the mills and certify premixes of good quality.

PART III. IN-PLANT QUALITY ASSURANCE SCHEME

- 3.1 What is QA/QC?
- 3.2 Overview of QA/QC of Wheat Flour Fortification
- 3.3 Quality Assurance in the Handling of Food Premixes
- 3.4 Quality Assurance in the Fortification Process
- 3.5 Quality Assurance in the Fortified Flour Distribution Process

3.1 What is QA/QC?

What is Quality Assurance (QA)?

Quality assurance refers to the implementation of planned and systematic activities necessary to ensure that products or services meet quality standards. The performance of quality assurance can be expressed numerically by means of quality control results.

What is Quality Control (QC)?

Quality control is defined as the techniques and assessments used to document compliance with established technical standards, through the use of objective and measurable indicators that are applicable to the products for services.

Most QA problems result from faults in the physical system rather than from deficiencies in employee abilities. It is not the purpose of the QA systems to penalize individuals. Thus it is important that employees do not fear blame but are quick to identify problems, if any, and their causes in order correct them in a timely manner. Producing a fortified food that is of consistently high quality is in the interests of both managers and employees, and the QA system should be regarded as a tool that helps to achieve this goal.

3.2 Overview of Quality Assurance Scheme of Wheat Flour Fortification

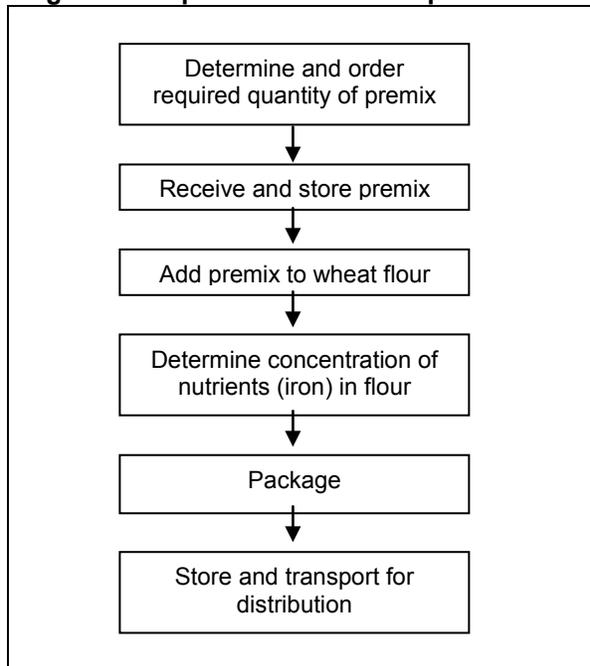
Each mill must have a written Quality Assurance Plan, and the control of the fortification process should be incorporated as part of the overall QA plan (See **Appendix 1** for an example of a mill QA plan). This is a written document approved by top management (including general manager and production manager) which sets out the quality goals and the specific activities that will be done to achieve them. By setting up a QA system, various aspects of the fortification process are systematically monitored and evaluated to ensure that the standards of quality and specifications laid down in the regulations are maintained at critical points in the milling sequence.

Quality guidelines and procedures for each component of the QA system must be defined. The Hazard Analysis Critical Control Point (HACCP) approach is recognized by the Codex Alimentarius and WHO as the best tool for guaranteeing food safety. It can also be applied to manage the quality of food products as it relates to manufacturing processes, which makes it complementary to other quality systems. Therefore, the QA plan may be based on critical control points in the

production process, which relies on identifying points in the production process where problems can occur and implementing measures to eliminate, prevent, or minimize these problems.

For the process of fortification of wheat flour, it is helpful first to identify and visualize the sequence of events in the fortification process in order to recognize the control levels and the critical control points throughout the production process. This can be done graphically through the use of flowcharts. **Figure 3** illustrates a general sequence of events in wheat flour fortification.

Figure 3. Sequence of events in production of fortified wheat flour



Based on the sequence of events, QC procedures for wheat flour fortification are defined for three control levels:

- (1) food premix control,
- (2) production and fortified food control, and
- (3) fortified food distribution control.

For the three critical control levels, **Table 2** shows who is generally responsible for executing and validating QC procedures.

Table 2. Examples of assignment of responsibility for executing and validating quality control procedures at the three control levels in the fortification process

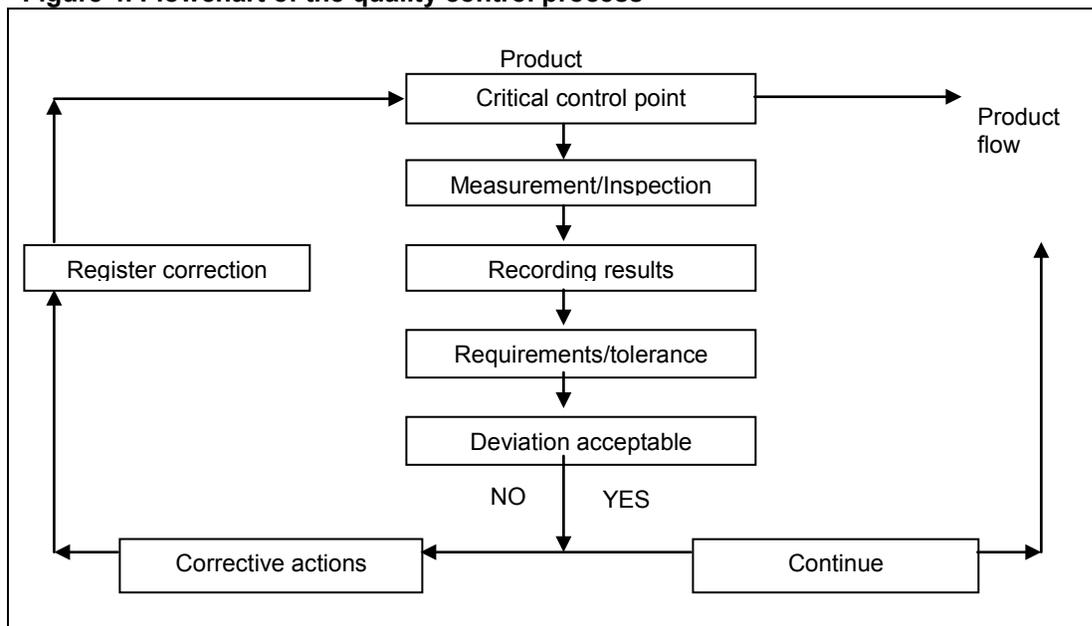
Control level	Responsible for executing	Responsible for validating
1. Handling of food premixes	Purchasing or receiving department of flour mill	QA department of flour mill
2a. Production of fortified wheat flour	Production department of flour mill	QA department of flour mill
2b. Assuring that finished product meets specifications	QA department of flour mill	Government food control agency
3. Distribution of fortified wheat flour	Packaging department of flour mill or packaging plant	Government food control agency

Adapted from: Nestel et al.

Critical control points at which important deviations are occurring must be identified immediately. Important deviations are those that may severely affect the quality of the fortified food or the cost-effectiveness of the production process. It is important to monitoring where, when, and by how much manufacturing processes deviate from standards and specifications

To control each critical control point in each control level, a defined set of *indicators, criteria for success, methods (procedure and frequency for checking the indicators), documentation (records and reports), corrective actions, and identification of person or people responsible for executing the QC task and performing corrective actions* must be defined. Key data must be collected and analyzed at each point to determine whether the objectives of wheat flour fortification are being met. **Figure 4** illustrates in flowchart form the QC process that should take place at each critical control point.

Figure 4. Flowchart of the quality control process



Thus, at each critical control point, employee(s) should:

- (i) Check a process or collect a sample.
- (ii) Record data.
- (iii) Analyze data.
- (iv) Report the results of steps (i-iii) to the person responsible for taking action.
- (v) Take corrective action in response to the report made at step iv.

Senior management must communicate the QA plan at regular intervals to all personnel, thereby stating Management's commitment to maintain high quality in the food fortification process. Senior management must also follow through on the plan by hiring sufficient number of qualified staff and designating them to manage and run the QA system, providing resources to fulfill requirements for laboratory location and facilities, providing periodic training of personnel to use the appropriate QA and QC tools and time to attend the training sessions, collecting information

on the quality of the company's products, analyzing the collected information and taking appropriate action, and budgeting adequate resources to operate the QA system.

Human resources already in place to run and manage the overall mill QA system should incorporate the control procedures for fortification. However, Management should consider the assignment of roles for:

- (i) carrying out the fortification process;*
- (ii) taking and analyzing the fortified flour samples (field and laboratory technicians);*
- (iii) supervising and controlling of all stages of the fortification process and data registration.*

3.2 Quality Assurance in the Handling of Food Premixes

Quality assurance of the wheat flour fortification process must begin with high quality nutrient additives and premixes. Thus, the first step to any QA system for food fortification programs is to assure the quality, handling, and storage of the fortificant or premix. Generally, problems with the premix quality are rare when it is purchased from a reliable company that issues a Certificate of Quality (CoQ) or Certificate of Analysis (CoA) with the shipment. Therefore, it is strongly recommended that food premixes be obtained from reputable suppliers.

3.2.1 Purchasing Food Premixes

Food premixes should be purchased in a programmed and timely manner from a reliable company that issues a CoQ or CoA with the shipment, stating that the shipment meets the relevant standards and specifications. The Mill Purchasing Department shall keep a list of approved suppliers of premixes. This list should include the name of the supplier, the contact information, the name of the principal officer of the company, the name of the sales associate or main contact person, and the brand of premixes carried by the supplier. The mill should meet with the suppliers' agent at least once per year to review premix performance with respect to timeliness of delivery, quality, and price.

Sufficient stocks of premixes should always be maintained. Therefore, premixes should be purchased well in advance of their running out. A reordering point in inventory levels should be specified in the mill QA plan to trigger the purchase order, but production schedules should also be regularly consulted.

3.2.2 Receiving and Handling Food Premixes

Each milling establishment shall have in place an effective QC procedure for receiving and handling food premixes, and a log of the results should be maintained. Physical examination of the consignment on arrival shall be done. The following shall be checked:

- Physical condition of the packaging
- Color,
- Texture (Free flowing, no lumps, no spots)
- Odor

A Certificate of Analysis provided by the manufacturer must accompany each consignment of premix.

All of these observations along with any corrective actions taken when the required specifications are not met must be properly recorded and filed for easy access. **Appendix 2** gives an example of the type of recording form that can be used.

Procedures for receiving and handling food premixes should include the following considerations:

- The Certificate of Analysis must state the following:
 - Chemical assay of the premix batch;
 - Batch number and the date of manufacture;
 - Date of packaging if different from date of manufacture;
 - Expiry date; and
 - Grade
 - Particle size
 - Certification that the premix is food grade.
 - Microbiological status
- All of the observations during the receiving and handling of premix shipments along with any corrective actions taken when the required specifications are not met must be properly recorded in a premix log or registration form and filed for easy access. The date received, the batch or identification number of shipment, the number of units (unit quantity and total quantity received), and the quality certificate number should be recorded. The log or registration form should be checked and signed by the Purchasing or Receiving Department supervisor or mill manager.
- All premix shipments received should be accompanied by fortification instructions. This can be written as part of the CoA. These instructions should state the proportion or quantity (in grams) of premix to be added per kg of flour in order to adequately meet fortification standards.
- The quality certificates of all premix batches received should be stored and made available for government public health inspectors.
- A copy of the CoA and fortification instructions should be kept by the chief mill operator in a separate file, and copies should be distributed and read by all mill personnel.
- On annual basis, premix quality should be verified (see **Part II**). Randomly selected premix samples should be sent for laboratory analysis to confirm that the premix composition meets specifications. In the case where one premix manufacturer supplies a number of mills in the country or various countries in the sub-region, it is recommended to conduct one sample testing at regular intervals and share the results on the conformity of the sample with all the millers through the coordination of the National Food Fortification Alliance in collaboration with the Executing Agency.
- At least once in every 8 to 10 shipments, the mill operator could also request to examine the premix batch records from the premix supplier, to see the weights of each ingredient that are added to constitute the particular premix and confirm that the correct ingredients are present in the premix and assist in the verification of premix quality.

3.2.3 Storing Food Premixes

Food premixes must be stored in a systematic manner under conditions specified by the manufacturer in order to maintain their quality and prevent contamination and deterioration.

Procedures for storing food premixes include the following considerations:

- Special care should be taken in the storage of the premix so that quality is maintained and contamination and deterioration are prevented. Storage conditions should adhere to the manufacturer's specifications/recommendations. The storage area should be enclosed, and protected from the environment and pests. The area should be cool and dry and free from direct sunlight. Premixes should be stored off the ground in well-ventilated conditions. Access premix storage facilities should be restricted to authorized personnel only.
- Physical organization of the premix containers is important. Storage areas should be designed to facilitate the "*First-In, First-Out*" (*FIFO*) system of stock rotation. Bags or boxes of the premix should be stored in consecutive order so that the oldest can be withdrawn first. When relevant, they should be organized according to brand or type, in addition to the lot number and date received. It is recommended to use a color-coded labeling system for the types of premix, lot numbers and dates received. Labels or stickers should be oriented so that they are visible to operating personnel collecting premix for use. There should be sufficient space between containers to allow for their easy access.
- In the case of multi-use storage facilities such as in factories where other types of fortificants or flavoring or spices share the same warehouse facility or storeroom, a physical separator should be provided between each additive to ensure that there can be absolutely no chance of mix-up or mistake in collection of additives. In addition, the storage bays for the various additives should be clearly marked with readily visible signs.
- The fortificant storage area should be maintained by rigorous housekeeping procedures. Any spillage or sweepings must be removed to proper waste disposal areas immediately. Waste packaging materials must also be disposed of immediately and not allowed to accumulate. Any returned, damaged, or contaminated premix should be stored separately from the undamaged stocks. They should be clearly marked as such, and arrangements for their removal and/or disposal should be made immediately.

3.2.4 Using Food Premixes and Premix Inventory Control

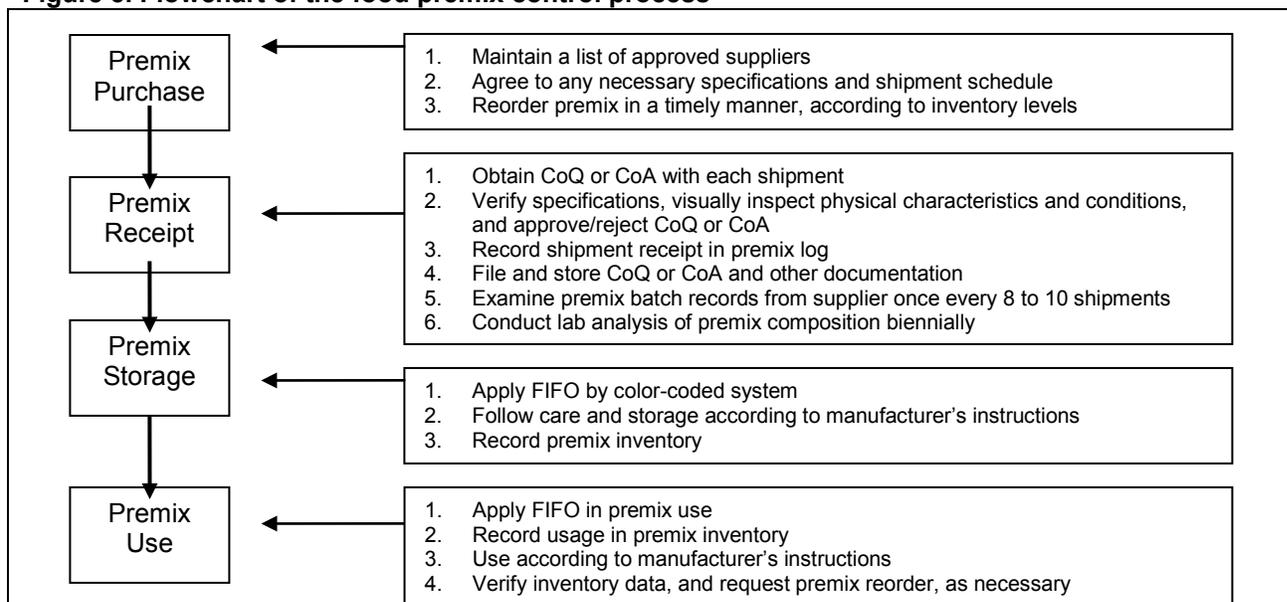
Food premixes should be used in a systematic manner, according to the “first-in, first-out” (FIFO) system, and their movement should be recorded properly.

Procedures for using food premixes should include the following considerations:

- The Mill Production Department, with supervision by the QA department, is responsible for the correct use of the premix in the production process.
- Premix should be withdrawn from the storage facility in accordance with the FIFO system. Thus, premix should be used in consecutively order so that the oldest is utilized first.
- Proper recording procedures to monitor movement of premix in and out of the warehouse should be implemented. The movement of premix for use in the mill must be recorded in a premix registry and/or premix reconciliation form for the fortification process (**Appendix 3**, further discussed in **Section 2.3.1c.**). For each withdrawal of premix for use in the mill, the date, the time, the quantity, the premix lot number, and the names of person and department receiving the premix should be recorded. Any premix that is returned, disposed of, or spilled should likewise be recorded.
- If only a portion of the premix is removed for use, the inner bag should be resealed and the outer container re-closed tightly. Once a premix box has been opened it should be used within a few weeks.
- Based on the information in the premix registry and/or premix reconciliation form for the fortification process, it will be possible to calculate a daily inventory of premix in storage. This inventory should be physically checked at regular intervals, e.g., weekly, in order to verify inventory data and identify any discrepancies between written and physical inventory for immediate investigation and explanation.
- Based on the level of premix for reorder specified in the Mill QAP, premix should be purchased to maintain sufficient stocks of premix. If necessary, the Production Department should request to the Purchasing Department that new shipment be order in sufficient time to avoid running out of premix. A reorder point in inventory levels often triggers the purchase order, but production schedules should also be consulted.

To highlight and review the critical points of food premix control, a flowchart of the food premix control process is shown in **Figure 5**.

Figure 5. Flowchart of the food premix control process

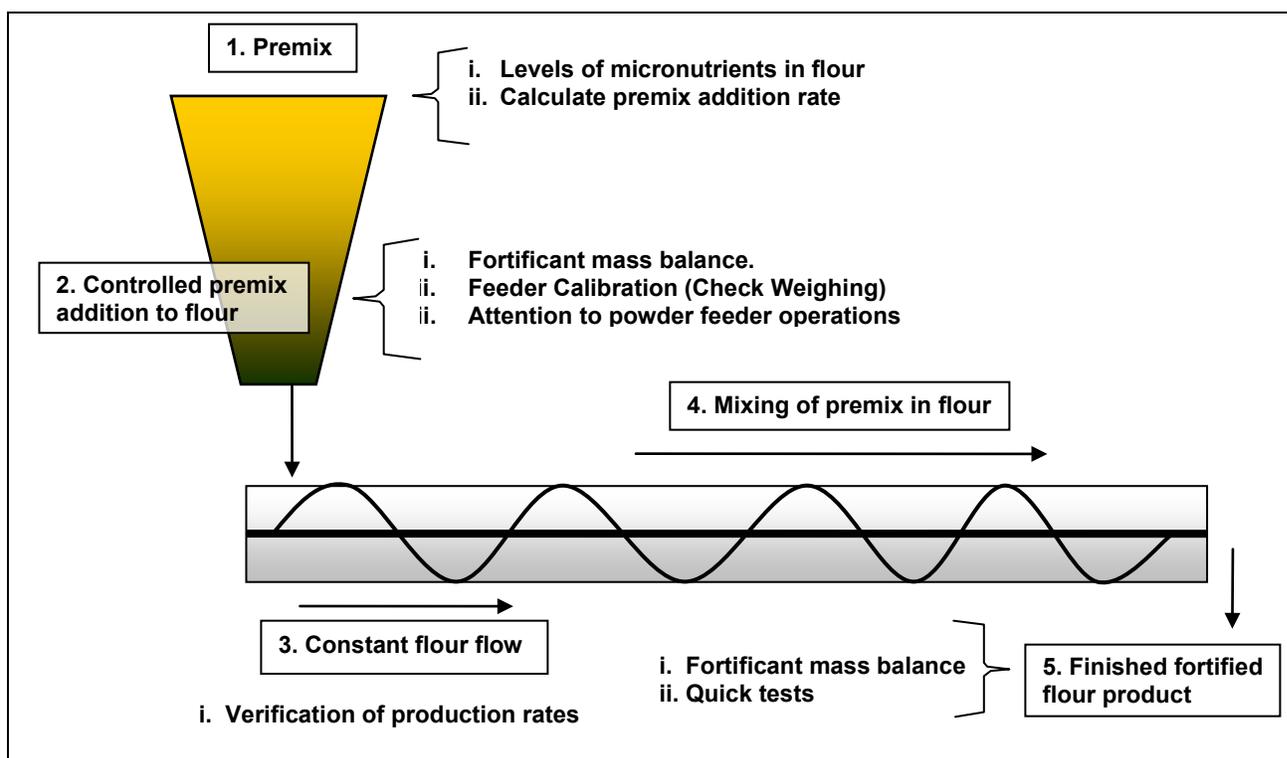


3.3 Quality Assurance in the Fortification Process

Most problems in food fortification relate to deviations from technical specifications at critical control points, which result in quality standards not being met. When a problem is identified, the goal is usually to solve it as quickly as possible without stopping production. Reprocessing of an occasional batch of inadequately fortified food is often not considered feasible for economic or technical reasons. However, if a defective batch of fortified wheat flour creates a risk to consumer health recall the product.

The wheat flour fortification process seeks to add, disperse, and homogenize a controlled and known amount of micronutrients to a controlled and known amount of flour. These steps, which are the same for both batch mixing and continuous processes, are illustrated in **Figure 6**. For a continuous metering system, in which the premix is continuously added into the flour using a precision powder feeder or dosifier, a constant flow of flour is required at the point of addition or a system in which the feeder continuously adjusts to the flow rate of the flour is required. In the case that these two conditions are not available, a conveying screw can be installed from a flour holding bin to another bin or to packing out.

Figure 6. Flour fortification production process



3.3.1 Addition of Premixes

The premix should be continuously added into the flour stream at an addition rate dependent on the flour flow. Proper operations of the powder feeder and its auxiliary components are indispensable for accurate and consistent addition of the premix to flour. It is important to ensure that the addition level is correct and that the flour flow and premix addition rate is known and consistent. The premix should be added to flour at the end of the milling process or during packing, provided that there is adequate mixing. The movement of premix during the production process should be recorded in a premix registry or premix reconciliation form for the fortification process (see **Appendix 3**).

3.3.1a. Addition Levels of Nutrients in Flour

Fortification standards established by the Ghana Standards Board are a way of regulating fortification and therefore it is required of industry ensure commercial feasibility of meeting the regulatory requirements. These standards are the minimum levels of the vitamins and minerals required to be in the wheat flour once it leaves the mill. The standards are different from the addition levels because they take into the account the natural levels of the micronutrients in the unfortified flour. The addition levels should also take into account the natural level in the flour and a normal processing loss for each micronutrient, while providing an overage to allow for process variation and analytical error. (Appendix 10)

3.3.1b. Premix Addition and Feed Rates

The premix addition ratio is the weight amount of premix to be added per unit weight of flour (usually in grams of premix per kg of flour), so as to achieve the fortification level required by standards. This addition ratio is generally provided by the premix supplier.

The premix feed or addition rate per minute must be calculated, depending on the actual flour production rate per minute, in order to adjust the feeder control to deliver the accurate weight of premix per minute. An example of a production rate record to determine the flour production rate is provided in **Appendix 4**. The formulas for calculating the flour production rate and the premix feed rate are shown below.

Formula for calculating flour production rate:

Weight of bags (kg) x Number of bags per hour (x/hr) x 1/60 (hr/min) = Weight of flour produced per minute (kg/min)

Formula for calculating premix feed rate:

Premix addition ratio (g/kg) x Flour production rate (kg/min) = Premix weight required per minute (g/min)

3.3.1c. Controlled Addition of Premix

Once the premix feed or addition rate is determined, the next critical point is the controlled addition of the premix according to the calculated feed rate. Controlled addition is maintained by ensuring that the powder feeder is functioning and maintained properly and by regularly checking the added premix quantity with mass balances.

(i) Feeder Calibration and Regular Weight Checks

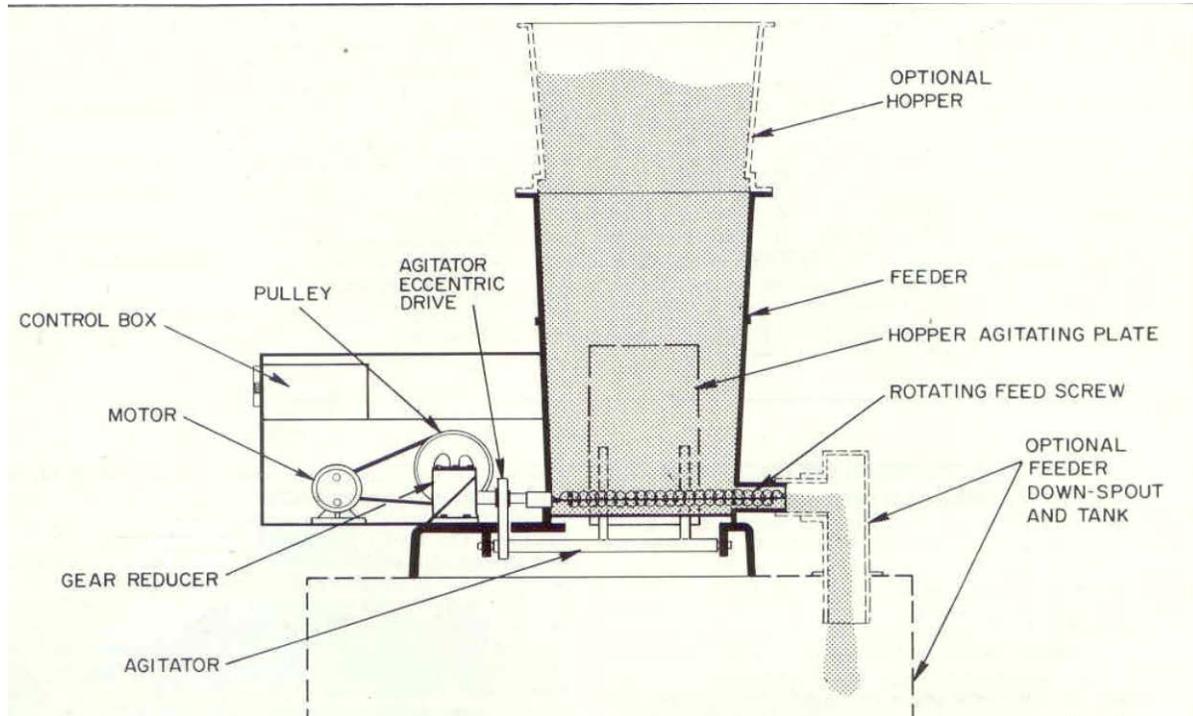
Premixes are added to the flour by means of powder feeders. These are precision machines that must consist of the following three components:

- 1- A hopper for storage of a suitable quantity of premix, usually sufficient for production during a shift or an entire day's production;
- 2- A means of gently agitating the premix so that it feeds smoothly without bridging or compacting (this could also a function of the hopper); and
- 3- A feeder mechanism or dosifier that can be controlled to vary and make fine adjustments to the rate of powder transported to the flour.

There are three types of powder feeders – screw, revolving disk, and drum or roll type. In all cases, these feeders must be installed, operated, and maintained according to the manufacturer's instructions. The feeders must be regularly calibrated.

The diagram in **Figure 7** shows a typical screw type powder feeder and its components. Many facilities rely on this type of feeder.

Figure 7. Diagram of a screw type powder feeder



For effectiveness of the dosing process, these two checks that should be performed regularly:

(1) The feeder or dosifier should be calibrated at the beginning of each shift and before processing each batch of flour. In addition, a monthly feeder calibration check should be conducted. The entire feeder setting should be checked, and the flow rate from the feeder should be measured. The results should be compared to previous calibration checks, through the use of a calibration chart. Deviations from the norm indicate that feeder maintenance may be required. If maintenance is required, calibration checks should be performed prior to returning the feeder to service.

(2) At least once per shift or every 8 hours, check to confirm that the premix addition rate is consistent and the premix is being added correctly. This check consists of capturing the premix flow from the feeder for one to three minutes and weighing the amount collected. The premix is weighed to determine if the feeder is dispensing the correct amount of fortificant at that setting; longer collection times are used for lower addition rates. The operator should record the time, weight and feeder setting. The recorded amount should be compared to the established premix addition rate. If the amount added is different from the required value, an adjustment must be made immediately and the action recorded. Automated, loss-of-weight feeders are also available, wherein the disappearance of premix should correspond with calculated usage and any adjustments to the feeder can be made based on these results.

(ii) Premix Usage Reconciliation

Premix usage reconciliation should be performed at each shift. Depending on the planned daily production of wheat flour, a specific quantity of premix is required each day. This value can be calculated by multiplying the premix addition rate by the total planned daily production. This calculation provides the premix quantity that should be used up during the day's production to achieve the correct fortification level.

Formula for calculating premix quantity required for daily flour production:

$$\text{Premix addition ratio (g/kg)} \times \text{Wheat of flour produced per day (x/day)} \times 1/24 \text{ (day/hr)} \times 1/60 \text{ (hr/min)} = \text{Premix weight required per minute (kg/min)}$$

The actual amount of premix used each day can be measured and compared to this planned usage. Furthermore, the total actual amount of premix used for the day can be divided by the total actual day's flour production to give the average actual daily premix addition ratio. This value should be compared to the premix addition ratio provided by the manufacturer. Any deviation from the required dosage should be recorded and explained.

During powder feeder operations, a routine must be set up to ensure regular checks of vital parameters. **Table 3** shows examples of the type and frequency of the routine checks for powder feeder operations.

Table 3. Examples of routine powder feeder checks

	Check	Frequency
1	Feeder or dosifier calibration	Beginning of each shift and/or every batch
2	Premix hopper level	Beginning of each shift and every 4 hours
3	Hopper agitation	Every 4 hours
4	Presence/absence of premix flow	Every 2 hours
5	Measurement of premix addition rate (regular weight checks)	Every 8 hours
6	Observation and implementation of proper feeder housekeeping	Every 8 hours
7	Premix usage reconciliation	Every 8 hours

3.3.2 Maintaining Constant Flour Production Flow

The premix addition rate is dependent on the flour production rate. Therefore, it is important to ensure that the flour production rate is constantly measured and monitored at different points of production. If there is any variation, then the fortification level will also vary.

It should be noted that the nominal or rated mill capacity is likely to change over time due to factors such as equipment modifications and changes, deterioration of equipment over time, mill upgrades, product changes, and different raw material used. The rated mill capacity provides the starting point with a range of where the actual measured production rate is expected to fall.

Procedures for carrying out regular production rate measurements should include the following considerations:

- Mills with continuous instrumentation. Most modern mills have instrumentation that continuously measures the flow rate of flour being fortified. This value is used to automatically calculate and adjust the powder feeder rate of premix addition. Although this is all done automatically, regular maintenance checks on the equipment needs to be performed according to the manufacturer's guidelines.
- Mills without continuous instrumentation. In this case, production is measured manually by means of counting the number of bags of a given weight produced over time. A production rate record should be kept. This record merely keeps track of the daily production and the actual mill run time. The conditions of production should also be noted, i.e. product being made, raw material being used, etc. The rate should then be calculated daily, weekly and monthly. An example of a production rate record is provided in **Appendix 4.**
- Production rate should be verified by means of a quarterly physical audit of the production rate. This involves randomly choosing a production day on a quarterly interval and appointing persons responsible for counting the mills production and recording the mill operating time. The production rate calculated hourly and for the day should be compared with the values on the production rate record. If the audit shows a serious discrepancy from the recorded values, the problem should be investigated and corrective measures taken.
- Preventative maintenance schedules for plant equipment and especially for the flour bagging scales should be fully upheld. Errors in the bagging weight will be transmitted to the production rate measurement.
- The daily average production rate obtained from the production rate record should be used to calculate the premix addition rate.
- For batch fortification processes, the batch weight in the batch mixer is used as the amount of flour to which premix is added. Calibration of the weighing device on the batch mixer should be done at least on a quarterly basis. This should be calibrated and checked according to manufacturer's recommendations

3.3.3 Mixing of Premix in Flour

This is a small but highly critical process detail that is indispensable for proper fortification. It makes no sense to add the correct amount of premix to the correct constant flow of flour if they are not mixed together properly. Premix must be distributed equally throughout the flour, i.e., it is homogenous. Although quality control at this stage must be built in during the design and installation of the equipment, the mill operator has the responsibility to ensure correct operations of the equipment.

For pneumatic mixing:

- Ensure proper functioning of airlock and venture.
- Follow manufacturer's operating instructions.
- Perform recommended preventative maintenance.

For mechanical mixing:

- Ensure good housekeeping of mixing screw or paddle mixer blades.
- Ensure that premix chute is clear and free from obstructions.

3.3.4 Finished Fortified Flour Control

There are four methods that can be used to supervise and control the fortified wheat flour. Proper recording of all the results of the QC procedures is essential. An example for recording the QC results of fortified flour is given in **Appendix 5**. Records of QC activities carried out should be up-to-date, stored in a safe place, and at the disposal of the food regulatory inspector.

The four methods include:

- (1) regular weight checks
- (2) premix usage reconciliation
- (3) semi-quantitative spot tests
- (4) quantitative tests

3.3.4a. Semi-quantitative spot tests

Flour samples should be tested to verify that it has been properly fortified. Fast and simple analytical assays are needed for the QC procedures, because the results must be known in the shortest period possible in order to implement corrective actions. These assays do not need to have high analytical resolution (to discriminate between small ranges of the micronutrient), but it is essential that they be able to determine whether the flour is markedly under- or over-fortified and the fortification standards are fulfilled (i.e. content not less than the production minimum nor more than the maximum tolerable level). To this end, mills can use a simple semi-quantitative spot test. Spot tests are quick and simple, and can be used at various points in the production line, particularly in the packaging line, to ensure that the flour is fortified according to fortification standards. The iron spot test (AACC method 40-40, Iron-Qualitative Method, see **Appendix 6**) is a fairly inexpensive method commonly used by millers, since iron is the most likely nutrient to be used as an indicator of adequate fortification in government control. Results of QC must be carefully recorded and kept, because they document the history of mill performance and the producer's supervision of the fortification process.

BOX 1: On-Site Semi-Quantitative Spot Test for Iron in Flour

A semi-quantitative analysis can be used to verify the level of iron fortificant in the finished product flour. When compared to known standards, it provides a good comparison of the level of iron in the product flour. The flour samples should be collected from the online production and tested as described below:

- ◆ Take a 1 kg sample of flour from the packaging line. Ensure the sample is representative and is properly sealed after collection to eliminate contamination.
- ◆ Flour samples should be taken twice per shift or every 4 hours to verify the level of iron in the flour. The results of the analysis should be compared to a flour standard and recorded.
- ◆ The samples should be tested according to the instructions. The method is sensitive enough to show the localized spots of iron in the flour sample. The distribution of the red color spots can therefore be used as a measure of mixing performance, and the density of the red color spots can be compared to standards as a measure of iron level.
- ◆ If the sample presents the required minimum level of iron, sampling is continued at the frequency of every 4 hours. Otherwise, sampling should increase to every 2 hours. If out of 5 samples collected at intervals of 2 hours, 2 are outside the established concentration, the sampling will intensify to every hour. When it still does not fulfill required fortification level, the problem should be investigated and corrected.
- ◆ Once the error has been corrected and it has been verified that the minimum required iron concentration is achieved, the frequency of sampling can be lowered again to every 4 hours.

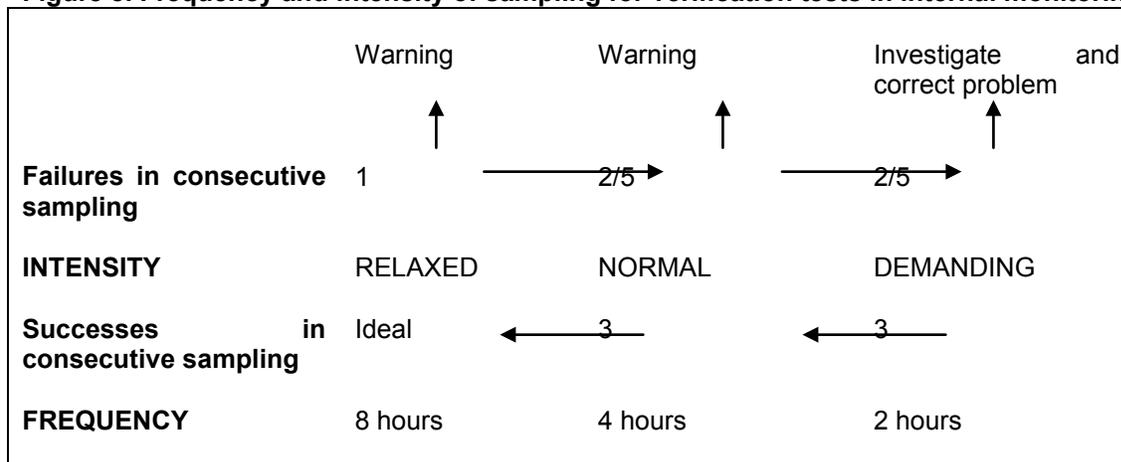
The point at which the flour is sampled, the sampling procedure, and how the sample is collected and handled are critical in obtaining reliable and useful results. Samples should be collected at a point in the production line after the addition of the premix as well as the mixing of fortified flour. Samples must be kept protected from high temperatures and humidity until analyzed. A good sample represents the entire production run averaging out any momentary variation in the fortification process.

The frequency of taking flour samples depends on the rate of flour production as well as the reliability of the fortification process at each mill. Thus, a highly homogenous and consistent operation would need less sampling than one with variable results. Nevertheless, even in the most reproducible conditions it is important to take and analyze samples to verify and to keep track of whether the technical standards are fulfilled. While it is recommended that semi-quantitative spot tests be conducted every 4 hours, sampling to verify nutrient content can be done at the same time that samples are taken for tests to determine moisture and protein levels, which is usually about every two hours in a continuous fortification process or for every batch of flour produced using the batch fortification process. The laboratory manager or a laboratory technician should be responsible for conducting these tests.

Figure 8 shows an example of a dynamic sampling system for a continuous process. Under optimal operations, one flour sample per shift might be sufficient, which categorizes a “relaxed” or low intensity of sampling. If the technical specifications of the product are not attained (i.e. the micronutrient content is lower than the factory minimum or higher than the maximum tolerable level), then sampling frequency should be increased from the relaxed intensity to a “normal” intensity and corrective actions should be taken. *Mills are recommended to begin sampling for semi-quantitative spot tests at this “normal” intensity.* In the normal situation, if on 2 out of 5 consecutive sampling times the product fails to meet the technical

requirements, then the intensity of sampling should be changed to a “demanding” or high intensity, and corrective actions should be implemented. If again, in 2 out of 5 consecutive sampling periods the technical requirements are not achieved, then the production should be stopped until the source of error is found and the necessary corrective measures are introduced. Once production is reinitiated, sampling should start at the demanding intensity, and switched to normal and then to relaxed intensities if in 3 consecutive sampling periods, the QC results are correct. Neither the relaxed nor the normal intensity should be viewed as positive or negative; they simply reflect the performance of the fortification process at the moment of the assessment.

Figure 8. Frequency and intensity of sampling for verification tests in internal monitoring



3.3.4b. Quantitative tests

Quantitative tests provide more precise data on the amount of nutrients added to flour. Composite samples are preferred for quantitative testing. A composite sample can be obtained by taking a “grab” of flour at a specified point in the production line every two hours over a shift and mixing them together. Composite samples could consist of the same flour samples collected for consecutive semi-quantitative spot tests pooled for each production shift that are mixed well and then analyzed. Quantitative tests for the various micronutrients in flour, however, differ greatly in complexity, analytical error, type of equipment and skills, and cost. Mill operators should carefully consider these factors before relying too heavily on these types of analytical procedures. Much can be accomplished through other simple consistent QC procedures such as record keeping, premix feed rate checks, and semi-quantitative spot tests.

3.4 Quality Assurance in the Fortified Flour Distribution Process

The process of getting the fortified flour from the factory to the consumer presents numerous challenges that can degrade the product’s quality. Shelf life is the time between the date of production and packaging of a fortified food and the date on which the food becomes unacceptable under defined environmental conditions. Packaging, storage, and transportation of fortified wheat flour must be planned and monitored to preserve the product’s shelf life. In addition, product labeling is necessary to ensure that fortified wheat flours are distinguishable

from unfortified flours and to inform consumers about the nutrient content in fortified wheat flour.

This section discusses hazards to quality and QA procedures at the following four critical control points in the distribution process:

- Packaging
- Labeling
- Storage and
- Transportation

3.4.1 Packaging

The primary purposes of packaging for a fortified food are to maintain the stability of the product's micronutrient content and to protect the integrity of the food. Micronutrients can degrade as result of exposure to light, oxygen, moisture and changes in temperature. For example, a 10°C increase in temperature approximately can double the rate of chemical decomposition within a product, and sudden changes in temperature can cause moisture condensation, leading to deterioration of packaging, loss of nutrient content, and infestation by pests.

Where feasible, packaging should be as suitable as possible to protect micronutrient integrity and the quality of the fortified food. In selecting or designing appropriate packaging, it is important to consider local climatic conditions. Packaging specifications must ensure that fortified food is always packaged properly to protect it from damage due to environmental factors or rough handling. A packaging specification should: (1) identify the protective characteristics necessary to maintain the integrity of the food, including the nutrient quality of a fortified food, and (2) define packaging material for primary (inner packaging that is in direct contact with the product) and secondary (outer packaging that provides additional protection) packaging, including its size color and other features, as necessary.

Fortified wheat flour is often packaged in polypropylene sacks of large quantities 50 kg for delivery to wholesale retailers or distributors or manufacturers of products made of flour wheat such as bakeries, pastry shops, etc. Flour in smaller paper sacks of 1 to 2 kg are used for multi-purpose flour for domestic purposes. It is important to note that the fortified flour should be used soon after the original packaging has been opened. Long periods of storage in intermediate warehouses and improper re-packaging should be avoided.

It is important to establish quality standards for the fortified flour in order to maintain the quality of the products. The following packaging procedures are recommended:

- Keep unused packaging materials clean and dry.
- Pack in a clean, dry, well-lit area.
- Inspect primary packaging carefully for defects before placing bags or boxes of fortified food into secondary packaging.

Even after the fortified food is properly packaged, it must be handled carefully. Rough handling may damage or rupture packaging. This causes product deterioration or loss, increases costs, and increases the risk of pest infestation. After the fortified food is sealed within its secondary packaging, avoid exposing it to excessive heat, high relative humidity, or poor ventilation.

3.4.2 Labeling

Labeling of fortified flour serves two purposes: (1) It identifies the fortified flour and (2) differentiates it from unfortified flour. This label shall include an appropriately descriptive name of the fortified flour, including the use of the approved symbol, a different packaging color, or a different print style on the package. The labeling shall also provide information about the fortified food's nutrient content.

Fortified flour shall be labeled in accordance with Labeling Requirements for Prepackaged Foods of Ghana. The following information shall be included in the labeling of fortified flour:

- Product name
- List of ingredients (in descending order of percentage weight composition)
- Net quantity of fortified food contained in the package (in the designated weight or volumetric system of the country in which the fortified food is sold to consumers)
- Name and address of the manufacturer, packager, importer or distributor
- Country of origin
- Batch/Lot number
- Expiration date (an *open dating* system is recommended, i.e., date of manufacture and shelf life of the fortified food [in months], or "use by" or "best if used by" date by which a fortified food should be consumed to ensure maximum quality)
- Logo indicating fortified flour

3.4.3 Storage

Storage means keeping a fortified food in a facility – often a warehouse – until it is transported further through distribution channels. General control procedures used for storing foods should be applied to ensure that the quality of a fortified food is maintained during warehouse storage. Fortified flour in storage is at particular risk for damage from pests such as insects, rodents, bats, and birds in addition to contamination with bacteria and molds. Bacteria and molds, which need moisture to survive, are controlled by maintaining a dry environment. Clean storage conditions usually control insects and rodents.

The control of inventory is a crucial QC procedure because many foods, including fortified flour, are perishable or have a limited shelf life. Although flours are often distributed quickly after milling to retailers and manufacturers of flour-based products, it is important to maintain inventory control, applying the FIFO system of stock rotation.

3.4.4 Transportation

It is common for packages of fortified food to be damaged in transit, resulting in loss of quality. Distribution channels are sometimes complex, and a variety of people and organizations can be involved in transporting the fortified food from its point of origin to its point of sale. Damage can occur in a variety of ways, but steps can be taken to prevent or minimize the risk of damage in transit. Flour exporters that transport fortified wheat flour over relatively long distances should place particularly careful attention to adequate transportation and handling.

Environmental hazards

Condensation due to moisture, humidity, or changes in temperature can weaken packaging and encourage pests. This causes deterioration or loss of the fortified food and increases costs. The use of appropriate packaging can help to reduce the risk of environmental damage to products in transit

Mode of transportation

Packages transported by road or rail can be damaged by vibration or bouncing of the load. Good loading procedures are essential to prevent or minimize such damage. Packages transported by water can be damaged by moisture as well as by pitching and rolling of the vessel.

Poor vehicle condition

Dirt, clutter, leaks, humidity, harsh odors, and pest infestation in vehicles used to transport food can damage packaging and reduce the quality of the fortified food. Before loading, inspect all vehicles used to transport fortified food to ensure that the following conditions are met:

- The driver's cabin is completely separated from the load compartment.
- The load compartment is clean and free of loose objects (e.g., nails) that can damage packaging.
- The load compartment does not leak and is free of humidity, harsh odors, and pests.
- The vehicle carries only wheat flour from the factory.
- The vehicle is dry and clean

Metal containers for loading flour must be fumigated with approved food grade fumigant prior to loading. It must be provided with adequate dunnage. Containers from temperate countries should have dessicants in addition.

Loading and unloading

Containers can be dropped or can collide while being loaded or unloaded. In general, dropping is most damaging for goods weighing up to 50 kg. The preferred weight range for packages is 10-25 kg. Within that range, packages are neither too heavy to handle nor light enough to be thrown.

PART IV. INSPECTION AND AUDITING

- 4.1 Development of an Annual Inspection Plan
- 4.2 Inspection and Auditing
- 4.3 Laboratory Analysis

Food control authorities must incorporate parameters into their food monitoring protocols to check that the quality and safety of wheat flour fortification is in accordance with the approved technical standards. External monitoring by governmental authorities is essential to assure that all flour producers are complying with national regulations and standards.

External monitoring of wheat flour fortification program involves two types of actions by the food control agencies:

- (1) Confirming that the technical specifications are fulfilled in the products at factories, packaging sites, and points of entry into the country (inspection); and
- (2) Checking the performance and records of the producers' QC/QA procedures (technical auditing).

4.1 Development of an Annual Inspection Plan

4.2 Inspection and Audit of Flour Mills, Packing Centers and Customs Sites

4.2.1 Inspection and Technical Auditing

Food inspectors from the Food and Drugs Board shall visit the mills, packing centers and customs sites regularly. Inspection guides and registration and necessary forms shall be developed to expedite the inspections. FBD inspectors will be assisted by Customs **Excise and Preventive Service**. The visits to the mills must be long enough, between one to two hours, to allow for detailed observation of the production activities. These visits must take place according to a schedule that is sufficiently flexible to take into account the need to assist the mill in improving its QA system and verifying the efficiency of process. During the visit, inspectors should perform the following activities:

- review QC records,
- review laboratory results,
- collect flour samples for analysis at reference laboratory, and
- discuss any obstacles or difficulties in the production process.

The intensity of inspection frequency depends on the reproducibility of the fortification process. The inspection program will be done twice monthly at the start of a fortification program for the first six months thereafter once monthly and then less frequent at every 6 months when program performance proves consistent and reproducible. The important issue is to assure that the technical standards of the product are enforced.

Imported wheat flour will be inspected at the port of entry for documentation Certificate of Analysis/Conformity from the country of origin by an accredited staff of FDB or CEPS. In addition, FDB will conduct Iron Spot Test to corroborate compliance of the technical standards in samples of the imported shipments.

The FDB will conduct auditing of mills once a year for the purpose of checking that companies are complying with their statutory obligations and that the mills are capable of producing fortified flour of the required quality and technical standards.

During an audit the following aspects of the flour mill and its operations are to be observed in detail.

- Fortification equipment.
 - Number, age and type of powder feeders.
 - Preventative maintenance schedule and record for powder feeders.
 - Breakdown maintenance records for powder feeders.
 - Feeder control type
 - Type of mixing of premix in flour
 - Condition of auxiliary equipment, hoppers, chutes, airlocks, injectors and pneumatic lines.
- Fortification procedures and operations
 - Presence of written procedures
 - Clear knowledge of critical control points
 - Premix storage and handling
 - Record keeping of premix usage and flour production
 - Verification of flour production rate
 - Calibration of powder mixer
 - Data recording, calculations and analysis.
 - Process capability with respect to meeting micronutrient concentration requirements
- Commitment to Quality
 - Written quality assurance policy (QAP)
 - Management's attitude to quality and fortification
 - Training of operating personnel.
 - Availability of QC manuals, operating procedures and best manufacturing practices
- Ability to share data
 - Frequency and type of data recording - automatic or manual
 - Type of data analysis and data storage - paper or electronic.

Inspectors should look at all aspects of the fortification process under as wide a variety of conditions as possible. The reactions of plant personnel to adverse conditions should be especially noted.

Each individual mill will be graded on a scale of 1 to 10 on the following topics:

1. The ability of the fortification system to provide the level, precision and consistency of fortification required, i.e., process capability
2. The degree and consistency of process control.
3. The degree of accuracy of the data being generated.
4. Sampling points and procedures.
5. The level of commitment to quality of fortification
6. The knowledge and diligence of the mill operators
7. Data handling, calculations, analysis of data generated and storage of data

The individual grades are summed, and an overall percentage grade calculated. An overall grade is then assigned as follows:

- A.....85 to 100 %
- B.....75 to 85 %
- C.....55 to 75 %
- F.....below 55 %

This initial inspection report and grade will set the level and rigorousness of future inspections, data analysis and sampling of the mill. The long term objective is to have all mills consistently maintain a grade of B average and above.

In addition to the results of sampling based on corroborating tests, the schedule of subsequent actions will be determined according to the scheme below based on an overall grade of the mill:

Initial Inspection Grade	A B C F
Monitoring Intensity	RELAXED NORMAL DEMANDING

Monitoring should be considered as a dynamic system, and it is expected that mills will continually improve and demonstrate that improvement with improving grades

4.2.2 Sampling

Inspection of flour and verification of legal compliance should be based on the analytical assessment of the micronutrient content by means of a quantitative assay. All samples should contain the fortificant, and at least 80% of samples in factories, importation sites, and warehouses should present the legal minimum, and less than 20% of them should have micronutrient content above but always near the maximum tolerable level. (Table 1 is an example of success criteria use for regulatory monitoring). If this is not the case, then more frequent visits to the factory will be carried out.

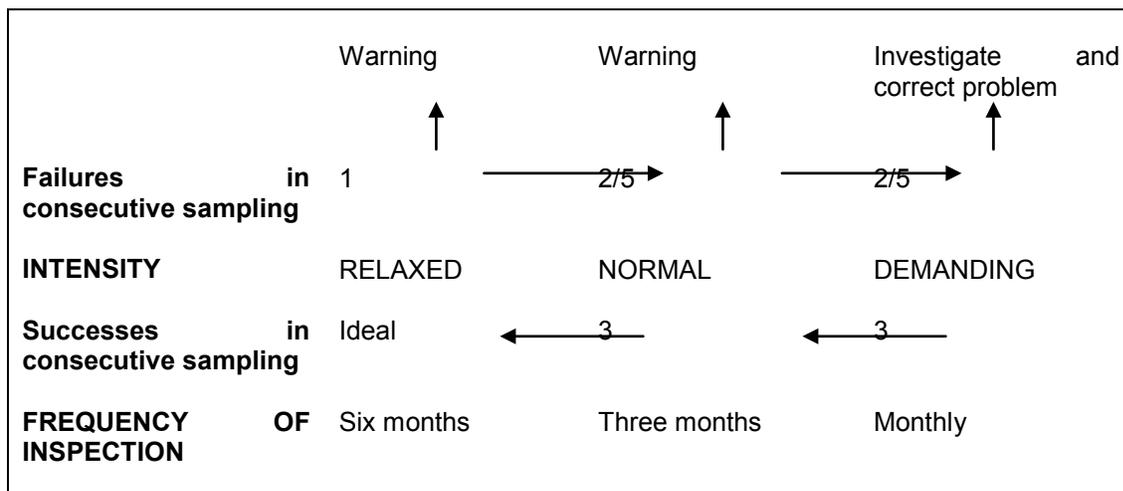
In theory, sampling should follow a statistically based approach, such as that recommended by the Codex Alimentarius (volume 13). However, in practice, the number of samples and the analytical work is overwhelming for the human, financial and material resources of any food

control body. The Board will reserve sampling procedure recommended by Codex for quality auditing for evaluation of conformity, for cases when the product requires a Certificate of Conformity for exportation, or if there is a legal controversy that might lead to serious penalties.

However for routine sampling, the Board will implement a simple and low cost monitoring system, through *corroborating tests*. These tests consist of checking compliance with fortification standards in a small number of samples (5-10 product samples from factories) during the moment of inspection visit, including samples from the line of production and those stored in the warehouses. In all cases, at least 80% of the samples must contain the legal minimum of the micronutrient, and less than 20% should be above, but never too far from the maximum tolerable level. If these criteria are not fulfilled, then a warning statement must be provided and more frequent visits for technical auditing and inspection should be planned to the factories responsible for the product. In extreme cases, a quality audit with conformity might be necessary. The concept of corroborating tests is based on the principle that quality is the main responsibility of producers; while enforcement agencies only act to represent the public, and guarantee that this is indeed the case.

Figure 9 shows an example of a dynamic sampling system during inspections for external monitoring. Under optimal operations, sampling at each site (about 5 flour samples per site) at every six months might be sufficient, which categorizes a “relaxed” or low intensity of inspection and sampling. If the technical specifications of the product are not attained, then inspection and sampling frequency should be increased from the relaxed intensity to a “normal” intensity and corrective actions should be taken. In the normal situation, if on 2 out of 5 consecutive sampling times the product fails to meet the technical requirements, then the intensity of inspection and sampling should be changed to a “demanding” or high intensity, and corrective actions should be implemented. If again, in 2 out of 5 consecutive sampling periods the technical requirements are not achieved, then the production should be stopped until the source of error is found and the necessary corrective measures are introduced. Once production is reinitiated, inspection and sampling should start at the demanding intensity, and switched to normal and then to relaxed intensities if in 3 consecutive sampling periods, the technical specifications are achieved.

Figure 9. Frequency and intensity of sampling for verification tests in external monitoring



During the visits, the inspectors should carry out the following activities:

- Confirm whether corrective measures were carried out, as indicated in the previous inspection results.
- Confirm that the producer carried out QC procedures, and review records to verify that they are up-to-date.
- Carry out verification tests: 5 individual samples of 1.5 kg weight will be collected from different packaged flours that were produced at the time of the visit. Each sample should be separated into three smaller samples of 500g each – one to remain at the mill, one to be sent to the laboratory for testing, and one that the regulatory agency will maintain as the official sample in case the other two do not agree to their results.
- Transfer flour samples into bottles or plastic sheaths closed and protected from light, moisture, and heat. The samples should be correctly labeled and clearly identified with the name or code of each mill, the date of production, the date of collection, and indication of where the sample was taken (production line or warehouse).
- Conduct quantitative iron determination and analysis of at least one of the complex B vitamin, if they are added as fortificants. The laboratory will send the results to the Project Manager of the EA within 15 days following the inspection visit.
- The PM of the EA will report the results to each mill and to the NFFA and Project Coordinator.
- Depending on the results, the frequency/intensity of the inspection visits will be maintained, increased or decreased. During the first six months of the launching the wheat flour fortification program, a twice monthly visit is recommended and subsequently reduced in frequency with consistently adequate results in performance.

4.3 Laboratory Analysis

Sampling and analysis of the wheat flour product of the various micronutrients is a vital part of regulatory monitoring. The accurate analysis of the constituent micronutrients is the final arbiter of their presence at regulation levels of these micronutrients.

The Food and Drugs Board laboratory will carry out most of the quantitative analysis of the sampled flour for Iron and Vitamin B to a rigorous system of quality control. Where necessary, samples will be analysed in any of the laboratories of the Universities of Ghana, Cape Coast and KNUST. In all cases, the same methodology shall be used.

The determination of iron, and in some, at least one complex B vitamin or one micronutrient constituent in a premix will be used as a proxy for the analysis of all others. Due to the complexity and cost of quantitative analysis of vitamins, these may not be performed on a routine basis. Iron analysis is relatively simple and well known will always be done and the levels of the other micronutrients may be assumed from the iron content results, where conducting other analytical methods on a routine basis is not feasible.

To ensure that this assumption holds, a routine of complete analysis of the premix should be done in order to verify the premix micronutrient levels at least once a year. (see **Part 2**).

Reporting:

The analytical reports of each sample will bear the following information to enable ease of traceability and identity:

- Sample Name
- Batch No.
- Date of fortification
- Milling Establishment:
- Date of sampling
- Level of IRON or VIT. B
- Date of testing

The reports will be reviewed monthly by the NFFA and the executing agency for corrective action to be taken when required

The laboratory report with the results will be sent to the PM of the EA and PC and NFFA Chairman who will be responsible for feedback to the mill.

PART V. POST-MARKET SURVEILLANCE

- 5.1 Development of an Annual Inspection Plan
- 5.2 Inspection and Auditing at Wholesale and Retail Sites
- 5.3 Laboratory Analysis
- 5.4 Dissemination of Information

Post Market Surveillance (PMS) or commercial monitoring will be conducted by the EA as a verification that the fortified wheat flour complies with national standards at the level of retail facilities and bakeries. The EA shall conduct corroborating tests to confirm quality and verify adequate labeling.

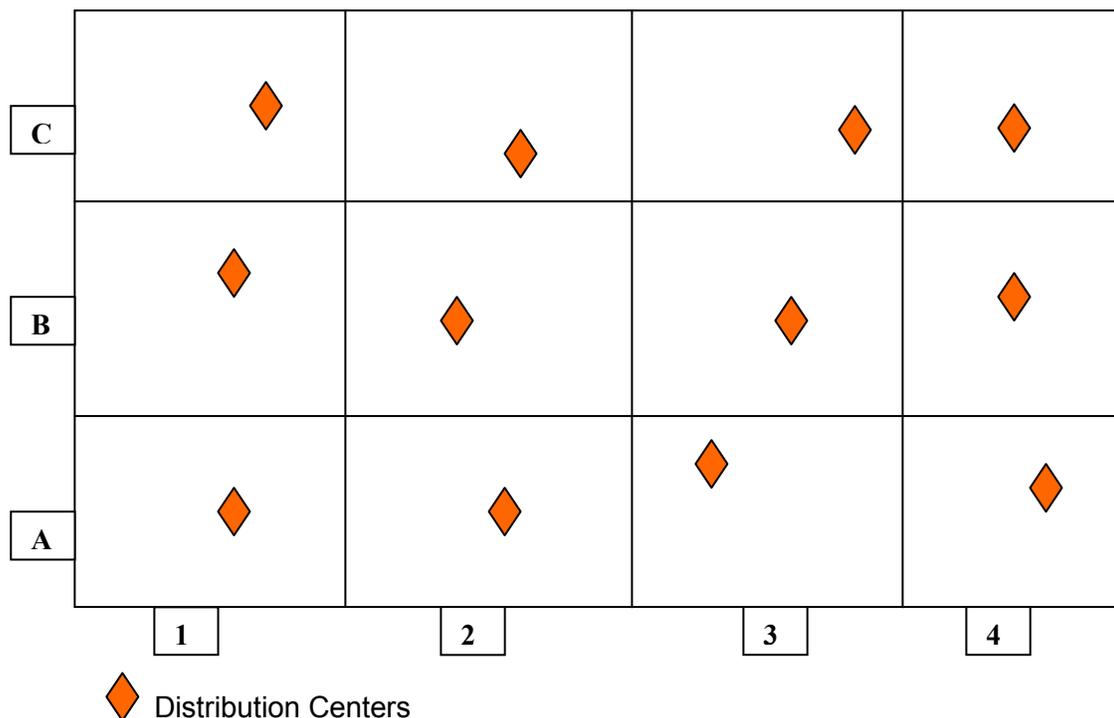
5.1 Development of an Annual Inspection Plan

In Post Market Surveillance/commercial monitoring, the time lag between manufacture of wheat flour and its purchase by the final consumer is acknowledged. The following information from the mills will be used in the design of the surveillance plan:

- Details of the wheat flour distribution system of each mill.
 - Number, location and capacity of flour mills
 - Number, location and capacity of bulk flour distribution centers and warehouses
 - Number, location and capacity of retail centers and facilities that use wheat flour as raw material
- Average distribution time based on details of the distribution system for fortified wheat flour at the national, regional and local levels. The distribution system should take into consideration the different types of flour and its derived products, e.g. flour for domestic use, bread, doughnut, etc. The objective is to determine which areas of the country have longer distribution times that might cause higher levels of deterioration of the fortificant concentrations.
- Classification of distribution times. Classification should be by 3 months or less, 3 to 6 months, 6 to 9 months, 9 to 12 months, and 12 + months. The determination of distribution times will guide decision making for the monitoring and inspection of flour distribution centers. Monitoring and sampling will be concentrated on areas of greater than 6 months.
- As part of the monitoring efforts the distribution center management shall show proof that flour is being warehoused and distributed according to FIFO.
- The following Sampling Protocol shall apply:
 - Sample size shall be 1 kg.
 - Sample shall be collected using clean plastic scoopers.
 - Samples shall be placed in heavy duty polyethylene bags or containers and sealed, with the sample data immediately recorded.
 - Sampling will be done randomly.
 - Numbers shall be assigned to rows, stacks and pallets to facilitate the collection of sample from position corresponding to a random number.

- If sample results show less than acceptable fortificant levels consistently due to degradation of fortificants, ways to reduce distribution time or other possible improvements shall be investigated.

Figure 10. Example of Flour Distribution Times and Inspection Priority



Region	Distribution Throughput (000) t/yr Inventory on Dec 31 (000) t		Distribution Time (month)	Sample & Inspection Priority 1 - 5
	Throughput	Inventory		
1A	35	5	1.7	5
2A	30	10	4	3
3A	50	10	2.4	4
4A	40	10	3.0	4
1B	60	20	4.0	3
2B	10	8	9.6	1
3B	100	10	1.2	5
4B	50	20	4.8	3
1C	20	15	9	1
2C	5	1	2.4	4
3C	80	20	3	4
4C	5	2	4.8	3
	475	131	3.3	

5.2 Inspection and Auditing at Wholesale and Retail Sites

5.2.1 Inspection and Auditing

Post Market Surveillance/commercial monitoring is an essential component of regulatory monitoring and can be particularly useful to identify brands and factories that deserve closer auditing. Retail centers shall be inspected for various aspects, and similar to the case of corroborating tests suggested for mills, one or two flour samples of each brand in each retail store shall be collected to check for compliance to national standards. If anomalies are found, then a technical audit of the responsible mill or importing factory is warranted. Semi-quantitative Iron Spot Tests will be conducted to monitor compliance at retail stores, and as a tool to stress enforcement at the local level. However, any legal action will be based on results obtained from quantitative assays as part of a quality auditing visit.

Inspectors shall visit bakeries, companies that use wheat flour as raw material, and wheat flour traders. Priority should be made to select the most important facilities, taking into account the sale in volume. Geographical areas where the population is more vulnerable should also be prioritized. Inspection visits should be conducted randomly or by selected criteria. **The sampling should be annual and programmed at the beginning of every year.**

In addition to the inspection of sanitary controls, food inspectors will examine the quality of the fortified flour being marketed. The local food control authorities (Environmental Health Officers) will be trained to assist in the of fortified wheat flour at the district and local levels. **The EHOs will be equipped with clear guidelines to enable them recognize registered and adequately labeled food, corroborate the presence of micronutrients in the fortified food utilizing semi-quantitative tests, and collect flour samples. They will also be trained on how to implement corrective measures and on mechanisms for handling failures to achieve national standards and regulations, including procedures for product seizure.**

Requirements for Inspectors:

- All inspectors should be familiar with the latest labeling and packaging specifications.
- Inspectors should observe if adequate packaging is used for the various flour types and sizes being produced and sold.
- Inspectors should observe for correct labeling and declaration requirements:
 - Date of manufacture
 - Declaration of net contents
 - Declaration of product shelf life and best used before date
 - List and level of fortification ingredients
 - Batch or manufacture number or code that allows traceability
- Inspectors should ensure that no false claims or declarations are made on packaging and labeling.

Imported Flour

Where fortified wheat flour is imported, nutrient content shall meet the same requirements as locally produced wheat flour. FDB inspectors and Customs authorities shall collaborate to

prevent any imported fortified wheat flour being released until its compliance with the norms is verified.

Along with the annual inspection plan, a proper sampling plan should be in place to determine the nutrient content of all imported fortified wheat flour. **When countries import unfortified wheat flour and national mandate is for all flour to be fortified, the government must ensure that this imported flour is fortified before it goes into the market.**

5.2.2 Sampling

The Head of Inspection Department of the EA is responsible for clearly communicating the inspection and sampling plan and procedures to all inspectors under his/her jurisdiction. Inspectors should collect 2 flour samples at each designated bakery or company that produced wheat flour products in the corresponding months. Samples should be taken in different municipalities, and a municipality should not be sampled again until all the other departmental municipalities have contributed samples. The frequency of sampling shall be based on the population density in the geographical area. However, priority shall be given to sampling at the most important facilities, taking into account the sale in volume, or where the population is more vulnerable.

Sampling Protocol

A sample of 1 kg of flour per brand should be taken in each retail facility.

Transported sample in flasks or plastic sheaths, closed, protected from light, moisture and heat.

Label samples indicating:

place of collection

the date of sampling,

the brand,

and any other relevant information.

The samples shall be sent to the corresponding laboratory for analysis and issuance of report within 15 days. Feedback on the results will be sent to the relevant factory. All samples shall be tested for Iron and one Vitamin B.

All flour samples should contain the required fortificants, and at least 80% of the samples should present the legal minimum, and less than 20% of them should have micronutrient content above but always near the maximum tolerable level. (Table 1 is an example of success criteria use for regulatory monitoring).

5.3 Laboratory Analysis

Sampling and analysis of the wheat flour product of the various micronutrients is a vital part of regulatory monitoring. The accurate analysis of the constituent micronutrients is the final arbiter of their presence at regulation levels of these micronutrients.

The Food and Drugs Board laboratory will carry out most of the quantitative analysis of the sampled flour for Iron and Vitamin B to a rigorous system of quality control. Where necessary, samples will be analyzed in any of the laboratories of the

Universities of Ghana, Cape Coast and KNUST. In all cases, the same methodology shall be used.

The determination of iron and in some, at least one complex B vitamin or one micronutrient constituent in a premix will be used as a proxy for the analysis of all others. Due to the complexity and cost of quantitative analysis of vitamins, these may not be performed on a routine basis. Iron analysis is relatively simple and well known will always be done and the levels of the other micronutrients may be assumed from the iron content results, where conducting other analytical methods on a routine basis is not feasible.

To ensure that this assumption holds, a routine of complete analysis of the premix should be done in order to verify the premix micronutrient levels at least once a year. (See **Part 2**).

5.4.1 Reports

The EA will issue quarterly reports on the quality results of fortified wheat flour to the GAIN Secretariat, millers and NFFA secretariat. Two types of report may be issued if necessary:

- 1- Public health personnel and policy planners, who may not be technical experts, but who make policy and program decisions. Program decisions will be based on the conclusions and recommendations in the general report, which should focus on operational issues related to meeting the program objectives; thus it should be written in a format that is clearly understood by non-technical people. This report should be submitted annually before the annual work plans and budgets are developed.
- 2- The scientific community, who will be interested in technical description of the intervention and details of all the activities, carried out including monitoring. The technical report should be sufficiently detailed to allow the reader to evaluate the quality of the program and the reliability of the conclusions. The evaluations should also be included in the technical report.

Once the wheat flour fortification program is fully operational and working effectively, only shorter annual reports that focus on the monitoring activities will be issued.

At least once a year, a performance summary of the fortification program should be made into a report that should be shared with the public.

APPENDICES

Appendix 1

Example of a Mill Quality Assurance Plan

X Quality Assurance Plan
PART IV: FLOUR FORTIFICATION.

1. Period:

January 1st 2005 to December 31st 2007

2. Approved:

J. Mensah, December 15th 2006.

3. Plan Review:

November 15th & 16th, 2006

2007 Plan ready by: November 30th, 2006, approval by December 15th, 2006

4. Objective:

To fortify mills entire target production of X metric tonnes per year according to national fortification regulations.

5. Fortification level:

Milled flour will be fortified to levels as shown in table below.

Micronutrient	Concentration in Flour Product mg/kg	Fortification Chemical
<i>Thiamine</i>	<i>6.2</i>	Thiamine Mononitrate
<i>Riboflavin</i>	<i>4.2</i>	Riboflavin
<i>Niacin</i>	<i>55</i>	Nicotinamide
<i>Iron</i>	<i>55</i>	Ferrous Fumarate
<i>Folic Acid</i>	<i>1.8</i>	Folic Acid

6. Process Description:

As shown in process flow diagram below, milled flour from sifter floor passes trough flow meter, MG-3, where premix from powder feeder bank, PF-1, 2 or 3 enters pneumatic delivery tube . The flow of premix is regulated by means of micro-processor controller MCP-8 automatically adjusting the fed rate of the powder feeders according to the flour flow measured by MG-3

Both premix and flour enter paddle mixer PM- 16, where mixing of the flour and premix is completed. Discharge from PM-16 flows out to elevator, BE-28 to storage hoppers, SH-P-1 to 5

Samples of product flour to storage are taken at elevator BE-28 discharge at sample point, SP #15.

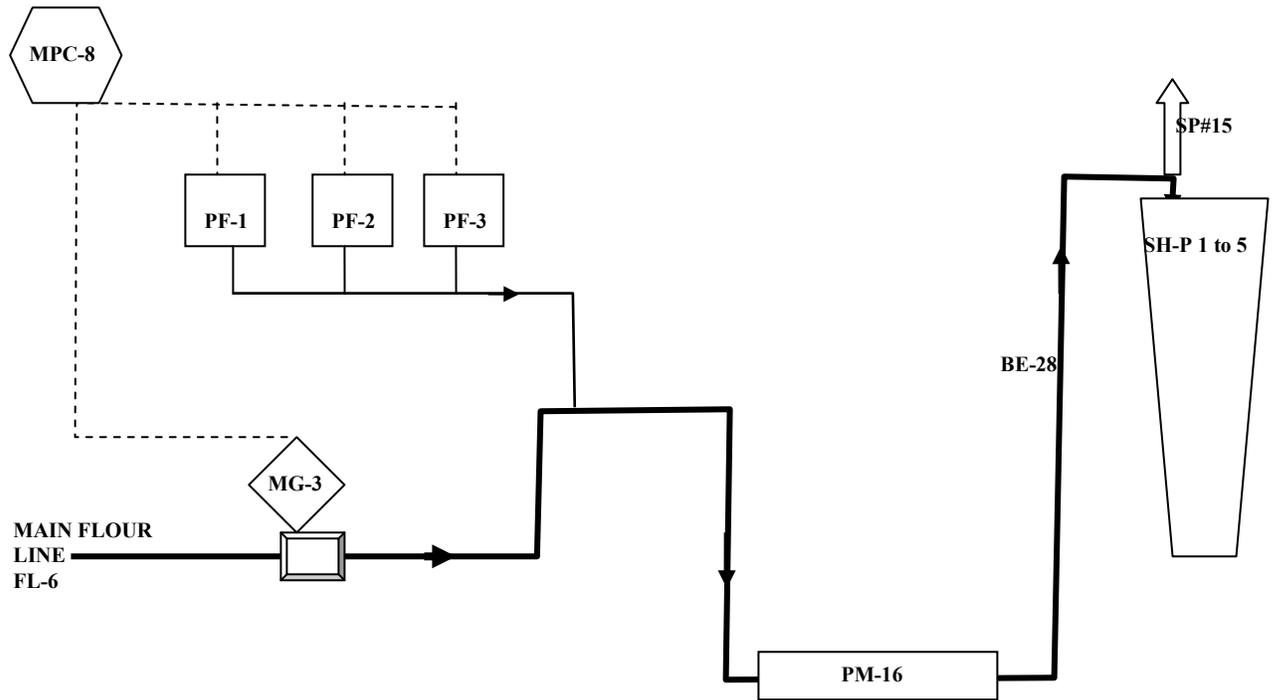


Figure I: Process & Instrumentation Flow Diagram for Fortification Process

7. Quality Assurance Activities & Procedures:

The main process parameters that ensure quality are as follows.

1. Ensure routine checks and preventative maintenance routine and calibration for main flour magnetometer flow meter MG-3. See *SOP Instrumentation MG-3* and
Responsibility: Instrument Technician K.Brown, Supervisor, E.Salia, monthly
2. Ensure routine checks and software routine for microprocessor controller MPC-3. See *SOP Instrumentation MPC-3*
Responsibility: Instrument Technician K.Brown, Supervisor, E. Salia, monthly
3. Ensure weight checks and calibration for powder feeders PF 1, 2 & 3. See *SOP Machines PF 1 to 3, & Maintenance Manual Powder Feeders.*
Responsibility: Ast.Miller E. Amoaful, Supervisor, K. Quarshie, daily weight checks, monthly calibration

8. Target Process Parameters:

(i) Premix:

Use approved pre-mix on of (brand name) purchased and dispensed by the stores. Premix brands are: *XX-1033*

(ii) Addition Rate & Formulation

Both premixes are designed to add at the rate of Y.0 gm premix per 100kg per flour. The formulations of the premix is as follows

	<i>Mescla-Quim premix nacional 224</i>		
	Wt in gm per kg pre-mix		
Thiamin	6.2gm		
Riboflavin	4.2gm		
Niacin	55.0gm		
Iron	55.0gm		
Folic Acid	1.8gm		
Inerts	877.8gm		

(iii) Pre-mix usage

Rate of premix usage at target production is shown as follows:

	hourly	Daily 24hr	Weekly 6 day	Monthly	Yearly
Target production, mt	26	620	3,700	16,670	200,000
Premix usage kg	2.6	62	370	1,667	20,000

(iv) Data Collection

- a. Premix usage record is to filled in daily and approved by the supervisor. The mass balance calculated will immediately show any problems associated with fortification. *Responsibility Ast Miller(all), Supervisor Miller(all)*
- b. Finished product flour samples of 5kg each are to be taken on a twice per shift basis or every 4 hours. The lab test performed by the laboratory analyst is to b observed and recorded by the assistant miller. *Responsibility Ast Miller(all)& Laboratory Ast(all), Supervisor Miller(all) & Lab Supervisor*

Appendix 3
Example of a Premix Reconciliation Worksheet

GAFCO TEMA
 Premix reconciliation work sheet

Week #, Month of, Monday to Saturday.....

Signed.....Supervisor

Date ----- To ----- day	P-mix stores Invent Kg	P-mix rec'd from stores	Premix Inventory			Premix used kg	Flour production ton	Prod'ntime (hr)	Premix add rate kg/hr	Ratio Premix/ Flour kg/ton
			plant	Pwder Feedr #1, kg	Pwder Feedr #2, kg					
1	bod*									
	dd**									
2	bod									
	dd									
3	bod									
	dd									
4	bod									
	dd									
5	bod									
	dd									
6	bod									
	dd									
7	bod									
Week total										
eow***										

Comments:

* bod = beginning of day at 8:00am
 **dd = during day
 *** eow= end of week physical inventory

Example of a Mill Premix reconciliation Worksheet – COMPLETED

GAFCO, TEMA
Pre-mix reconciliation work sheet

Week #, month of, Monday to Saturday.....

Signed.....Supervisor

Date ----- To ----- day		P-mix stores Invent Kg	P-mix rec'd From stores	Premix Inventory			Premix used kg	Flour production ton	Prod'ntime (hr)	Premix add rate kg/hr	Ratio Premix/ Flour kg/ton
				plant	Pwder Feedr #1, kg	Pwder Feedr #2, kg					
1	bod*	4000		50	25	0					
	dd**		30				70	690	24	2.92	.10
2	bod	3970		25	10	0					
	dd		100				75	700	24	3.13	.11
3	bod	3870		50	10	0					
	dd		100				40	400	15.25	2.62	.10
4	bod	3770		100	20	0					
	dd		150				70	680	24	2.92	.10
5	bod	3670		150	0	50					
	dd		150				65	630	24	2.71	.10
6	bod	3520		200	0	85					
	dd		30				65	630	24	2.71	10
7	bod	1600		200	0	50					
Week total			560				385	3730			
eow***		1600		200	0	50					

* bod = beginning of day at 8:00am
**dd = during day
*** eow= end of week physical inventory

Appendix 4
Example of a Production Rate Record

GAFCO, TEMA: Weekly Production Rate Record

Mill Rated Production 200MT per day, 138.8 kg/min Target Production 200 MT per day

Date	Shift Details						Production				Production Rate		
	#	Letter	Begin	End	Down time	Total Run-time	25 kg bags	Trucks Loaded		Total Prod. mt	Mt/hr	Kg/min	
							#	mt					
	1	A	06:00	14:00	3.5	4.5	500	1	25	37.5	8.33	138.9	
	2	B	14:00	22:00	0	8	2700	0	0	67.5	8.44	140.6	
	3	C	22:00	06:00	0	8	2680	0	0	67.0	8.38	139.6	
	TOTALS						20.5	5880	1	25	172.0	8.39	139.8
	4	A	06:00	14:00	0	8	2766	0	0	69.15	8.64	144.1	
	5	B	14:00	22:00	0	8	2734	0	0	68.35	8.54	142.3	
	6	C	22:00	06:00	0	8	2693	0	0	67.33	8.42	140.3	
	TOTALS						24	8193	0	0	204.8	8.53	142.2
	7	A	06:00	14:00	0	8	500	0	0	65.98	8.25	137.5	
	8	B	14:00	22:00	2	6	2700	0	0	50.25	8.38	139.58	
	9	C	22:00	06:00	6.5	1.5	2680	0	0	11.40	7.60	126.7	
	TOTALS					8.5	15.5	5105	0	0	127.6	8.23	137.2
	10	A	06:00	14:00	2	6	106	2	47	49.65	8.28	137.9	
	11	B	14:00	22:00	0	8	632	2	48	63.80	7.98	132.9	
	12	C	22:00	06:00	0	8	2680	0	0	67.00	8.38	139.6	
	TOTALS					2	22	3418	4	95	180.5	8.20	136.7
	13	A	06:00	14:00	0	8	1768	1	23	67.20	8.40	140.0	
	14	B	14:00	22:00	3.3	4.7	1487	0	0	37.18	7.91	131.8	
	15	C	22:00	06:00	7.5	0.5	196	0	0	4.90	9.80	163.3	
	TOTALS					10.8	13.2	3451	1	23	109.3	8.28	137.97
	16	A	06:00	14:00	3.5	4.5	500	1	25	37.50	8.33	138.9	
	17	B	14:00	22:00	0	8	2700	0	0	67.50	8.44	140.6	
	18	C	22:00	06:00	0	8	2680	0	0	67.00	8.38	139.6	
	TOTALS					3.5	20.5	5880	1	25	172.0	8.39	139.8
	19	A	06:00	14:00	0	0	0	0	0	0	0	0	
	20	B	14:00	22:00	0	0	0	0	0	0	0	0	
	21	C	22:00	06:00	0	0	0	0	0	0	0	0	
	TOTALS					0	0	0	0	0	0	0	
	WEEK TOTAL					28.3.3	115.7		7	168	966.2	8.35	139.18

Appendix 6

[Semi-Q Methods for ALL IRON to be included here](#)

Semi-quantitative Spot Test for Iron - INCAP method IV

(Adaptation of the Official Methods of Analysis of the American Association of Chemists of Grains – AACC. Method No. 40-40 qualitative method for iron)

I. Materials

Watch glass
Droppers

II. Equipment

None

III. Reagents and Solutions

Hydrochloric acid, HCl, 37% Merck 317

Hydrogen peroxide, H₂O₂, 30%, Merck 7209 (it is possible to replace this reagent with commercial oxygenated water)

Potassium thiocyanate, KSCN, Merck 5124 or 5125

KSCN - 10%: Dissolve 10 g of KSCN in 100 ml distilled water.

HCl - 2M: To a 500 ml beaker add 100 ml distilled water, then 17 ml concentrated HCl, and finally 83 ml distilled water.

H₂O₂ - 3%: Add 9 ml concentrated H₂O₂ (30%) to 81 ml distilled water.

Reagent 1

Immediately before using, mix equal amounts of 10% KSCN and 2M HCl. Mark the levels of 20 and 40 ml on a flask using a pipette. Add 2M HCl up to the first mark and then add 10% KSCN up to the second mark. This is reagent 1. Use within 1 day. Discard the remainder.

Reagent 2

3% H₂O₂. Discard remaining solution at the end of the day.

IV. Procedure

1. Take a sample of 100 g of flour and place it on the watch glass. With the lower part of another watch glass, press on the flour sample so that it forms a flat surface.
2. Add 5 drops of reagent 1 with the dropper so that it covers an area of 4x4 cm (1.5x1.5 inches). Let stand 15 to 30 seconds.
3. Add 5 drops of reagent 2 on the surface covered by reagent 1. Let stand 1 to 2 minutes.

V. Interpretation

The appearance of red-colored spots indicates the presence of iron. The number of spots is a rough estimate of the amount and homogeneity of iron in the sample. If a more accurate estimation is required, test with known concentrations of iron (30, 60, and 90 ppm) and compare the results with those of the test samples.

Appendix 8

Quantitative Method for Iron Analysis

Quantitative:

Spectrophotometric method (AACC 40-41B, Appendix 3.6; INCAP method VI, Appendix 3.7) — Cereals, cereal products, premixes, various other food products and ingredients
Atomic absorption method (AACC 40-70, Appendix 3.8; AOAC 975.03, Appendix 3.9;
Wet ashing, Appendix 3.10) — Cereals, cereal products, premixes, and other plant foods

A. Spectrophotometric method

This method is approved by AACC for quantitative determinations of iron in cereals and cerealbasedfood products. (See Appendix 3.6.)

Principle

Organic constituents in a food sample are broken down by dry or wet ashing at a high temperature and the inorganic constituents are dissolved in a mildly acidic solution. Solubilized ferrous iron is then reacted with a chromogenic reagent, orthophenanthroline, in the presence of a reducing agent (such as hydroxylamine hydrochloride), resulting in a pink-colored complex. The concentration of iron is determined by its spectrophotometric absorbance at 510 nm.

Advantages

1. It is applicable to various types of food products and ingredients.
2. It is a sensitive technique with a detection limit of less than 1 ppm (1 mg/g or 1 mg/Kg) of iron in sample.
3. It is relatively inexpensive compared with atomic absorption spectroscopy (AAS) or emission spectroscopy methods.
4. The ashed solution can be used for the determination of other inorganic elements.

Limitations

1. It requires personnel trained to handle corrosive chemicals and to operate the spectrophotometer or colorimeter.
2. It is a time-consuming procedure involving overnight dry ashing. Samples with high protein content may take longer to be ashed.
3. It is relatively expensive involving costs of reagents, muffle furnace (approximately US\$1,500), and spectrophotometer (between US\$8,500 and 12,000; Appendix 3.1). A fume hood (between US\$3,500 and 13,000) is needed for wet ashing of samples.

Notes

1. It requires the preparation of an iron standard curve.
2. The reagents must be stored in the refrigerator.
3. Chromogens other than ortho-phenanthroline, such as a,a-dipyridyl, bathophenanthroline, and ferrozine, also react with ferrous iron and are widely used for iron determinations in various food laboratories. (See INCAP method VI, Appendix 3.7.)
4. Although dry ashing is recommended, wet ashing may also be used for spectrophotometric iron determination. Wet ashing procedures are described in Appendices 3.9 (sample preparation) and 3.10.

Iron spectrophotometric method

AACC method 40 40-41B

-Final approval May 5, 1960; reapproval November 3, 1999

This method determines iron content by reaction with orthophenanthroline and spectrophotometric measurement. It is applicable to cereals and cereal-based products.

I. Materials

Volumetric flask, 1 L

Volumetric flasks, 250 mL

Volumetric flasks, 100 mL

Volumetric flasks, 25 mL

Beakers, 250 mL

Manual volumetric pipettes, 1000 mL

Watch glasses

Pipette tips

Graduated tubes

Tips for 'blue' pipettes

Test tubes, 10 mL

II. Equipment

Muffle furnace capable of maintaining 550 °

Platinum, silica, or porcelain crucible, approximately 60 mm diameter, 35 ml capacity. Porcelain evaporating dishes of about 25 ml capacity are satisfactory. Do not use flat-bottomed dishes of greater diameter than 60 mm.

Spectrophotometer or colorimeter

Eppendorf pipettes, 100 mL and 500 mL

Analytical balance

Vortex mixer

Hot plate

III. Reagents

1. Orthophenanthroline solution. Dissolve 0.1 g *o*-phenanthroline in about 80 ml water at 80°, cool, and dilute to 100 ml. Store in amber bottle in refrigerator. (Stable for up to several weeks.)

2. Iron standard solution, 10 µg Fe/ml. a) Dissolve 0.1g analytical grade Fe wire in 20 ml HCl and 50 ml water, and dilute to 1 liter. Dilute 100 ml of this solution to 1 liter; or b) dissolve 3.512 g Fe(NH₄)₂(SO₄)₂·6H₂O in water, add 2 drops HCl, and dilute to 500 ml. Dilute 10 ml of this solution to 1 liter.

3. Hydroxylamine hydrochloride solution. Dissolve 10 g NH₂OH·HCl in water and dilute to 100 ml. Store in amber bottle in refrigerator. (This solution is stable for several weeks.)

4. Acetate buffer solution. Dissolve 8.3 g anhydrous sodium acetate (previously dried at 100°) in water, add 12 ml acetic acid, and dilute to 100 ml. (It may be necessary to redistill the acetic acid and purify sodium acetate by recrystallization from water, depending on amount of Fe present.)

5. Prepare working standards as follows: Place aliquots of the 10 µg/ml standard solution according to table below into 100 ml volumetric flasks, add 2 ml concentrated HCl to each, and dilute to volume.

22

**Aliquot of 10 µg/ml Final Fe concentration
solution taken (ml) (ppm)**

0	0
2	0.2
5	0.5
10	1.0
15	1.5
20	2.0
25	2.5
30	3.0
35	3.5
40	4.0
45	4.5

Mix thoroughly by inverting flask 10-20 times. Using 10 ml of each of these standard solutions, continue under procedure beginning with step 8.

6. Ashing aid

- a. Magnesium nitrate solution. Dissolve 50 g $\text{Mg}(\text{NO}_3)_2 \cdot 6\text{H}_2\text{O}$ in water and dilute to 100 ml *or*
- b. Redistilled HNO_3

IV. Procedure

1. Accurately weigh 2-10 g of sample (depending on concentration of iron expected) into clean crucible. (Begin to prepare blank solution at this point in same manner as sample.)
2. Char on hot plate or under infrared lamp (optional).
3. Ash overnight in muffle furnace at $<550^\circ$. See Notes.
4. Remove crucible from furnace and cool to room temperature.
5. Carefully add 5 ml concentrated HCl, letting acid rinse upper portion of crucible; evaporate to dryness on steam bath.
6. Dissolve residue by adding 2 ml concentrated HCl, accurately measured; cover with watch glass and heat 5 min on steam bath.
7. Rinse watch glass with water, filter quantitatively into 100 ml volumetric flask, dilute to volume, and mix thoroughly.
8. Pipet 10 ml aliquot into 25 ml volumetric flask, and add 1 ml hydroxylamine HCl solution. Mix thoroughly.
9. After 5 min, add 5 ml buffer solution and 1 ml *o*-phenanthroline; dilute to volume. Mix thoroughly.
10. Let stand 30 min, then measure absorbance of samples, standards, and blank solutions in spectrophotometer at 510 nm. Note:
 - a. If color intensity is too great, make appropriate dilution of ash solution and continue beginning at step 8.
 - b. Color produced is permanent for several hours. Keep out of direct sunlight.

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V. Interpretation/Calculations

1. Plot absorbance vs concentration (in ppm) for standard solutions.
2. Obtain concentration of sample solutions from standard curve, subtracting blank value from each.
3. Iron content (mg/100 g) = $(C \times DF \times 10) \div W$
where C = concentration of sample solution (in ppm), DF = dilution factor (if any) from step 10, note a, W = sample weight in grams.

VI. Notes

To diminish ashing time or for samples that do not burn practically carbon-free, use one of the following ashing aids: Moisten ash with a) 0.5-1.0 ml magnesium nitrate solution *or* b) redistilled HNO₃. Dry contents and carefully ignite in muffle to prevent spattering. (A white ash with no carbon results in most cases.) Do not add these ashing aids to self-rising flour (products containing NaCl) in platinum dish, because of vigorous action on dish.

VII. References

1. Andrews, J.S. and Felt, C. The iron content of cereals. Cereal Chem 18:8 19.
2. AOAC International. 1998. Official Methods of Analysis of AOAC International, 16th ed., 4th rev, Method 944.02. The Association, Gaithersburg, MD.
3. Howe, M. 1944. Report of the 1943-44 methods of analysis subcommittee on the determination of iron in cereal products. Cereal Chem. 21:412.

Appendix 8
Quantitative Methods...

B vitamins

