

Quality Assurance as Applied to Micronutrient Fortification

Guidelines for Technicians,
Supervisors, and Workers
Concerned with Nutrition

Editors:
Penelope Nestel, PhD
Ritu Nalubola, PhD
Eleanor Mayfield, ELS

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This publication has had a long gestational period. The idea to produce a quality assurance document on micronutrient fortification was initially conceived in 1995 under the OMNI Research Project, a cooperative agreement (HRN-5122-A-00-3046-00) between the U.S. Agency for International Development (USAID) and the International Life Sciences Institute (ILSI) Research Foundation. Food fortification with vitamin A and iron was beginning to be implemented on a large scale in a number of developing countries. The OMNI Research Peer Review Panel identified quality assurance as a critical step in the successful implementation of food fortification and funded two applied research projects to determine the minimum requirements for an effective yet economical quality assurance and control system applicable to food fortification.

In May 1997, a workshop on “Quality Assurance Systems for Improved Nutrition in Developing Countries” was held in Washington, D.C., to report on the research findings and put them into the broader quality assurance context. The following individuals are gratefully acknowledged for providing the background papers for that workshop: Drs. Charles Beck, Stewart Blumenfeld, Omar Dary, Agide Gorgatti Netto, and Herbert Weinstein. The background papers were used by Dr. Paula Trumbo, OMNI Research Project Manager, and Dr. Weinstein to develop the first full draft of the guidelines. Their initiative and hard work were critical in the early phase of this project.

Under the later Micronutrient Global Leadership (MGL) cooperative agreement (HRN-A-00-98-00027-00) between USAID and the ILSI Research Foundation, the draft was transformed by the current editors into a user-friendly document to guide those interested in a broad overview of quality assurance requirements in the production of micronutrient-fortified foods. The MGL project is very grateful for the time and expertise provided by the editors, Dr. Penelope Nestel, Dr. Ritu Nalubola, and Ms. Eleanor Mayfield.

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Table of Contents

LIST OF FIGURES _____	vii
FOREWORD: PURPOSE OF THESE GUIDELINES _____	viii
GLOSSARY OF TERMS _____	ix
CHAPTER 1: INTRODUCTION _____	1
Definitions of Quality Assurance and Quality Control _____	1
What is Quality Assurance? _____	1
Why Implement a Quality Assurance System in Food Fortification? _____	2
Implementing a Quality Assurance Policy _____	2
Elements of a Quality Assurance System for Food Fortification Programs _____	3
Understanding the Production Process _____	5
Section Summary _____	7
Government’s Role in Quality Assurance for Food Fortification Programs _____	7
Regulations and Standards _____	8
Inspection and Certification _____	8
Identification of Substandard Products _____	9
Product Recalls _____	9
Section Summary _____	11
Chapter Summary _____	11
CHAPTER 2: PLANNING QUALITY ASSURANCE SYSTEMS FOR FOOD FORTIFICATION PROGRAMS _____	12
Planning a Quality Assurance System _____	12
Establishing Technical and Nutritional Criteria _____	12
Defining Quality Assurance Criteria _____	13
Section Summary _____	14
Designing a Process for Monitoring Critical Control Points in the Fortification Process _____	18
Section Summary _____	20
Issues to Consider in Setting Up a Quality Assurance System _____	21
Section Summary _____	21
Costs of Developing and Implementing a Quality Assurance System _____	22
Costs of Designing a QA System _____	22
Costs of Maintaining a QA System _____	22
Potential Costs of Failing to Maintain an Adequate QA System _____	23
Another Approach to Calculating Quality Costs _____	24
Using Cost Information to Identify Quality Problems _____	24
Section Summary _____	26
Chapter Summary _____	26

CHAPTER 3: GENERAL GUIDELINES FOR IMPLEMENTING QUALITY ASSURANCE SYSTEMS FOR FOOD FORTIFICATION PROGRAMS	27
Quality Assurance in the Handling of the Premix	27
Section Summary	28
Quality Assurance in the Manufacturing Process	28
Identifying and Correcting Quality Problems	28
Section Summary	31
Quality Assurance in the Fortified Food Distribution Process	32
Packaging	32
Labeling	34
Storage	34
Transportation	35
Section Summary	36
Chapter Summary	36
Appendix 1. Regulation of Fortified Foods in the Philippines: Extracts from Implementing Rules and Regulations for the Philippine Food Fortification Act of 2000 (Republic Act No. 8976)	37
Appendix 2. Model Principles for Sugar Fortified with Vitamin A	39
Appendix 3. Template for a Quality Assurance/Quality Control Record	41
Appendix 4. Sugar Fortification with Vitamin A: Example of a Completed QA/QC Record	42
BIBLIOGRAPHY	43

List of Figures

Figure 1.1. The triad of modern quality management

Figure 1.2. Fortification: A systems framework

Figure 1.3. Sequence of events in production of vitamin-A-fortified sugar

Figure 1.4. Addition of fortificant to sugar: Detailed sequence of events

Figure 1.5. The quality assurance/quality control process

Figure 2.1. Using costs data to identify errors in fortification levels

Figure 2.2. Using costs data to identify quality problems in a 3-line production plant

Figure 3.1. Common-cause and special-cause variation

Figure 3.2. Fishbone diagram: Causes and effects of potassium iodide precipitation

Foreword: Purpose of These Guidelines

Micronutrient deficiencies in developing countries are widespread, particularly deficiencies of iron, vitamin A, and iodine, although the need for other micronutrients such as folic acid, vitamin B12, and zinc is becoming more evident.

Micronutrient deficiencies can be controlled through the use of pharmaceutical supplements and food fortification. Food fortification is an excellent option where one or more centrally processed foods are eaten on a regular basis and in regular amounts by a large number of people. To be successful, however, all food fortification programs require a system be in place to ensure that the food being fortified contains the desired amounts of micronutrients. The system that is widely applied to any industrial process is known as quality assurance, which includes quality control. These guidelines describe the principles of quality assurance as they relate to a food fortification program.

A sustainable fortification program requires the collaboration of food processors, the public sector, researchers, and donors. The purpose of this document is to provide program managers with the necessary information to ensure that good-quality fortified food is manufactured in order to control micronutrient deficiencies.

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Glossary of Terms

Acceptable range: A range between the minimum and maximum levels of micronutrient fortification that is considered acceptable according to national fortification standards, where they exist, or according to norms recognized by the industry.

Assay: Analysis to determine the presence and quantity of a substance.

Critical control point (CCP): Identified key point in a manufacturing sequence at which measures can be implemented to eliminate, prevent, or minimize a problem or potential problem that adversely affects product quality.

Deviation: Departure from an accepted or approved criterion, norm, or standard.

Fortificant: The micronutrient that is added to a fortified food.

Indicator: A measurable value used to verify that a process is working according to specifications. For example, feed rate can be used as an indicator to verify the correct functioning of a fortification process.

Inspection: Act of measuring, testing, or verifying one or more characteristics of a product or service to establish compliance with standards and specifications.

Integrity: Unimpaired condition.

Inventory: Quantity of goods or materials on hand; stock.

Monitoring: A systematic way of assuring product quality throughout the production process from handling of the raw ingredients to presentation of the product to consumers.

Norm: Recognized standard that products or services must comply with before being made available to consumers.

Nutrition labeling: Information about a food's nutrient content that appears on the food product label.

Open dating: The practice of printing on a food product package the date by which the product should be consumed.

Packaging specifications: Written procedures for packaging a product in a systematic, consistent manner.

Primary packaging: Packaging that is in direct contact with a food product.

Proactive: Acting in anticipation of future problems, needs, or changes.

Quality assurance: The totality of the organized activities undertaken to ensure that a product meets the standards of quality required for its intended use by the consumer.

Quality control: A set of techniques and assessments used to document compliance with established technical standards through the use of objective, measurable indicators. Quality control encompasses supervision and continuous monitoring of inputs, outputs, processes, and outcomes against standards.

Quality design: The design of systems within an organization to assure a focus on quality. Quality design encompasses organizational vision, staff training and empowerment, recognition of customer needs, adoption of a quality assurance policy, and establishment of a quality-control system.

Quality improvement: A component of quality assurance in which processes are examined with the intent of improving them. Quality improvement encompasses problem identification; priority setting; and solution development, implementation, assessment, and refinement.

Quality improvement team: A group of workers who are assigned to identify the cause(s) of and propose solutions for a production problem that is adversely affecting product quality. Usually the workers assigned to the quality improvement team are familiar with the production process in which the problem is occurring.

Quality management: All management activities that determine an organization's quality policy, objectives, and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement.

Quantitative: Designed to determine accurate amounts or proportions of a measurable substance.

Reorder point: A predetermined point at which supplies are ordered to avoid outages or minimum inventories.

Regulation: A standard or requirement of conduct set by a government agency under statutory authority granted by a legislative body. Regulations describe in detail how a piece of legislation is to be implemented and enforced. As such, regulations have the force and effect of law.

Reproducibility: Ability to repeat an action or process and achieve exactly the same outcome.

Secondary control point: Identified control point, secondary to a CCP in a manufacturing sequence, at which measures can be implemented to eliminate, prevent, or minimize a potential problem that may adversely affect product quality. Control points are designated critical or secondary depending on where they are likely to occur in the manufacturing process and how critical they are to maintaining product quality.

Secondary packaging: Outer packaging of a food product that provides additional protection from the environment and from rough handling.

Semiquantitative: Involving less than quantitative precision but accurate enough to estimate the quantity of a measurable substance.

Shelf life: The time between the date of production and packaging of a product and the date on which the product becomes unacceptable for consumption under defined environmental conditions.

Specification: Explicit statement that defines the criteria to be met in a fortified food, e.g., particle size, bulk density, content of micronutrient, moisture, and contaminants.

Stability: The quality of being resistant to changes in chemical or physical properties.

Standard: An approved or accepted criterion that underlies norms and regulations and against which performance or quality may be measured or judged.

Technical auditing: Systematic, independent examinations to determine whether activities undertaken to assure product quality and the outcomes associated with those activities meet standards and specifications.

Unadulterated: Pure, not contaminated.

Chapter 1: Introduction

Key words in this chapter:

<i>acceptable range</i>	<i>integrity</i>	<i>quality improvement</i>	<i>shelf life</i>
<i>assay</i>	<i>monitoring</i>	<i>quality management</i>	<i>specification</i>
<i>critical control point</i>	<i>proactive</i>	<i>quantitative</i>	<i>stability</i>
<i>fortificant</i>	<i>quality assurance</i>	<i>regulation</i>	<i>standard</i>
<i>indicator</i>	<i>quality control</i>	<i>reproducibility</i>	<i>technical auditing</i>
<i>inspection</i>	<i>quality design</i>	<i>semiquantitative</i>	<i>unadulterated</i>

This chapter covers

- definitions of quality assurance and quality control,
- implementing a quality assurance policy,
- elements of a quality assurance system for food fortification programs,
- understanding the production process, and
- government's role in quality assurance for food fortification programs.

Definitions of Quality Assurance and Quality Control

What Is Quality Assurance?

Food industries worldwide apply the principles of *quality management* to improve and sustain the quality of their products. Modern quality management has three interrelated elements: *quality design*, *quality improvement*, and *quality control*. Figure 1.1 shows the major components of each element and their relationship to one another.

Quality assurance (QA) encompasses the totality of the organized activities that are undertaken to ensure that a fortified food meets

the *standards* of quality, which include the criteria stipulated in any relevant food *regulations*. It is a wide-ranging concept that covers everything that influences the quality of the fortified food. QA is a *proactive*, continuous system for monitoring *reproducibility* and reliability of performance by

- setting quality standards and designating responsibility for ensuring that these standards are met,
- defining corrective actions that must be taken when standards are not met, and
- performing quality control measures with a stated level of confidence.

Figure 1.1. The triad of modern quality management



Courtesy of the Quality Assurance Project 2000, Washington DC, USA

Quality control (QC) comprises a set of techniques and assessments used to document compliance with established performance standards through the use of objective, measurable *indicators*. QC is a subset of QA. Effective QC and QA systems have the following features:

- They are designed to allow quick, timely corrections to be carried out when deviations from performance standards are identified, e.g., the concentration of a particular micronutrient is outside the acceptable limits.
- Written records are maintained of all QC and QA activities.

Why Implement a Quality Assurance System in Food Fortification?

In general, the benefits that can be obtained from the implementation of a food fortification QA system include the following:

- Increased control over raw materials or ingredients.

- Improved quality of the fortified food.
- Improved manufacturing of the fortified food, resulting in savings in production costs and higher profits.
- Standardization of and uniformity in the fortified food.
- Better organized manufacturing facility.
- Greater consumer confidence in the uniformly high quality of the fortified food.

Implementing a Quality Assurance Policy

Implementation of a QA policy begins with the most senior people in the food plant. By developing a QA policy and communicating it to all staff in the company, management states its commitment to maintaining high quality in the food fortification process. The policy should be detailed enough to show that management knows exactly how it intends to achieve and sustain a high-quality fortified food.

A typical QA policy statement might read as follows:

- Our company is committed to producing fortified food of the highest possible quality that current technology and acceptable cost permit.
- We will strive to continuously improve the quality of our fortified food.
- All employees of the company will participate in the quality assurance program and will be trained to use the tools and techniques they need to participate effectively.

Senior managers must communicate this policy at regular intervals to all employees. Senior managers must also follow through on the policy statement by

- training all staff to use QA tools that are appropriate to their activities in the company,
- collecting information on the quality of the company's fortified food, and
- analyzing the collected information and taking appropriate action.

Most QA problems result from faults in the physical system rather than from deficiencies in employee abilities. If employees are afraid that problems in quality will be blamed on them, they will worry more about protecting themselves than about identifying problems and their causes. However, it is not the purpose of QA and QC systems to penalize individuals. Producing a fortified food that is of consistently high quality is in the interests of both managers and employees; QA and QC systems should be regarded as tools that help to achieve this goal.

Elements of a Quality Assurance System for Food Fortification Programs

A QA system for food fortification programs must have the following features:

- A defined set of indicators and methods for assuring that at the end of the fortification

process the fortified food has certain expected characteristics.

- A systematic process for demonstrating compliance with established *specifications* and standards through systematic *inspection*, *technical auditing*, and *monitoring* to assure that a defined level of quality is maintained at production, distribution, and marketing centers.
- Systematic documentation of quality assurance activities in the form of records and reports.

QC procedures are required at the following points in the production process for a fortified food:

- **Raw material control.** Appropriate specifications must be adopted for all ingredients, and all ingredients must be inspected to ensure that they conform with these specifications.
- **Production control.** Quality factors and hazards relating to the production process must be identified. *Critical control points* must be established and monitored.
- **Fortified food control.** The fortified food must satisfy all quality parameters, be *unadulterated*, and be properly labeled. It must be protected from the environment through appropriate packaging that maintains product *integrity* and the *stability* of its micronutrient content throughout the *shelflife* of the product. To ensure that product integrity is maintained until the product reaches the consumer, the fortified food must be stored in clean, dry, well-ventilated conditions and transported with care by a safe, clean, appropriate mode of transportation.

Because government enforcement of food laws and regulations is weak or nonexistent in

many developing countries (due to the limited degree of industrial development and resources), the fortification of a food must be continuously monitored at the production level. These guidelines emphasize government participation at that level. As food regulatory systems mature, inspection and monitoring can be expanded to eventually rely on routine verification of food quality at distribution and retail outlets.

Essential elements of a QA system for food fortification programs are as follows:

- **Rapid, simple analytical assays.** Corrective decisions must be made in a timely fashion because once a fortified food is produced, it is hardly ever reprocessed. Micronutrient *assays* must be performed using quick, easy laboratory methods, which may be *quantitative* or *semiquantitative*. If semiquantitative, they must be sensitive enough to establish a range for the level of the nutrient(s) being added, and the analyzed food sample must represent the fortified food produced in a specified time.
- **Packaging in labeled bags.** Fortified foods must be prepackaged for retail sale. In developing countries, programs to fortify sugar with vitamin A and salt with iodine sometimes fail to deliver an effectively fortified food to the consumer because the foods are marketed in bulk and sold to consumers in small quantities from a bag or drum at the retail shop. Until such practices cease, QA systems in fortified food production cannot result in an effective program to control micronutrient deficiency. The label on the fortified food must include the name of the food, a list of ingredients used to make it, the name and address of the producer, and the minimum acceptable level of micronutrients.
- **Inspection, technical auditing, and monitoring.** The purpose of these activities is to verify as accurately as possible that the fortified food complies with the appropriate standards and specifications for food fortification. These activities therefore must be based on quantitative analytical methods. To ensure that results are meaningful, expertise will be required to develop a plan for statistical sampling so that a sufficient number of representative samples of the fortified food are tested at the production plant. For QC purposes, 90% of individual analyzed samples should fall within the specified *acceptable range* for micronutrient content.
- **Documentation and general supervision.** One of the most important factors limiting the success of food fortification programs in developing countries is the absence of adequate documentation. Because food control agencies are often weak, quality audits, inspections, and monitoring activities are rarely performed and, when they are performed, poorly documented. As a result, companies lose interest in maintaining their QA and QC practices, and food fortification programs cease to be effective and in some instances cease to exist.

To overcome this problem, it is recommended that an interinstitutional group be set up to oversee food fortification programs. This group should include, at a minimum, representatives of the relevant food industries and officials of government agencies responsible for supervising and evaluating fortification programs. Consultants from national and international agencies that provide technical assistance to fortification programs can also be invited to join. In ad-

dition to maintaining general supervision of fortification programs and publishing regular reports on the status of these programs, this group would provide a forum in which to discuss problems and arrive (preferably by consensus) at solutions.

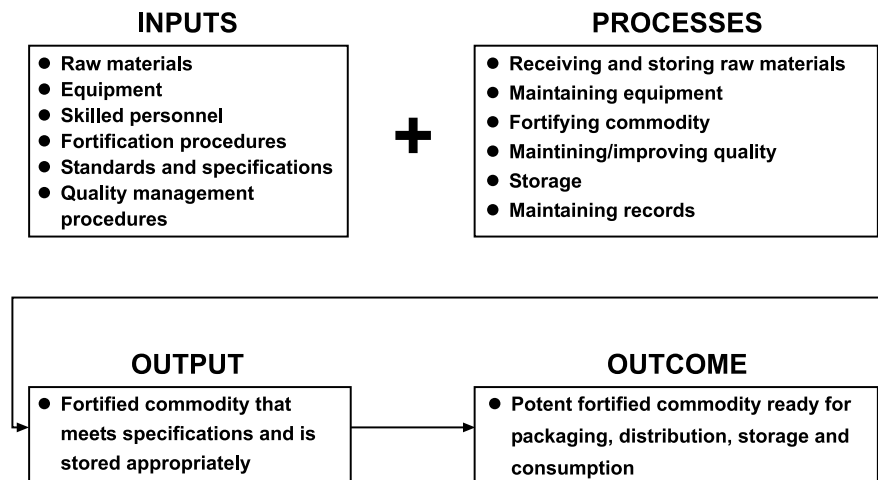
Understanding the Production Process

The key to maintaining standards of quality is to identify and correct problems in the fortification process. However, problems can be identified and corrected only when the flow of the fortification process is thoroughly understood. A systems framework such as that depicted in Figure 1.2 identifies the resources needed and the steps that must be carried out for the system to function properly. A systems framework is particularly helpful when design-

ing a new system, but it can also be used to check an existing system.

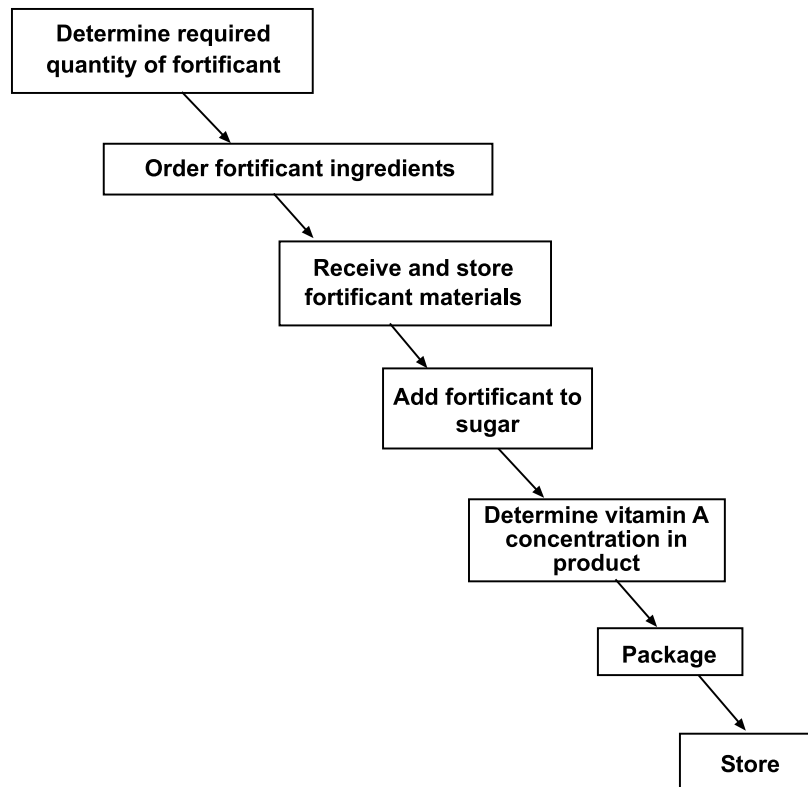
The next step is to identify and visualize the sequence of events in the fortification process. This can be done graphically by the use of a flowchart. Flowcharts may be simple, illustrating a sequence of events in broad terms, or more detailed, focusing on the components that comprise one step in the fortification process. Figure 1.3 illustrates in broad terms the sequence of events in the fortification of sugar with vitamin A. Figure 1.4 shows in detail the steps that take place from “Add *fortificant* to sugar” to “Assess vitamin A in product.” Figure 1.5 illustrates the quality control process in flowchart form.

Figure 1.2. Fortification: A systems framework



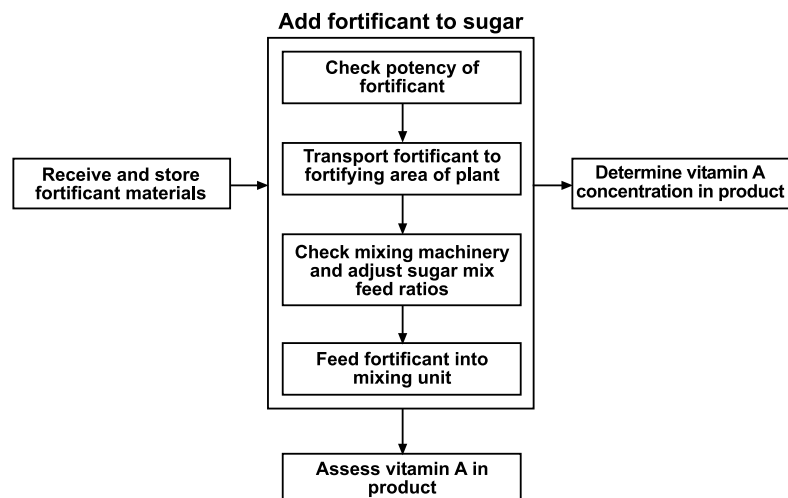
Courtesy of Dr. Stewart Blumenfeld, Healthcare Quality Systems, Las Vegas, NV, USA

Figure 1.3. Sequence of events in production of vitamin-A-fortified sugar

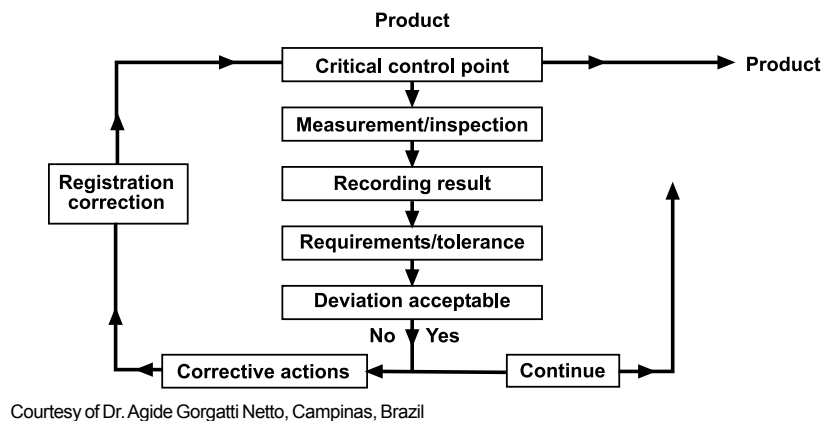


Courtesy of Dr. Stewart Blumenfeld, Healthcare Quality Systems, Las Vegas, NV, USA

Figure 1.4. Addition of fortificant to sugar: Detailed sequence of events



Courtesy of Dr. Stewart Blumenfeld, Healthcare Quality Systems, Las Vegas, NV, USA

Figure 1.5. The quality assurance/quality control process

Section Summary

- Quality assurance encompasses the totality of the organized activities that are undertaken to ensure that the fortified food meets the standards of quality required for its intended use at the consumer level.
- Quality control comprises a set of techniques and assessments used to document compliance with established technical standards through the use of objective, measurable indicators. Quality control is a subset of quality assurance.
- Implementing a quality assurance policy begins with the most senior people in an organization.
- A quality assurance system for food fortification programs has four essential elements: rapid, simple analytical assays; packaging in labeled bags; inspection, technical auditing, and monitoring; and documentation and general supervision.
- The key to maintaining standards of quality is to identify and correct problems in the fortification process. This can be done only when the flow of the fortification process is thoroughly understood.

Government's Role in Quality Assurance for Food Fortification Programs

It is now a generally accepted principle that people have the right to expect their food to be safe, of good quality, and suitable for consumption. Food-borne illnesses are unpleasant at best; at worst, they can be fatal. Poor-quality food can destroy the commercial credibility of suppliers, both nationally and inter-

nationally. Food spoilage, in addition to being wasteful and costly, can adversely affect trade and consumer confidence.

The United Nations General Assembly, in adopting guidelines for consumer protection in 1985, declared: "When formulating national policies and plans with regard to food, governments should take into account the need of all consumers for food security...." Throughout much of the world, governments are be-

coming aware of food quality and safety issues and of the need to ensure that only safe food of acceptable quality is sold and that the risk of food-borne health hazards is minimized. Governments have the responsibility of protecting and promoting public health.

Regulations and Standards

Government agencies play a crucial role in assuring the quality and safety of a nation's food supply. The enactment and enforcement of food laws—and *regulations* promulgated in accordance with the food laws—are one way to monitor and ensure food quality and safety. Appendix 1 (p. 37) is an example of how one developing country, the Philippines, regulates the production and distribution of fortified staple foods to protect the interest of consumers.

Governments should seek industry input on the development of food standards and other regulations to ensure the commercial feasibility of meeting the regulatory requirements. Governments should also work with the industry to assist them in meeting regulatory requirements. Given the weak enforcement systems in most developing countries, it is important to have open communication and dialogue between the public and private sectors to work toward the goal of providing consumers with fortified foods that are safe and of high quality.

Both developed and developing countries have established quality and safety standards specific to flour, sugar, and salt. These standards define product characteristics as well as fortification requirements. In addition, international standards and specifications exist for several finished food products as well as for food ingredients and other additives.

The Codex Alimentarius Commission, an

intergovernmental organization whose role is to protect consumers' health and encourage trade among the world's food markets, has established standards for foods, including flour and sugar. Two United Nations organizations—the Food and Agriculture Organization (FAO) and the World Health Organization—have responsibility for the Commission.

The Food Chemicals Codex (FCC) provides accepted standards of quality and purity for several food additives considered safe for use in foods, including iron fortificants. The FCC is an activity of the Food and Nutrition Board of the U.S. Institute of Medicine, supported by the U.S. Food and Drug Administration. Codex food standards and FCC specifications are universally recognized (and adhered to in the absence of national regulations) by manufacturers and must be considered in developing national regulations.

Inspection and Certification

Food businesses should be encouraged to implement quality assurance procedures voluntarily to increase confidence in the quality of foods produced. Governments should, however, retain fundamental responsibility for ensuring, by official inspection and certification, that foods conform to quality requirements. Official inspection and certification systems should take into account the manufacturer's quality assurance measures through the adaptation of control methods and procedures. Indeed, the degree to which industry effectively implements quality assurance procedures can influence the methods and procedures by which the government verifies the quality of food products.

For example, the U.S. Food and Drug Administration (FDA) has enforced the Current Good Manufacturing Practice (CGMP) regu-

lations for human foods since 1969. The CGMPs set standards for plant facilities, maintenance, laboratory controls, etc., to prevent errors or accidents that could harm consumers. Today, FDA inspectors look for CGMP violations as well as other product violations and adherence to CGMPs is recognized as critical to ensuring a consistently high level of safety and quality in FDA-regulated food products.

Government agencies should develop and maintain the ability to determine whether a food manufacturer has acceptable controls in place and is producing a quality product on a continuing basis. The FDA, for example, drafts manuals and guides to facilitate efficient and thorough investigations of food manufacturing plants by its field inspectors. The Investigations Operations Manual (IOM) is one such document that is applicable to all FDA-regulated products, including foods. The IOM deals with issues such as sampling, establishment inspection, laboratory analyses, and auditing.

The FDA also provides its field personnel with specific inspection guides related to different food products. For example, the inspection guide for grain product manufacturers deals with inspections of grain elevators, mill inspections, bakery inspections, and inspections of macaroni and noodle products. These inspections monitor the quality and fortification requirements for these grain products that are specified in their respective standards of identity and in the CGMP regulations.

Identification of Substandard Products

Governments can enhance compliance with regulatory requirements by publishing guidance documents that clearly describe compliance policies. A regulation or standard for a fortified food may include several specifica-

tions, some of which will be critical to the quality of the fortified food. Violation of these critical specifications will render the food unacceptable for sale. Such key specifications and their action levels (levels below or above which the food is unacceptable for sale and government action is warranted) should be the primary focus of government inspections and should be clearly communicated to food manufacturers to enable them to comply with government regulations.

For example, a standard for iron-fortified flour may state, among other things, that the flour must be of a certain granulation and must contain no more or less than a specified amount of iron of a certain particle size. Compliance with the specified particle size is important to ensure that a product meets the government standard for fortified flour; violations of this standard should be reported and corrected. However, government action at the production or retail level may be warranted only if the level of iron fortification in the flour is outside the specified acceptable range.

Governments should set action levels for all characteristics of a fortified food that are essential for quality and safety. These action levels should be documented for use by government officials during inspections as well as by industry during the implementation of routine quality control measures.

Product Recalls

To a large extent, governments can fulfill their responsibility to protect the public from adulterated, unsafe, or fraudulent foods by encouraging voluntary compliance by the food industry. Governments can take several measures, including conducting inspections, issuing certifications, providing guidance, and issuing warnings, to promote voluntary compliance

with regulatory requirements for food quality and safety. In some instances, however, when an unsafe or substandard food enters the marketplace, it is appropriate for governments to employ enforcement tools such as recall procedures to remove the product from the market.

Governments should develop guidelines for recall procedures and follow-up corrective actions. Manufacturers should be expected to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful. Additionally, manufacturers should be expected to develop contingency plans for product recalls that can be put into effect when needed. Governments should monitor company recalls, assess the adequacy of a firm's actions, and make sure the defective product is destroyed or suitably reconditioned.

Governments should also develop a strategy for each individual product recall to determine—depending on the seriousness of the violation—how extensively the recall will be monitored. For example, a fortified food containing an excessive amount of iron or vitamin A presents a risk to public health and must be destroyed. Such a violation requires more extensive government monitoring than would be necessary in the case of a food that is appropriately fortified but improperly labeled. In the latter case, the food can be re-packaged or re-labeled and introduced into the market.

Government oversight and enforcement are essential to ensure the rapid identification and removal from the marketplace of foods that are impure, adulterated, or otherwise po-

tentially harmful to public health. The crucial elements of government's role in this process are

- inspection,
- a method of identifying adulterated products,
- a way to recall those products and either recondition or destroy them, and
- a system of sanctions and penalty for violations.

The way food products are produced and regulated in a country is critical to domestic public health protection. As goods move more freely across borders, both food manufacturers and regulatory agencies should begin to think of their responsibilities and obligations not simply in the domestic arena but in more global terms. Regulatory agencies in different countries can advance public health protection through international activities such as equivalence agreements and harmonization of food regulations and standards. The safety, quality, and effectiveness of food products can then be ensured worldwide through regulatory oversight of compliance with regulations, inspection protocols, and other requirements.

An example of regional harmonization can be found in Central America, where Guatemala, El Salvador, Honduras, and Nicaragua have held periodic meetings to establish a free-trade area. In June 2002, these countries agreed to fortify wheat flour with a minimum of 45 ppm ferrous fumarate and 1.8 ppm folic acid as well as with vitamins B1, B2, and niacin. Negotiations are ongoing to establish standard fortification levels for corn flour in these four countries.

Section Summary

- Food businesses should be encouraged to implement quality assurance procedures voluntarily to increase confidence in the quality of foods produced. Governments should, however, retain fundamental responsibility for ensuring, by official inspection and certification, that foods conform to quality requirements.
 - The degree to which industry effectively implements quality assurance procedures can influence the methods and procedures by which the government verifies the quality of food products.
 - Government oversight and enforcement are essential to ensure the rapid identification and removal from the marketplace of foods that are impure, adulterated, or otherwise potentially harmful to public health.
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Chapter Summary

- Modern quality management has three inter-related elements: quality design, quality improvement, and quality control.
- Quality assurance is a proactive, continuous system for monitoring reproducibility and reliability.
- Effective quality control and quality assurance systems are designed to allow quick, timely corrections to be carried out when deviations from quality standards are identified.
- By developing a quality assurance policy and communicating it to all staff in the organization, management states its commitment to maintaining high quality in the food fortification process.
- Most QA problems result from faults in the physical system rather than from deficiencies in employee abilities.
- Government agencies play a crucial role in assuring the quality and safety of a nation's food supply. Food laws and regulations and their enforcement are one way to monitor and ensure food quality.

Chapter 2: Planning Quality Assurance Systems for Food Fortification Programs

New key word in this chapter:
deviation

This chapter covers

- planning a quality assurance system,
- designing a process for monitoring critical control points in the production process,
- issues to consider in setting up a quality assurance system, and
- costs of developing and implementing a quality assurance system.

Planning a Quality Assurance System

Planning a quality assurance (QA) system applicable to fortified foods has the following two basic elements:

- establishing the technical and nutritional criteria, and
- defining the QA criteria for each component of the fortification process.

Responsibility for these tasks is shared by the producers of fortified foods and the government officials responsible for the food fortification program.

Establishing Technical and Nutritional Criteria

Since 1962, the Codex Alimentarius Commission has issued technical standards for foods. Note, however, that technical standards have

not been established for all foods, nor do all technical standards address food fortification.

The Commission's member countries have agreed that the technical requirements for fortified foods should conform as closely as possible to the standards described in the "General Principles for the Addition of Essential Nutrients to Food," published by the Commission. Each country can fortify foods for domestic use to its own specifications, although FAO encourages neighboring countries to harmonize their standards to the extent possible.

When a food is traded internationally among Codex countries, the exporting country must scientifically justify a request to add to a food nutrients or additives different from any technical or nutritional requirements laid

down by the Commission. Whether for justification to Codex or for domestic use only, nutritional and fortification specifications should be carefully defined and the inherent characteristics (e.g., moisture content) of local foods documented. Appendix 2 (p. 39) is a model set of technical specifications for sugar fortified with vitamin A.

Nutritional criteria are set primarily on the basis of the amount of the food vehicle consumed each day; the deficits in micronutrient intake; and, where relevant, the bioavailability of the micronutrient. These issues are discussed in detail for sugar in Arroyave and Dary (1996), for wheat in Nestel and Nalubola (2000), Nalubola and Nestel (2000a,b), and for salt in Sullivan et al (1995).

Defining Quality Assurance Criteria

When a QA system is developed, quality guidelines and procedures for each component of the system must be defined. In recent years many companies in the food industry have adopted QA systems based on critical control points in the production process. This approach relies on identifying points in the production process where problems can occur and implementing measures to eliminate, prevent, or minimize these problems.

When identifying critical control points, it is important to consider critical specifications or essential characteristics that are defined by government regulation and used in the course of government inspection and certification procedures. For example, the point at which a micronutrient is added to a food is a critical control point.

In the production of a fortified food, quality control (QC) activities that might be performed at critical control points include the following:

- verifying the proper functioning of the dosifier or mixer equipment,
- monitoring the feed rate,
- checking for a uniform, smooth flow of the premix, and
- checking for continuous agitation of premix in the feeder hopper.

To control each identified critical control point in a fortification sequence, the following are required:

- indicators (e.g., feed rate);
- criteria for success (e.g., optimum feed rate and acceptable *deviations* in the feed rate);
- method (e.g., procedure for checking the feed rate and for when or how often it should be checked);
- documentation (e.g., records to log the feed rate);
- corrective actions; and
- identification of person or people responsible for executing QC tasks and performing corrective actions.

Table 2.1 shows who is responsible for executing and validating quality control procedures at certain critical stages in the fortification process. Tables 2.2, 2.3, and 2.4 list critical control points, problems, and corrective actions for, respectively, fortification of sugar with vitamin A, fortification of wheat flour with iron and other micronutrients, and iodization of salt.

Section Summary

Planning a QA system applicable to fortified foods has two basic elements: establishing the technical and nutritional criteria, and defining QA criteria for each component of the fortification process.

Table 2.1. Examples of assignment of responsibility for following up and executing quality control procedures for critical stages in the fortification process

Critical stage	Responsible for executing	Responsible for validating
Handling of premix	Purchasing or receiving department of food processor	QA department of food processor
Manufacturing of fortified product	Production department of food processor	QA department of food processor
Assuring that finished product meets specifications	QA department of food processor	Government food control agency (when required)

Courtesy of Dr. Omar Dary, formerly with INCAP/PAHO and currently with MOST/The USAID Micronutrient Program, Rosslyn, VA, USA

Table 2.2. Fortification of sugar with vitamin A: Examples of critical control points, problems, and corrective actions

Critical control point	Problem	Corrective action
Premix		
Premix available 1 month before sugar harvest starts	Supplies not available Less than 3 months' supply in stock	Follow up status of order and expedite shipment. Monitor use of threshold level for triggering new order.
Equipment for making premix checked 1 month before sugar harvest starts	Equipment is faulty	Adjust equipment and/or order missing/replacement parts.
Adequate retinol concentration in premix at production site	Retinol/kg sugar outside established range (usually 15-20 g/kg sugar)	<ul style="list-style-type: none"> • Reprocess batch to increase retinol concentration. • Identify source of problem. If necessary or appropriate, follow up with retinol supplier for technical support. • Check proportions of ingredients. • Increase mixing time. • Verify retinol concentration in premix.
Inventory properly maintained	First-in, first-out policy not being followed	<ul style="list-style-type: none"> • Review procedures for receiving, storing, and distributing premix so bags are used in order received. • Reorganize storage area to facilitate first-in, first out policy.
Fortified sugar		
Adequate retinol concentration in fortified sugar at mill	Retinol/kg sugar outside established range (usually 10-20 mg/kg sugar)	<ul style="list-style-type: none"> • Check proportions of ingredients. • Adjust dosifier speed. • Extend mixing time. • Check that QC sampling has been done correctly. • Check storage conditions of premix. • Verify retinol concentration of premix.
Storage of fortified sugar at mill	Not separated from unfortified sugar	Store fortified and unfortified sugar in separate areas.
Fortified sugar at mill and in retail outlets correctly labeled	Labeling does not meet specifications	Depending on severity of non-compliance, fortified food may be recalled. Re-label correctly before sending fortified food to retail outlets.
	Unlabeled	Identify source of labeling problem and take corrective action as needed.
Adequate retinol concentration in fortified sugar at retail outlets	Retinol/kg sugar below minimum level (usually 5 mg/kg)	<ul style="list-style-type: none"> • Identify source of problem. Double check above critical control points. • Ensure fortified food is packed in appropriate packaging materials. Change packaging material if necessary. • Fortify appropriately or earmark for industrial use. Food control authorities may remove fortified food from market and conduct audit at mill.
Certificate of import for fortified sugar at food control laboratory	Does not meet specifications	Fortify appropriately or earmark for industrial use.
Record-keeping		
Monitoring records	Not available to government inspectors	Make available at all times: <ul style="list-style-type: none"> • maintenance and inspection records, • in-process monitoring records and control charts, and • final fortified food QC data.

Table 2.3. Fortification of wheat flour with iron and other micronutrients: Examples of critical control points, problems, and corrective actions

Critical control point	Problem	Corrective action
<i>Iron/mineral fortificant</i>		
Quality of fortificant	Color, texture, or odor of newly procured fortificant not acceptable	<ul style="list-style-type: none"> • Check and verify certificate of compliance provided by manufacturer. • Assay fortified food for iron content. • Follow up with supplier if necessary.
Fortificant in stock	Less than 2 months' supply in stock	<ul style="list-style-type: none"> • Review inventory control and procurement procedures. • Monitor use of threshold level for triggering new order.
Shelf life of fortificant	Shelf life has expired	<ul style="list-style-type: none"> • Review inventory control and procurement procedures. • Maintain records of returned materials, their use, and control.
Inventory properly maintained	First-in, first-out policy not being followed	<ul style="list-style-type: none"> • Review procedures for receiving, storing, and distributing fortificant so containers are used in order procured. • Reorganize storage area to facilitate first-in, first out policy. • Ensure that fortificant is stored under conditions specified by manufacturer.
<i>Fortified wheat flour</i>		
Equipment for fortifying wheat flour checked daily	Equipment is faulty	<ul style="list-style-type: none"> • Adjust equipment and/or order missing/replacement parts. • Review dosifier calibration data.
Adequate fortificant concentration in wheat flour at mill	Does not meet specifications	<ul style="list-style-type: none"> • Check proportions of ingredients. • Adjust dosifier speed. • Check that QC sampling has been done correctly • Check that conditions for storing iron/mineral fortificant comply with manufacturer's specifications. • Verify iron content of iron/mineral fortificant.
Storage of fortified wheat flour at mill	Not separated from unfortified wheat flour Stored in suboptimal conditions	Store fortified and unfortified wheat flour separately. If possible, store away from excessively hot, humid conditions. If this is not possible, overfortify to allow for loss of nutrient content in humid storage conditions.
Fortified wheat flour at mill and in retail outlets correctly labeled	Labeling does not meet specifications Unlabeled	Depending on severity of non-compliance, fortified food may be recalled. Re-label correctly before sending fortified food to retail outlets. Identify source of labeling problem and take corrective action as needed.
Adequate fortificant concentration in fortified wheat flour at retail outlets	Does not meet specifications	<ul style="list-style-type: none"> • Identify source of problem. Doublecheck above critical control points. • Fortify appropriately or earmark for industrial use. <p>Food control authorities may remove fortified food from market and conduct audit at mill.</p>
<i>Record-keeping</i>		
Monitoring records	Not available to government inspectors	Make available at all times: <ul style="list-style-type: none"> • maintenance and inspection records, • in-process monitoring records and control charts, and • final fortified food QC data.

Table 2.4. Salt iodization: Examples of critical control points, problems, and corrective actions

Critical control point	Problem	Corrective action
Fortificant Adequate ingredients and spare parts in storage	Less than 6 months' supply of potassium iodate or anti-caking agent (e.g., magnesium carbonate) in store.	<ul style="list-style-type: none"> • Review inventory control and procurement procedures. • Monitor use of threshold level for triggering new order.
Quality of ingredients (salt, potassium iodate, anti-caking agent)	Specifications not met (salt purity less than 94%; salt contains extraneous materials, too much moisture, does not meet granulation requirements, etc.). Inappropriate concentration of active ingredients.	<ul style="list-style-type: none"> • Check certificate of quality and packaging specifications. • Store ingredients properly to avoid contamination and/or loss of iodine content.
Shelf life of potassium iodate	Shelf life has expired	<ul style="list-style-type: none"> • Review inventory control and procurement procedures. • Check that storage area is set up to facilitate first-in, first-out policy.
<i>Wet method:</i> Solutions of potassium iodide for washed (97% pure) or refined (99% pure) salts or potassium iodate for raw salt (94%-97% pure) at correct concentration	Solution not at 4%	<ul style="list-style-type: none"> • Check that fortificant has not degraded. • Check proportions of ingredients being used, weighing scales, method used to measure water volume.
<i>Dry method:</i> Potassium iodate at correct concentration	Iodine content in premix not at required level (30-60 g/kg salt)	<ul style="list-style-type: none"> • Check that fortificant has not degraded. • Check proportions of ingredients. • Increase mixing time.
Iodized salt Salt quality	Salt is lumpy	<ul style="list-style-type: none"> • Check storage conditions. • Crush and refine salt. • Move salt to appropriate storage area.
<i>Wet method:</i> Salt iodized at correct level	Iodine content does not meet specifications	<ul style="list-style-type: none"> • Review calibration data. • Check flow rate of salt. • Check nozzle setting on sprayer. • Check that QC sampling has been done correctly. • Check that conditions for storing potassium iodate comply with manufacturer's specifications. • Re-iodize and re-test inadequately iodized batches.
<i>Dry method:</i> Salt iodized at	Iodine content does not meet	<ul style="list-style-type: none"> • Check dosifier and mixing time. • Check correct level specifications that QC sampling has been done correctly. • Check that conditions for storing potassium iodate comply with manufacturer's specifications. • Re-iodize and retest inadequately iodized batches.
Equipment functioning properly	Equipment not checked twice daily	<ul style="list-style-type: none"> • Review inspection procedures to ensure that faulty equipment is adjusted or replaced. • Order missing or replacement parts.
Storage of iodized salt	Not separated from non-iodized salt. Stored in suboptimal conditions	Store iodized and non-iodized salt separately. If possible, store away from excessively hot and humid conditions. If this is not possible, overfortify to allow for loss of nutrient content in humid storage conditions.

Table 2.4. Salt iodization: Examples of critical control points, problems, and corrective actions (continued)

Critical control point	Problem	Corrective action
Iodized salt in retail outlets correctly labeled	Labeling does not meet specifications	Depending on severity of non-compliance, fortified food may be recalled. Re-label correctly before sending fortified food to retail outlets.
	Unlabeled	Identify source of labeling problem and take corrective action as needed.
Iodized salt in retail market	Does not meet specifications	Check that packaging quality meets minimum specifications. Review findings with salt producer. Re-iodize where appropriate.
Record-keeping		
Monitoring records	Not available to government inspectors	Make available at all times: <ul style="list-style-type: none"> • maintenance and inspection records, • in-process monitoring records and control charts, and • final fortified food QC data.

Designing a Process for Monitoring Critical Control Points in the Fortification Process

Monitoring is a systematic way of assuring the quality of a fortified food during processing, from handling of the raw ingredients to presentation of the fortified food to consumers. It is important to monitor where, when, and by how much manufacturing processes deviate from standards and specifications. A monitoring system collects and analyzes data to

- ensure food safety,
- determine whether the objectives of the food fortification program are being met,
- ensure that manufacturing processes are functioning without significant deviation from key standards, and
- identify critical control points at which important deviations are occurring.

Important deviations are those that may severely affect the quality of the fortified food or the cost-effectiveness of the production process. Cost-effectiveness is important because a manufacturer should not be meeting a production goal by including discarded forti-

fied food that does not meet specifications.

Monitoring involves a planned sequence of observations designed to answer questions such as

- Does the fortified food comply with specifications and standards?
- Is the fortified food visually inspected?
- Are critical control points measured and accurately recorded?
- Are sampling and laboratory analyses routinely done for quality control? Are the results reported and recorded? Are corrective measures recommended? Are corrective measures taken?
- Is fortified food that does not meet specifications handled and disposed of according to defined procedures? Is the disposal of this fortified food reported and recorded?

Monitoring provides many benefits, including:

- an early warning of problems associated with the quality of a fortified food,
- a way to keep records of corrective actions when standards and specifications are not met, and

- a check on the sustainability of improvement of the quality of a fortified food.

In designing a monitoring process, it is helpful to use a what-where-when-who-how framework.

- **WHAT is monitored?** Critical control points where deviations from standards and specifications are occurring, or may occur.
- **WHERE is monitoring done?** The location of monitoring depends on the location of the activity being monitored. Table 2.5 presents two examples.
- **WHEN is monitoring done?** The frequency of monitoring varies depending on which critical control point is being monitored. Table 2.6 presents three examples.
- **WHO carries out monitoring?** The following steps can help to ensure that the people responsible for monitoring are clearly identified.
 - For each critical control point, identify an individual or group responsible for

monitoring that activity. Invite staff to take part in this process.

- Clearly define the tasks to be performed by those responsible for monitoring (Table 2.7).
- Ensure that those responsible for monitoring receive the support they need to perform their assigned tasks.
- Review the assignment of responsibility for monitoring at regular intervals.
- **HOW is monitoring done?** (Refer to steps in Table 2.7.)
 - a. Checking a process. Check that processes such as agitator operation and the dosifier flow rate are functioning properly.
 - b. Collecting a sample. The purpose of sampling is to ensure that representative small quantities of fortified food meet specifications. The frequency of sampling should be appropriate to the production rate. In general, sampling should

Table 2.5. Examples of where monitoring may take place

Activity	Where monitored
Calibrating the dosifier before processing each batch of food	At machinery location
Batch-testing of fortified food for potency at 2-hourly intervals	In laboratory

Table 2.6. Examples of frequency of monitoring for specific critical control points

Activity	When and how frequently monitored
Dosifier calibration	At beginning of each shift
Fortificant content of product	Every 2 hours
Quality of raw, unfortified product	On arrival at processing plant and after every 14 days of storage

Table 2.7. Monitoring tasks for which responsibility should be assigned to specific individuals or groups

1. (a) Checking a process. (b) Collecting a sample.
2. Recording data.
3. Analyzing data.
4. Reporting the results of Steps 1, 2, and 3 to the person responsible for taking action.
5. Taking action in response to the report made at Step 4.

be done at least once per shift. Alternatively, sampling may be done intermittently during a selected period of time or for a production batch; individual samples are mixed together to form a composite sample. Always ensure that composite samples are thoroughly mixed. Results can be presented either as a value for a particular point in time or to represent a batch. A description of the statistical techniques for analyzing results is beyond the scope of these guidelines but can be found in a standard statistics text book.

2. Recording data. Use forms that enable monitoring data to be recorded quickly and accurately. Develop and provide clear instructions for the proper use of all forms used to record monitoring data. Forms should indicate compliance or lack of compliance with specifications for each of the following elements of the production process:
 - raw product (i.e., sugar, flour, salt),
 - fortificant, premixes, and other additives,
 - steps in manufacturing the fortified food, and
 - quality of the fortified food.

Appendix 3 (p. 41) is a sample template for a quality control record form. Appendix 4 (p. 42) shows a completed

quality control record for the fortification of sugar with vitamin A.

3. Analyzing and reporting data. Analyze samples in duplicate by an accepted and approved assay method. It is desirable that analysis be conducted as quickly as possible so that corrective action, if required, can be implemented rapidly to minimize production of off-specification product. However, to ensure that assay results are reliable, valid methods must be used. (In the United States, for example, the Association of Official Analytical Chemists develops methods of analysis for several food products that are referenced in government regulations and routinely used by industry.) Establish procedures to ensure that the results of analyses are reported promptly to the person or people responsible for taking action.

In cases of multiple fortification—particularly when a standard multiple-fortification premix is used—it may be most efficient to select one micronutrient for regular, routine sampling and analysis. Other micronutrients need only be checked once within the shelf life of the premix. (Use this approach only if the quality of the fortificant premix has been previously verified or is assured by the supplier.)

Section Summary

- Monitoring involves a planned sequence of observations designed to answer certain questions.
 - In designing a monitoring process, it is helpful to use a what-where-when-who-how framework.
-

Issues to Consider in Setting Up a Quality Assurance System

Management must be fully committed to the implementation of a QA system. The QA unit or department must report directly to management rather than to the production department or to another department. This implies that management alone will make the decisions when choices need to be made between quality and quantity. Although the QA department reports directly to management, it is important that channels are set up to ensure that information is shared with relevant departments, such as the production department.

Appropriately qualified staff will be needed to manage and run the QA system. The number of staff required will depend on the fortified food, the size of the production facility, and the amount of oversight deemed necessary by management.

Consideration must also be given to the requirements for laboratory facilities and the location of the laboratory. The size of the laboratory will depend on production levels, but it must be large enough to accommodate the equipment required for effective implementation of quality control procedures. The labo-

ratory must be free of contamination (especially dust) and dry but well ventilated.

Because assay methods vary, the laboratory equipment needed will depend on the food vehicle and the fortificants being used. The equipment necessary to run recognized, standardized quality control procedures can be purchased. (Refer to the technical manuals for fortification of sugar, flour, and salt for descriptions of these procedures. These manuals are listed in the bibliography.)

Expertise will be required to develop a plan for statistical sampling. The plan should specify how many samples to collect, how to collect them, and how many to evaluate. The QA personnel must include someone with the capability to interpret quality control data.

The following issues must also be considered when setting up a QA system:

- Reporting procedures must be established and adhered to.
- Staff must receive adequate initial training as well as periodic refresher training. Time must be made available for staff to attend these training sessions.
- Adequate resources must be budgeted to operate the QA system.

Section Summary

- Management must be fully committed to the implementation of a QA system. The QA unit or department must report directly to management rather than to the production department or to another department.
 - Appropriately qualified staff will be needed to manage and run the QA system. Staff must receive adequate initial training as well as periodic refresher training.
 - The QA personnel must include someone with the capability to interpret quality control data.
-

Costs of Developing and Implementing a Quality Assurance System

Developing and implementing a QA system incurs costs for manufacturers of fortified foods. However, having an effective QA system in place can reduce other costs that manufacturers might otherwise incur, such as the costs associated with product recalls and loss of sales due to negative advertising for non-compliance. Costs associated with quality assurance fall into the following three main categories:

- costs of designing a QA system,
- costs of maintaining a QA system, and
- potential costs of failing to maintain an adequate QA system.

Costs of Designing a QA System

The costs of implementing and maintaining a QA system fall into the following categories:

- **Analysis.** This includes the costs of breaking the entire manufacturing process into manageable, logical subunits and analyzing them to establish critical control points and parameters to which the manufacturing systems are capable of performing.
- **Planning and preparation.** This includes the costs of planning the details of the system: translating fortified food and customer quality requirements into specific controls on quality of materials, processes, and products. This heading also includes the costs of creating or updating standard operating procedures and conducting reliability studies and pre-production quality analysis.
- **Development.** This includes the costs of the technical/engineering expertise necessary to establish how measurements will be taken as well as the design or selection of equipment necessary for process control.
- **Initial training.** Where routine QA for

production of the unfortified food is not practiced, initial training on QA procedures is usually a more onerous task than ongoing training because there is usually no institutional background upon which to build. This is an intensive effort; in many ways the success of the entire effort may depend upon how effectively initial training communicates the basic principles and importance of quality to employees who are carrying out day-to-day quality duties. Where QA is already in place for production of the unfortified food, training on QA procedures specific to fortification will be straightforward.

- **Design and development of quality assurance information.** This heading covers any engineering costs incurred during the development of QA systems as well as the personnel costs associated with measurements, data, and related equipment and devices for determining the quality of both the fortified food and the fortification process.
- **Implementation.** This refers to the cost of staff time spent studying and analyzing manufacturing processes to control quality problems in the production process. This may be thought of as the cost of providing technical support during production.
- **Verification.** This refers to the costs of evaluating the quality, reliability, and safety of the fortified food before production begins.
- **Administration.** This refers to administration of the design process, which is typically carried out by senior management.

Costs of Maintaining a QA System

- **Equipment and consumables.** This refers to the cost of disposable laboratory equipment, chemicals and power for testing. It may also cover costs incurred for mainte-

nance, calibration, and repair of laboratory instruments and inspection equipment.

- **Testing.** This covers the costs of all aspects of testing, including ensuring that raw materials meet specifications; calibrating testing equipment; and time spent by operations, engineering, clerical and supervisory staff to ensure that quality is being met.
- **Ongoing training.** This includes all ongoing training that is provided to operations staff to keep them motivated and aware of systems improvements. It also covers new employees' quality training.
- **Quality auditing.** This refers to the cost of the time operators spend checking the quality of the fortified food and procedures at planned points in the manufacturing process, including sorting lots that are rejected for failing to meet quality requirements and otherwise evaluating the quality of the fortified food.
- **Administration.** This refers to the cost of management checks on the whole system to ensure it continues to work as designed, as well as to the cost of quality audits and field-testing.
- **Other maintenance costs.** These may include the costs of the time engineers spend reviewing test and inspection data before the fortified food is released for shipment; the costs of field-testing the product at the customer's site before final release; as well as external laboratory fees, insurance inspection costs, and any other associated costs.

Potential Costs of Failing to Maintain an Adequate QA System

Failure to maintain an adequate QA system incurs both direct and indirect costs. Direct costs may be subdivided as follows:

- **Wastage.** In processes that use expensive raw materials, inadequate quality control may lead to overuse, resulting in higher costs and possible adverse effects on the quality of the fortified food.
- **Increased losses.** Inadequate quality control can lead to inadvertent losses of raw materials, ingredients or reactants, and fortified food. This can be costly and may have environmental impact.
- **Increased reworking of product.** Fortified food that fails to meet specifications must be either discarded or reworked. In either case, the result is unnecessary costs.
- **Customer complaints.** Fortified food that fails to meet customer specifications and that is not identified before it enters the distribution chain results in higher costs because it must be retrieved and may lead to loss of customer confidence and loss of sales.
- **Fortified food recall and liability issues.** Quality control is of the utmost importance for fortified foods because grossly excessive intakes of some micronutrients may cause harm. Failure to identify fortified food containing micronutrients at levels that exceed specifications may lead to product recalls and, in some cases, legal action to extract compensation. The cost of compensation may represent many times the cost of the fortified food. This is a situation to be avoided at all costs.

Indirect costs may be subdivided as follows:

- **Procurement costs.** Quality is a continuous process that extends well beyond the bounds of an individual food manufacturer. Quality must begin at the raw materials stage. More food manufacturers are insist-

ing that vendors of raw materials undergo an initial certification process. Otherwise, significant costs can be incurred for the return of out-of-specification raw materials to the vendor and procurement of replacement materials.

- **Engineering costs.** This refers to the time spent and equipment used by engineering personnel to correct production problems involving quality. For example, if the amount of the micronutrient being added does not conform to quality specifications, factory engineering staff may be asked to review the feasibility of changing the specifications for the micronutrients. This may happen when the amount of the micronutrient being added is very low and it is difficult to get a homogeneously fortified food.

Another Approach to Calculating Quality Costs

Another way of thinking about the costs of developing and implementing an effective QA system is to subdivide costs into the following categories:

- **Prevention costs** are incurred to establish systems for preventing deviations from or maintaining food fortification quality standards.
- **Appraisal costs** are incurred to evaluate production processes and the quality of fortified food to ensure that they meet specifications.

Prevention and appraisal costs may be thought of as the costs of “doing it right the first time.” Having an effective QA system in place can also reduce recurrent costs that manufacturers might otherwise incur. These include costs associated with internal or external failure.

- **Internal failure costs** occur when produc-

tion processes deviate from their specifications, resulting in a fortified food that fails to meet quality standards.

- **External failure costs** occur when fortified food fails to meet quality standards after it leaves the manufacturer for distribution.

Using Cost Information to Identify Quality Problems

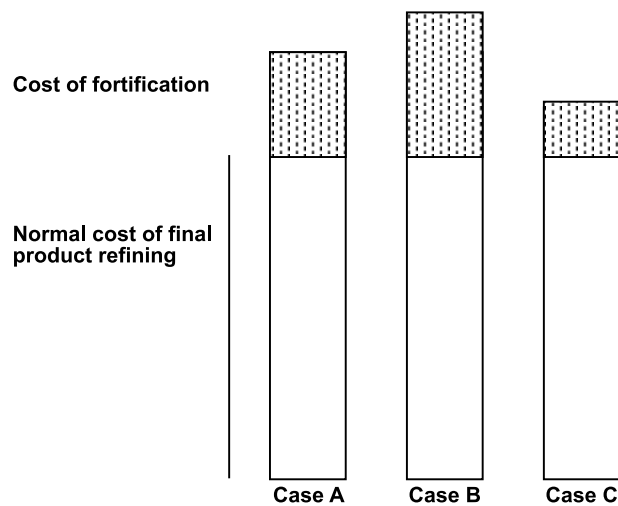
Quality assurance is employed to ensure customer satisfaction and continuity of sales revenues, but also to avoid unnecessary costs. Analysis of costs data can be a useful tool for signaling quality problems. Although this is a somewhat reactive method that suggests proactive quality practices have failed, it may be useful as a “wake-up call.” The following are two examples of the use of cost information to identify quality problems.

Case study 1. A sugar refinery has undertaken a fortification program, adding vitamin A to white sugar. This involves a combination of manual and automatic processes. In the manual process, a premix is made from vitamin A concentrate such that a known dilution yields the correct level of fortificant. The automatic portion is the actual dosage of premix added to the finished product.

In such a system, the cost of fortificant is incremental. Fractions of a penny can account for the added cost per package. However, for a sugar refinery producing half a million metric tons of white sugar, the total costs over a growing period may be enormous.

As shown in Figure 2.1, errors in dosage may go either way: the sugar may be insufficiently fortified (Case C), resulting in less than adequate health benefits for consumers who are paying extra for sugar fortified with vitamin A; or it may be overfortified (Case B),

Figure 2.1. Using costs data to identify errors in fortification levels.



Courtesy of Mr. Ian Knight, Knight International, Advance, NC, USA

resulting in possible toxicological problems and significantly higher manufacturing costs.

Careful analysis of cost information at regular intervals (for example, monthly) and comparison with standard costs (Case A) can provide an early warning of either of these situations. Cost overruns can be detected and remedied before an enormous deficit is produced and consumers are affected; conversely, identification of lower than expected costs that may indicate inadequate fortification enables the necessary operational corrections to be made.

Case study 2. A wheat flour miller has three production lines that produce 5-kg packages. Cost information is broken out for each production line. All three lines have quality prevention programs and appraisal programs, which may differ, depending upon the type of flour being made. Costs are also cross-referenced so that both internal failures and external failures can be attributed to the production line on which they occurred.

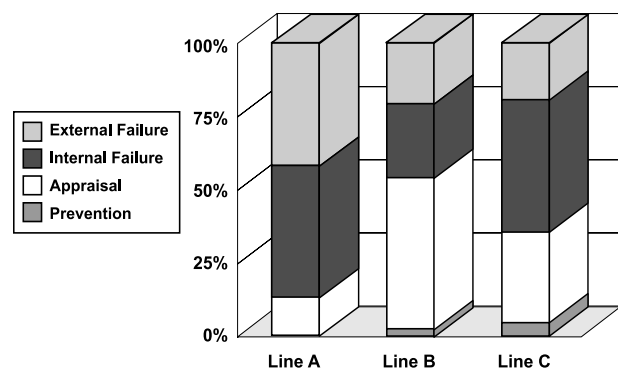
With packaged products, failures arise from factors such as

- foreign material in the package (caused by improper sealing or introduction of foreign material during filling),
- formulation problems or contamination of ingredients,
- damage to the structural integrity of packaging, and
- improper sealing.

Figure 2.2 shows hypothetical costs for each of the three production lines.

- Line A shows a disproportionately high failure rate with very little prevention and appraisal effort. A higher level of prevention and appraisal effort would likely reduce both internal and external failures.
- Line B appears to have high appraisal costs. A concentrated effort is needed to improve the efficiency of appraisal without sacrificing low failure rates.
- Line C shows a high internal failure rate despite a substantial prevention effort. A more concentrated preventive effort is needed that focuses on internal failures.

Figure 2.2. Using costs data to identify quality problems in a 3-line production plant.



Adapted from Feigenbaum AV (1991)

Section Summary

- Costs associated with quality assurance fall into three main categories: costs of designing a QA system, costs of maintaining a QA system, and potential costs of failing to maintain an adequate QA system.
 - The costs of developing and implementing an effective QA system may also be divided as follows: prevention costs, appraisal costs, internal failure costs, and external failure costs.
-

Chapter Summary

- Planning a QA system applicable to fortified foods has two basic elements: establishing the technical and nutritional criteria and defining QA criteria for each component of the fortification process.
- Monitoring is a systematic way of assuring fortified food quality throughout the production process from handling of the raw ingredients to presentation of the fortified food to consumers. It is important to monitor where, when, and by how much manufacturing processes deviate from standards and specifications.
- In setting up a QA system, it is important that management be fully committed to the system's implementation. The QA unit or department must report directly to management rather than to the production department or to another department.
- Developing and implementing a QA system incurs costs for manufacturers of fortified foods. However, having an effective QA system in place can reduce other costs that manufacturers might otherwise incur.

Chapter 3: General Guidelines for Implementing Quality Assurance Systems for Food Fortification Programs

New key words in this chapter:

inventory

packaging specifications

reorder point

norm

primary packaging

secondary control point

nutrition labeling

quality improvement team

secondary packaging

open dating

This chapter covers

- quality assurance in the handling of the premix,
- quality assurance in the manufacturing process, and
- quality assurance in the distribution of the fortified food.

Companies that decide to fortify an unfortified food that they have been producing, and for which they have a QA system in place, may need to modify and update their existing procedures for handling, packaging, and storage to accommodate the QA requirements of the fortified food.

Quality Assurance in the Handling of the Premix

The first step in any quality assurance system for food fortification programs is to confirm the quality, handling, and storage of the fortificant or micronutrient premix. Problems with fortificant quality are rare when the premix is purchased from a reliable company that issues with the shipment a certificate of compliance, stating that the shipment meets the relevant standards and specifications.

The Food Chemicals Codex (FCC) provides standards of quality and purity for many food

chemicals used in foods, including micronutrient fortificants. The manufacturer should ensure that the premix contains ingredients and fortificants that meet FCC specification and/or any national regulations. The food manufacturer's purchasing department should obtain or develop a list of premix suppliers* whose products meet established requirements.

Quality assurance (QA) in the handling of the premix is the responsibility of different departments at varying stages in the production process.

* The Micronutrient Initiative (www.micronutrient.org) has compiled a list of premix suppliers around the world.

- The receiving department is responsible for checking that each lot of premix meets specifications when it is received.
- The manufacturing department, with strict supervision by the QA department, is responsible for the correct use of the premix in the product.
- The QA department is responsible for deciding what to do with the fortified food when it fails to meet specifications.

The following actions during receiving and storage of the premix will help to assure the quality of the premix:

- With each shipment, suppliers must include a certificate of compliance. Keep a copy of the certificate of compliance with the permanent records.
- Establish a procedure for maintaining a “first in, first out” (FIFO) policy. For example, use stickers of different shapes or colors for each lot. Number lots consecutively in the order they are received. For each lot, write the lot number and the date of receipt on the sticker.
- Design storage areas to facilitate the FIFO policy. Store bags or boxes of the premix in consecutive order so that the oldest can be withdrawn first.
- Store the premix in conditions that maintain its quality and prevent contamination or deterioration (out of direct sunlight; off the ground; in dry, well-ventilated conditions).
- Develop proper recording procedures to monitor movement of premix in and out of the warehouse. Ensure that the amounts of mixture used in manufacturing are adequately controlled.
- Maintain proper records of returned materials and their use and control.
- Maintain sufficient stocks of premix. Request that the purchasing department order a new shipment in sufficient time to avoid running out of fortificant. Sometimes a *re-order point* in inventory levels will trigger the purchase order, but consult production schedules as well.
- To confirm that the composition of the premix meets specifications, send samples of the fortificant for laboratory analysis at regular intervals.

Section Summary

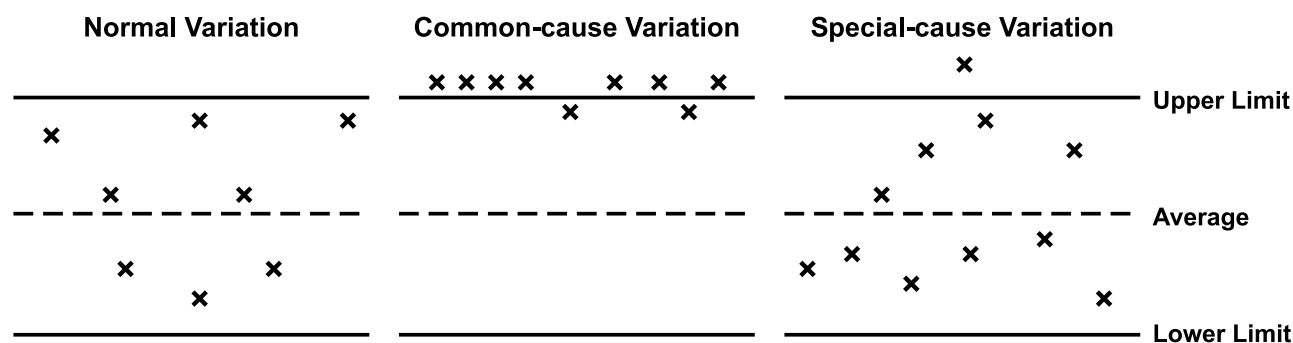
The first step in any quality assurance system for food fortification programs is to confirm the quality, handling, and storage of the fortificant, or micronutrient premix.

Quality Assurance in the Manufacturing Process

Identifying and Correcting Quality Problems

Most problems in food fortification relate to deviations from technical specifications, 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. If, however, a defective batch of fortified food creates a risk to consumer health—for example, if nutrient levels

Figure 3.1. Main types of deviations: common-cause variation and special-cause variation

Courtesy of Dr. Agide Gorgatti Netto, Campinas, Brazil

are so high as to be toxic—the food must be reprocessed or destroyed.

Follow a systematic, step-wise procedure to identify and correct quality problems.

1. **Identify problems in the system.** Any deviation from standards and specifications is a quality problem. Deviations are of two main types (Figure 3.1).

- **Common-cause variation.** This means deviation that varies up and down from the mean more or less equally. Regular common-cause variation indicates a problem in the production process that is likely to be persistent. Typical “common causes” of problems include poor supervision, lack of instructions, varying quality of incoming materials, poorly controlled machinery, uncomfortable working conditions (for example, humidity, noise, confusion, excessive heat or cold, poor ventilation, poor light), lack of performance data, and poor process design. If the highest and lowest deviations from the mean regularly go outside the bounds of the acceptable range, the quality problem needs to be corrected.
- **Special-cause variation.** This means a deviation that is a one-time or otherwise

rare event. Generally, special-cause variation indicates a problem less worthy of targeting for a quality improvement effort. If, however, special-cause variation occurs frequently or severely, the reasons for it must be analyzed and a solution implemented that addresses the cause of the problem.

Because significant deviations from standards at critical control points can have immediate, serious consequences, the collection of monitoring data from these points is a priority. However, it may be useful to monitor *secondary control points* at regular intervals. Even when monitoring at all critical control points shows acceptable results, other points in the system may be falling short of standards. Small deviations at secondary control points may not have an immediate effect on the quality of a fortified food, but over time they may add up to a significant problem.

2. **Prioritize problem solving.** Available resources (time, money, and staff) sometimes dictate that problems be solved in sequence. A problem that is causing output of a useless or dangerous fortified food is more important than a problem that results in a

fortified food that is of diminished economic or nutritional value. Solve the most serious problem first. This will be decided by the person in charge of fortified food quality—for example, the QA supervisor or the manager of the section, division, or plant where the quality problem is occurring.

The following examples illustrate the importance of setting priorities. Which of these problems is more serious?

- The magnets for removing impurities from flour are located at the end of the conveyor belt leading to the bagging area. As a result, some of the added elemental iron is being removed from the fortified flour.
- Because of an uncalibrated dosifier, iron-fortified wheat flour is being significantly overfortified.

The second example causes sensory problems and would probably result in complete shutdown of the production line. In the case of the first example, however, production could probably continue while the magnets are re-located to a site further up the production line before fortification occurs.

Quantitative data should be used as much as possible to prioritize problems. For this reason, it is important to collect data on the frequency of different problems. In many processes, 20% of the control points cause 80% of the problems.

3. **If the solution to a problem is obvious, implement it immediately.** A temporary or permanent solution to a problem may be completely obvious. If this is the case, implement the solution as quickly as possible. The following is an example of a problem with an obvious solution that can be implemented immediately.

Problem: All four spray nozzles for potassium iodate solution in a salt iodizing machine are completely blocked. Inspection shows that the solution contains a precipitate.

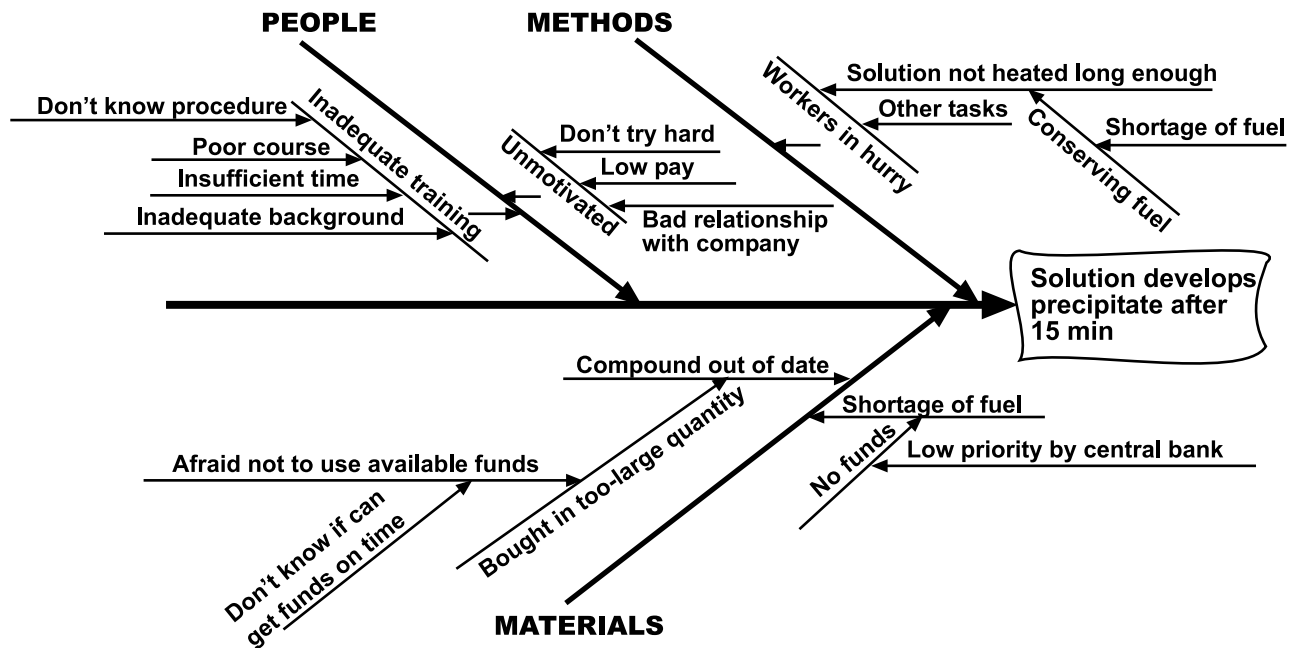
Solution: Clear the nozzles. Replace the solution.

If the problem recurs, however, it is not a good idea to simply repeat the corrective action without first gaining a better understanding of the causes of the problem.

4. **Identify the primary causes of a problem.** If the cause of a problem is not obvious, convene a group of workers from the unit(s) where the problem is occurring. Such a group is sometimes called a *quality improvement team*. The team's job is to suggest possible causes of the problem. On the basis of this analysis, the team should then be able to suggest one or more solutions to the problem.

Besides continually asking “Why, why, why?” until the problem is solved and brainstorming to generate a list of possible causes in order of importance that are then reviewed, a “fishbone” diagram can be used to help identify the primary causes of a problem (which may not be the most obvious causes). Figure 3.2 is a fishbone diagram that might have been developed by a quality improvement team to answer the question “Why is our potassium iodide solution developing a precipitate that blocks the spray nozzles?”

5. **Monitor the effect of the solution.** Once a solution has been implemented, monitor to ensure that the problem is solved. If the focus of problem-solving activity is a critical control point, monitoring should already be routine. However, the quality improve-

Figure 3.2. Fishbone diagram: Causes and effects of potassium iodide precipitation

Courtesy of Dr. Stewart Blumenfeld, Healthcare Quality Systems, Las Vegas, NV, USA

ment team may identify a step or procedure that is not routinely monitored as the primary cause of a problem. In this case, implement a special monitoring effort until the team is convinced the problem has been solved.

6. **Recall product.** Recall, or removal of a fortified food from the market, should be used by a food manufacturer when warranted, such as when the safety of the food

is in questions. Procedures to be established by a manufacturer for recalling fortified food are beyond the scope of these guidelines. From a quality assurance perspective, however, a recall signifies that monitoring procedures have failed. The techniques described above for identifying and correcting problems can also be used after a recall to identify and correct the problem that led to the recall.

Section Summary

- Follow a systematic, step-wise procedure to identify and correct quality problems.
- Set priorities and solve the most serious problem first.
- Once a solution has been implemented, monitor to ensure that the problem is solved.

Quality Assurance in the Fortified Food Distribution Process

For a food fortification program to be successful, the fortified food must reach the consumer in a condition that the consumer considers acceptable while complying with production standards and *norms*. (Because the consumer is the final judge, the food manufacturer's definition of acceptability should be as close as possible to the consumer's.) The process of getting a fortified food 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 foods must be planned and monitored to preserve the product's shelf life.

The ultimate goal of any food fortification program is to increase consumption of specific micronutrients in the target population. Product labeling is necessary to ensure that fortified foods are distinguishable from unfortified varieties and to inform consumers about the fortified food's nutrient content.

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.

The monitoring procedures described in **Designing a Process for Monitoring Critical Control Points in the Fortification Process** (pp. 18–20, Chapter 2) can be applied with minor modifications to the monitoring

of these critical control points in the distribution process.

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 a result of exposure to light, oxygen, moisture, and changes in temperature. The following are examples of the effects that changes in temperature may have on a food or its packaging.

- A 10°C increase in temperature approximately doubles the rate of chemical decomposition within a product.
- Sudden changes in temperature can cause moisture condensation, leading to deterioration of packaging, loss of nutrient content, and infestation by pests.

Fortified foods differ greatly in their susceptibility to degradation by various environmental agents. For this reason, it is important to design packaging to protect the food against the specific agents that threaten its stability. Table 3.1 provides examples of the effects of environmental factors on nutrient stability and food quality.

Use of ideal packaging materials may be unrealistic because of economic constraints. Nevertheless, where feasible, packaging should be as suitable as possible to protect micronutrient integrity and the quality of the fortified food. For example, if a fortified food is sensitive to moisture, its packaging should be impermeable to water. Overages of micronutrients to compensate for micronutrient loss as a result of suboptimal packaging may also be considered.

In selecting or designing appropriate packaging, it is also important to consider local

Table 3.1. Factors influencing deterioration of food quality

Factor	Effect on stability and interaction of food components	Overall effect on fortified food quality
Light	Destruction of fat-soluble vitamins A and E	Loss of nutritional quality
	Destruction of water-soluble vitamins, including riboflavin	Loss of nutritional quality
	Oxidation of fats and oils	May cause off-flavor, odor, and color changes
	Changes in proteins and amino acids	Loss of nutritional quality
Temperature	Acceleration of chemical decomposition	Loss of nutritional quality and decreased fortified food quality
	Increase in microbial growth rate	Decreased fortified food quality, food spoilage, lowered shelf life, and food safety concern
Oxygen	Destruction of certain vitamins and insolubility of certain minerals	Loss of nutritional quality
	Changes in proteins and amino acids	Loss of nutritional quality
	Oxidation of fats and oils	May cause off-flavor, odor, and color changes
Moisture	Increase in potential for microbial growth	Decreased fortified food quality, food spoilage, lowered shelf life, and food safety concern
	Facilitates chemical decomposition	Loss of nutritional quality and decreased fortified food quality
	Oxidation of fats and oils	May cause off-flavor, odor, and color changes
Pest infestation	Loss of product	Decreased fortified food quality
	Contamination of fortified food with urine and feces	Decreased fortified food quality, food safety concern
	Breach of package barrier to accelerate losses due to light, oxygen, moisture, and microbial growth	All of the above

climatic conditions. For example, if the local climate is predominantly hot and humid, packaging should protect the fortified food from both heat and moisture.

Primary packaging is packaging that is in direct contact with the product. *Secondary packaging* is the outer packaging that provides additional protection from the environment and from rough handling. For example, small bags or boxes of fortified food may be placed in larger boxes made of paperboard or corrugated cardboard.

Packaging specifications. The use of *packaging specifications* ensures that fortified food is always packaged properly to protect it from damage due to environmental factors or

rough handling. A packaging specification should

- identify the protective characteristics necessary to maintain the integrity of the food, including the nutrient quality of a fortified food; and
- for both primary and secondary packaging, define the packaging material, including its size, color, and other features.

Packaging procedures. It is important to establish packaging procedures to ensure that quality standards for the fortified food are maintained during packaging. 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.

Handling. 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.

Labeling

Labeling of fortified food serves two purposes:

- It identifies the fortified food and differentiates it from unfortified products. This must include an appropriately descriptive name of the fortified food and, in addition, may include the use of a symbol, a different package color, or a different print style on the package.
- It provides information about the fortified food's nutrient content. It is in the best interests of a food manufacturer to provide this information, although most developing countries do not require *nutrition labeling*.

Fortified food should be labeled in accordance with government regulations. Codex guidelines on nutrition labeling require the following information to be included in the labeling of fortified foods:

- 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, pack-

ager, importer, or distributor.

- Country of origin.
- Lot number.
- Expiration date (an open dating system is recommended).

Various types of *open dating* (printing on the package the date by which the fortified food should be consumed) can be used.

- Date of manufacture and shelf life of the fortified food (i.e., number of months from date of manufacture).
- “Use by” or “Best if used by” date. This indicates the date by which a fortified food should be consumed to ensure maximum quality.

Storage

Storage means keeping a fortified food in a facility—often a warehouse—until it is transported further through distribution channels. The following steps are recommended to ensure that the quality of a micronutrient premix or a fortified food is maintained during warehouse storage:

- Keep the warehouse at normal room temperature.
- Keep the storage area clean, well lit, and ventilated with fresh air.
- Ensure that the warehouse floor is above street level to permit water drainage.
- Use safety-proof lamps or enclose lamps in plastic shields to prevent contamination of the premix or fortified food if a lamp should break.
- Place sinks and bathrooms in a part of the warehouse separate from the area where premix and fortified food are stored.
- Locate sewer and water disposal systems away from the area where premix and fortified food are stored. If this is not possible, keep toilets flushed and lids closed to avoid

off-odors and keep pests out.

- Keep defective premix and fortified food (returned, marked for disposal, etc.) in a separate area isolated from the main storage area.
- Keep the roof free of leaks.
- Keep external areas near the warehouse paved and free of debris and scrap.

Pest control. Premix and fortified food in storage is at particular risk for damage from pests such as bacteria, molds, insects, rodents, bats, and birds. Bacteria and molds, which need moisture to survive, are controlled by maintaining a dry environment. Clean storage conditions usually control insects and rodents.

The following steps are recommended to control pests in warehouse storage facilities:

- Place removable screens on all windows to keep pests out of the area where the premix and fortified food are stored.
- Keep floors, walls, and walkways clean, dry, and free of obstructions.
- Ensure that all surfaces are smooth and painted.
- Repair all cracks and holes immediately to prevent moisture.

Inventory control. The control of *inventory* is a crucial aspect of quality assurance in the food industry because many foods, including fortified food, are perishable or have a limited shelf life. The following steps are recommended to assure quality in the control of inventory.

- Establish procedures to ensure that fortified food is rotated on a FIFO basis. For example, use stickers of different shapes or colors for each lot. Number lots consecutively in the order they are received. For each lot, write the lot number and the date of receipt on the sticker.
- Design storage areas to facilitate the FIFO

policy, with bags or boxes of fortified food stored in consecutive order so that the oldest can be withdrawn first.

- Make a written record of any lot or sub lot that does not meet specifications. Fortified food may fail to meet specifications because its “use by” date has expired or because its packaging was damaged in manufacturing, storage, transportation, or handling.
- Establish procedures to ensure that fortified food failing to meet specifications is disposed of and does not go back into distribution.

Transportation

It is common for packages of fortified food to be damaged in transit, resulting in a 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.

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 moisture-resistant packaging can help to reduce the risk of environmental damage to products in transit (see ***Packaging***, pp. 32–34).

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.

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 about 50 kg (110 lb). The preferred weight range for packages is 10-25 kg (22-55 lb). Within that range, packages are neither too heavy to handle nor light enough to be thrown.

Section Summary

- The process of getting a fortified food from the factory to the consumer presents numerous challenges that can degrade the quality of the fortified food.
- 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.
- Labeling identifies a product as a fortified food, differentiates it from unfortified foods, and provides information about the fortified food's nutrient content.
- It is important to establish procedures to maintain the quality of the fortified food during the storage and transportation stages of the distribution process.

Chapter Summary

- The first step in any quality assurance system for food fortification programs is to confirm the quality, handling, and storage of the fortificant or vitamin premix.
- Most problems in food fortification relate to deviations from norms, which result in quality standards not being met.
- For a food fortification program to be successful, the fortified food must reach the consumer in a condition that the consumer considers acceptable while complying with production standards and norms.

Appendix 1. Regulation of Fortified Foods in the Philippines: Extracts from Implementing Rules and Regulations for the Philippine Food Fortification Act of 2000 (Republic Act No. 8976)

Mandatory implementing rules and regulations for the Philippine Food Fortification Act of 2000 were established in November 2000 and will take effect in November 2004. The following are verbatim extracts from these regulations. Other sections of the regulations cover the definition of terms; voluntary food fortification; implementation, monitoring, and review; and administrative sanctions for noncompliance. For a complete picture of the regulation of food fortification in the Philippines, please refer to the Philippine Food Fortification Act of 2000 and its implementing rules and regulations.

Rule VI - Mandatory Food Fortification

SECTION 1. The following staple food products shall be fortified in accordance with standards set by the DOH [Department of Health] through BFAD [Bureau of Food and Drugs], except as provided in Section 2, Rule X, as follows:

1. All rice, except brown rice and locally produced glutinous rice, to be fortified with iron. For this purpose, the DOH through BFAD, in consultation with the National Food Authority and the Philippine Confederation of Grains Association (PHILCON), hereby sets the minimum standard for rice fortification, to wit:

Fortificant	Minimum acceptable level	Maximum tolerable level
Iron		
Ferrous sulfate	60 mg Fe/kg raw rice	90 mg Fe/kg raw rice
Others approved by DOH/BFAD	Levels set by BFAD	Levels set by BFAD

2. Wheat flour to be fortified with vitamin A and iron. The DOH through BFAD, in consultation with the Philippine Association of Flour Millers and the Philippine Chamber of Flour Manufacturers, hereby sets the minimum standards for wheat fortification, to wit:

Fortificant	Minimum acceptable level	Maximum tolerable level
Vitamin A		
Retinol palmitate/acetate	3.0 mg/kg as retinol	6.5 mg/kg as retinol
Or others approved by BFAD	Levels set by BFAD	Levels set by BFAD
Iron		
Elemental iron (electrolytic, H reduced, particle size should be ≤ 50 microns)	70.0 mg Fe/kg	105 mg Fe/kg
Ferrous sulfate or ferrous fumarate	50.0 mg Fe/kg	75.0 mg Fe/kg
Others approved by BFAD	Levels set by BFAD	Levels set by BFAD

3. Refined sugar for human consumption to be fortified with vitamin A. The DOH through BFAD, in consultation with Sugar Regulatory Administration (SRA) and sugar industry organizations, hereby sets the minimum standards for refined sugar fortification, to wit:

Fortificant	Minimum acceptable level	Maximum tolerable level
Vitamin A		
Retinol palmitate	5.0 mg/kg	30.0 mg/kg
Or others approved by BFAD	Levels set by BFAD	Levels set by BFAD

4. Cooking oil for human consumption to be fortified with vitamin A except for export. The DOH through BFAD, in consultation with the Philippine Coconut Authority (PCA), the United Coconut Association of the Philippines (UCAP), the Coconut Refiners Association (CORA), and the Philippine Coconut Research and Development Foundation (PCDRF) hereby sets the minimum standards for fortification of cooking oil, to wit:

Fortificant	Minimum acceptable level	Maximum tolerable level
Vitamin A		
Retinol palmitate	12.0 mg RE/L	23 mg RE/L
Or others approved by BFAD	Levels set by BFAD	Levels set by BFAD

5. Other staple food products shall be fortified with appropriate nutrients as may be required by the National Nutrition Council (NNC) when nutrition surveys show the need for fortification of such other staple food, and scientific findings show the feasibility of fortifying such food products.
6. Such food fortification that may be required by the NNC does not need further legislation but only through regulations to be promulgated by the DOH through BFAD, in consultation with other concerned agencies and industry organizations.

Rule VII - Quality Assurance

SECTION 1. In accordance with the mandate of Sec. 7 of Rep. Act No. 8976, the agencies responsible for the implementation of this law shall establish a quality assurance system with respect to food fortification. However, manufacturers and importers of processed food or food products or repackers shall also establish their own quality assurance system, which shall conform to the quality assurance system of the implementing agency. Annex 1 (General Quality Assurance System for Food Fortification) is to be used as a guide.

Rule X - Noncompliance with Fortification Process

SECTION 1. The following acts shall be considered as noncompliance with the food fortification process:

- a. If the food fortification level does not comply with the requirements as mentioned in Rule VI, Section 1 except when the deviation from the fortification levels are justified [stet] and are properly declared on the label of the product.
- b. If the fortificant used is different from that approved by the DOH/BFAD, and
- c. If the process of fortification does not conform to Rule VII of this IRR.

SECTION 2. The above process notwithstanding, exceptions subject to approval by BFAD, may be allowed as in the following cases:

- a. Dietary supplements for which established standards have already been prescribed by the DOH through BFAD.
- b. Those intended for exports or for use in the production of other processed food products, such as beverages where the fortified product used for food processing may affect the processed product by the fortificant.

Annex 1 - General Quality Assurance System for Food Fortification

The quality assurance system of the manufacturers and importers in the fortification of food products should include or address the following:

- 1. Imposing quality control on the fortificant(s) to ensure that specifications are met:**
 - 1.1 require certificate of analysis for every delivery of the fortificant(s)
 - 1.2 checking if the fortificant(s) used is still within the market shelf-life.
- 2. Identifying quality control measures for fortificant(s) handling and storage**
 - 2.1 fortificant(s) properly sealed and stored in a cool, dry place
 - 2.2 sensitive fortificant(s) in packing size that can be consumed for one batch of product or for one day's production
 - 2.3 one package of fortificant(s) good for several batches produced within a few day, i.e., not more than one week
 - 2.4 fortificant(s) properly weighed and appropriate records maintained
 - 2.5 weighed fortificant(s) properly handled; used within a day
 - 2.6 container source of the fortificant(s) immediately sealed after weighing and stored in a cool dry place.
- 3. Establishing/identifying quality control on the fortification process**
 - 3.1 equipment used appropriate for product being fortified
 - 3.2 mixing method as described is an approved production process
 - 3.3 mixing time observed and recorded.
- 4. Routinely undertake analyses of the fortification level of the fortified products (indicating frequency)**
 - 4.1 in-house analysis of the fortificant(s) in the finished product
 - 4.2 analysis done by external laboratories.
- 5. Conduct equipment calibration**
 - 5.1 equipment measuring devices calibrated as scheduled
 - 5.2 calibration records maintained.
- 6. Putting in place a recall system in case a product recall is needed**
 - 6.1 identifying fortified product by its lot identification code.
- 7. Record keeping of all the quality control activities for the fortified products**

Appendix 2. Model Principles for Sugar Fortified with Vitamin A

This model of technical specifications for sugar fortified with vitamin A is based on specifications proposed for Central America. These criteria complement the current Codex standard for sugar—which provides technical specifications only for essential composition and quality factors—by proposing specific parameters related to fortification with vitamin A, packaging and labeling requirements, and QA criteria for fortified sugar.

Variable	Definition																																				
Scope of application	This proposal applies to sugar sold directly to the consumer, including a fine crystallized dry product in normal presentations as well as a prepackaged product in envelopes or sugar cubes in presentations of 1-2 teaspoons. The proposal is applicable to refined sugar, white “standard” or direct sugar, and brown sugar.																																				
Description	Sugar is a commercial product consisting mainly of sucrose, which has been purified and crystallized from vegetable sources such as sugar cane or beet. Sugar fortified with vitamin A is sugar that contains a retinyl ester that has adhered to the sugar crystals by means of a vegetable oil coat or any other substance adequate for human consumption. The retinol compound is dispersible in cold water.																																				
Essential composition and quality factors	<p>Sugar, regardless of its type, has to be clean and free of foreign substances.</p> <p>Refined white sugar (specification A)</p> <table> <tr><td>Polarization (minimum)</td><td>99.7 degrees S</td></tr> <tr><td>Inverted sugar</td><td>0.04% wt/wt</td></tr> <tr><td>Ash</td><td>0.04% wt/wt</td></tr> <tr><td>Moisture</td><td>0.1%</td></tr> <tr><td>Color without retinol (maximum)</td><td>60 U. ICUMSA^a</td></tr> <tr><td>Color with retinol (minimum)</td><td>60 U. ICUMSA</td></tr> <tr><td>Color seen by the human eye</td><td>white to yellowish white</td></tr> </table> <p>Standard or direct white sugar (specification B)</p> <table> <tr><td>Polarization (minimum)</td><td>99.5 degrees S</td></tr> <tr><td>Inverted sugar</td><td>0.1% wt/wt</td></tr> <tr><td>Ash</td><td>0.1% wt/wt</td></tr> <tr><td>Moisture</td><td>0.1%</td></tr> <tr><td>Color without retinol (maximum)</td><td>150 U. ICUMSA</td></tr> <tr><td>Color with retinol (minimum)</td><td>200 U. ICUMSA</td></tr> <tr><td>Color seen by the human eye</td><td>white to yellowish white</td></tr> </table> <p>Brown sugar (specification C)</p> <table> <tr><td>Polarization (minimum)</td><td>93.0 degrees S</td></tr> <tr><td>Ash</td><td>3.5% wt/wt</td></tr> <tr><td>Moisture (maximum after 3 hrs. At 105°C)</td><td>1.00%</td></tr> <tr><td>Color seen by the human eye</td><td>brown</td></tr> </table>	Polarization (minimum)	99.7 degrees S	Inverted sugar	0.04% wt/wt	Ash	0.04% wt/wt	Moisture	0.1%	Color without retinol (maximum)	60 U. ICUMSA ^a	Color with retinol (minimum)	60 U. ICUMSA	Color seen by the human eye	white to yellowish white	Polarization (minimum)	99.5 degrees S	Inverted sugar	0.1% wt/wt	Ash	0.1% wt/wt	Moisture	0.1%	Color without retinol (maximum)	150 U. ICUMSA	Color with retinol (minimum)	200 U. ICUMSA	Color seen by the human eye	white to yellowish white	Polarization (minimum)	93.0 degrees S	Ash	3.5% wt/wt	Moisture (maximum after 3 hrs. At 105°C)	1.00%	Color seen by the human eye	brown
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Moisture (maximum after 3 hrs. At 105°C)	1.00%																																				
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Food additives	<p>Specifications for A, B, and C</p> <p>Vitamin A Dry, dispersible retinyl ester, type 250 CWS (Roche) or 250-CWD (BASF), containing 75 g of retinol per kg or 250,000 units of vitamin A per gram, or other products with similar or better biological and stability properties.</p> <p>Retinol (minimum during the normal marketable life of sugar) 5 mg/kg^b</p> <p>Specification A (Refined white sugar)</p> <table> <tr><td>Sulfur dioxide (maximum)</td><td>20 mg/kg</td></tr> </table>	Sulfur dioxide (maximum)	20 mg/kg																																		
Sulfur dioxide (maximum)	20 mg/kg																																				

^a International Commission for Uniform Methods of Sugar Analysis

^b To comply with this requirement, if fortification occurs when the sugar is produced, it is recommended that the average amount of retinol be 15 mg/kg, with a tolerance range of 10-20 mg/kg. This level is applicable to Central America where the consumption of sugar is high.

Specification B (Standard or direct white sugar)

Sulfur dioxide (maximum) 70 mg/kg

Specification C (Brown sugar)

To be determined

Contaminants

Contamination levels for the following elements must be less than the following values:

Specifications A and B**Contaminant****Maximum level**

Arsenic (As)

1.0 mg/kg

Copper (Cu)

2.0 mg/kg

Lead (Pb)

0.5 mg/kg

Specification C

To be determined

Packaging and labeling**Packaging:**

Sugar for sale directly to the consumer should be prepackaged in new containers, manufactured from a safe, resistant, nontoxic material that assures the product's stability, avoids contamination, and does not alter the product's sensory characteristics. Small containers (0.5-10 kg) are preferred.

Labeling:

In addition to other requirements from the Codex General Standards for Labeling Prepackaged Foods, the following are emphasized:

Labels shall be printed on top of the packaging material, in the official language of the country, easily legible, and printed in such a way that the label does not wear off under normal conditions. Labels should include:

- Name and type of food: Sugar (type) fortified with Vitamin A
- Commercial brand
- Name and address of manufacturer, packer, or distributor
- Country of origin. Product of ... (name of producing country), Fortified and packaged in... (name of country), or Packaged in... (name of country), as appropriate
- Because the package contains only one ingredient, a list of ingredients is unnecessary.
- Declaration of retinol content: Minimum retinol content 5 mg/kg, assured until ... (day, month, year)
- Logotype (optional for the producer, packer, or distributor, according to the conditions of the country)

Fortification quality assurance criteria**Quality control and quality assurance (Manufacturing plants or packaging centers):**

Retinol concentration >10 mg/kg in all composite samples and an average of 15 mg/kg

Inspection and quality audit (Department of Food Control):

- Confirmation of quality control records
- **Verification tests:** Five individual samples taken at random from each brand during each visit, for retinol levels >5 mg/kg
- **Quality audits with compliance evaluation:** See volume 13 of Codex Alimentarius regarding sampling methods

Monitoring (Department of Food Control and compliance verification units, standards control or consumer protection agencies):

Checking containers and labeling of all authorized brands and, if possible, verification tests: two individual samples taken at random from each brand at each site, for retinol levels >5 mg/kg

Surveillance (Department of Nutrition and collaborators)

Retinol concentration >5 mg/kg in >90% of samples collected in target households representative of the nation

Appendix 3. Template for a Quality Assurance/Quality Control Record

(See Appendix 4 for an example of a completed record)

Harvest _____ - _____ PAGE #: _____ - _____
 (Year) (Year) (Year) (Page)

Date	Shift	Assay method (specify)					Fortified food (MT)* (A)	Used premix (kg) (B)	A/B x 1000	Observations
		Time of day								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
		[Nutrient]								
ACCUMULATED THIS PERIOD										

Range of sensitivity of the method:

*MT=metric ton

Lab. Supervisor _____

Appendix 4. Sugar Fortification with Vitamin A: Example of a Completed QA/QC Record

Harvest: 1996 - 1997 PAGE #: 96-002

Date	Shift	Colorimetric analysis†					Fortified sugar (MT)* (A)	Used premix (kg) (B)	A/B × 1000	Observations
		[Retinol]	15-20	15-20	15-20	—				
Nov. 12	2pm-10pm	[Retinol]	15-20	15-20	15-20	—	45	50	900	—
Nov. 12	10pm-6am	[Retinol]	—	—	—	—	25	25	1,000	—
Nov. 13	6am-2pm	[Retinol]	15-20	15-20	15-20	15-20	45	50	900	—
Nov. 13	2pm-10pm	[Retinol]	10-15	15-20	15-20	15-20	40	50	800	—
Nov. 13	10pm-6am	[Retinol]	10-15	15-20	10-15	—	25	25	1,000	—
Nov. 14	6am-2pm	[Retinol]	5-10	5-10	15-20	—	45	50	900	Dosifier set too low.
Nov. 16	2pm-10pm	[Retinol]	10-15	15-20	15-20	—	40	50	800	—
Nov. 16	10pm-6am	[Retinol]	15-20	15-20	15-20	15-20	50	50	1,000	—
Nov. 17	6am-10pm	[Retinol]	15-20	-5	ND	15-20	50	25	2,000	New worker forgot to feed dosifier.
ACCUMULATED THIS PERIOD							365	375	973	—

*MT=metric ton

† — = No sample

ND = Not detected

- 5 = Less than 5 mg/kg

5-10 = Between 5 and 10 mg/kg

10-15 = Between 10 and 15 mg/kg

15-20 = Between 15 and 20 mg/kg

+ 20 = More than 20 mg/kg

Lab. Supervisor _____

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Web Sites

American Society for Quality (<http://www.asq.org>)

Association of Official Analytical Chemists (<http://www.aoac.org>)

Codex Alimentarius Commission (<http://www.codexalimentarius.net>)

International Nutritional Anemia Consultative Group (<http://inacg.ilsis.org>)

International Vitamin A Consultative Group (<http://ivacg.ilsis.org>)

Micronutrient Initiative (<http://www.micronutrient.org>)

MOST - The USAID Micronutrient Program (<http://www.mostproject.org>)

Other Reading Materials Relevant to the Implementation of a Food Safety And Quality Assurance Program

Codex Food Standards: The Codex Standards, Guidelines, and Recommendations are available on-line at www.codexalimentarius.net/STANDARD/Volume_E.html

Codex sampling plans for prepackaged foods, Codex Stan 233-1969: Provide sampling plans

that may be applied to prepackaged foods to determine defective units in lots. The sampling plans are intended to be used in accordance with the provisions dealing with the classification of defectives and lot acceptance in the Codex standards for the individual foods. Also see Recommended Methods of Analysis and Sampling, Codex volume 13. www.codexalimentarius.net/standards_list.asp Food Chemicals Codex: The fourth edition, published in 1996, and subsequent supplements can be purchased through the National Academy Press at www.nap.edu

Current Good Manufacturing Practices (CGMP): A compilation of the U.S. Food and Drug Administration's (FDA) CGMP regulations for manufacturing, packing, and holding foods for human use. <http://www.cfsan.fda.gov/~lrd/cfr110.html>

Food Safety and Quality Assurance: Outlines the concepts of food safety and the quality assurance process and their application in milk processing. Available through the Institute of Food Technologists in the United States. http://www.ift.org/education/food_industry/lesson1.shtml?L+mystore+

Inspections Guides, Grain Product Manufacturers: Prepared by the Office of Regulatory Affairs, U.S. Food and Drug Administration, this guide specifically deals with inspections of grain processors and grain/bakery food manufacturers. This guide is used in addition to general inspectional instructions provided in the Investigations Operations Manual. http://www.fda.gov/ora/inspect_ref/igs/grain.html

Inspection Guides, Miscellaneous Food Products Vol. 2, General: Prepared by the Office of Regulatory Affairs, U.S. Food and Drug Administration, this guide is applicable to in-

spections of manufacturers foods including sugar and salt. This guide is used in addition to general inspectional instructions provided in the Investigations Operations Manual. http://www.fda.gov/ora/inspect_ref/igs/foodsp2.html#SECTION%201:

Investigations Operations Manual (IOM): Prepared by the Office of Regulatory Affairs, U.S. Food and Drug Administration, the IOM is the primary source of guidance for FDA field investigators and inspectors. It directs the conduct of all fundamental field investigational activities related to all FDA-regulated products, including foods. FDA investigators ad-

here to this manual to assure quality, consistency, and efficiency in field operations. http://www.fda.gov/ora/inspect_ref/IOM/iomtc.html

Quality Management Principles: This document introduces the eight quality management principles on which the quality management system standards of the revised ISO 9000:2000 series are based. This document was prepared by experts from the ISO Technical Committee on quality management and quality assurance, which is responsible for developing and maintaining the ISO 9000 standards. www.iso.org/iso/en/iso9000-14000/iso9000/qmp.html