Code of Practice
for
Food Premix Operations

Nutrition Unit
Family and Community Health Area
Washington D.C.

Pan American Health Organization
Regional Office of the
World Health Organization

FCH/NU/66-16/04
Original: English
Distribution: GENERAL








PAHO HQ Library Cataloguing-in-Publication

Pan American Health Organization. Family and Community Health Area. Nutrition Unit
Code of practice for food premix operations.

Washington, D.C: PAHO, © 2005.
FCH/NU/66-16/04

ISBN 92 75 12589 9

I. Title

1. FOOD QUALITY
2. FOOD INDUSTRY
3. FOOD INSPECTION
4. FOOD - standards
5. LEGISLATION, FOOD

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Graphic design: Alex Winder

NLM WA 695

This document is available online at www.paho.org.

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Acknowledgements

This Code of Practice was produced under the overall direction of Dr. Wilma Freire of the PAHO Nutrition Unit. The document was prepared by Drs. Manfred Septinus and Hector Cori of DSM Nutritional Products in close collaboration with the Pan American Institute for Food Protection and Zoonoses (INPPAZ), and edited by Ms. Sunny Kim of the PAHO Nutrition Unit. Special thanks are extended to Drs. Claudio Almeida, Enrique Pérez, and Juan Cuellar, and Ms. Ana María Ribetto of INPPAZ; Dr. Omar Dary of the MOST Project/USAID Micronutrient Program; Dr. Eva Hertrampf of the Institute of Nutrition and Food Technology (INTA), University of Chile; and Ms. Monica Guamuch of the Institute of Nutrition for Central America and Panama (INCAP/PAHO), for their contributions in reviewing this document.

PREFACE

Food fortification with micronutrients is one of the most important strategies for increasing the intake of vitamins and minerals of public health significance and improving the nutritional status of people on a continuous and self-sustaining basis. In the Americas, wheat and/or corn flour are widely consumed and are excellent vehicles for fortification with micronutrients. Nearly all the countries in the Region are already fortifying wheat and/or corn flour with iron, folic acid, and other B-complex vitamins. Other widely-consumed staple foods, such as sugar, milk and vegetable oil, and targeted foods consumed by specific population groups, such as infant formulas and cereals and commercial complementary foods, are being fortified with micronutrients.

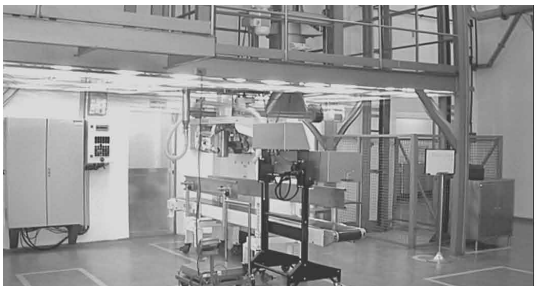
Experience in food fortification gathered over many years have helped to identify specific actions to strengthen food fortification programs and assure that designated foods are adequately fortified and delivered to the population. Factors for limited success of food fortification programs include the lack of or weak regulations, suboptimal types and concentrations of fortificants, poor manufacturing practices and standards for fortified foods, lack of or weak quality control/quality assurance systems, and lack of demand generation through consumer awareness and participation. Developing methods and implementing actions to address these issues are key to assuring effective and sustainable food fortification programs.

In the Americas, PAHO/WHO and various partner organizations are working to address these issues, particularly in developing guidelines for taking sound actions. In January 2001, PAHO, the Human Nutrition Institute of the International Life Sciences Institute (ILSI), and the U.S. Agency for International Development (USAID) through the International Nutritional Anemia Consultative Group (INACG) organized a technical consultation to develop practical guidelines on the types and levels of iron compounds recommended for food fortification. These guidelines based on currently available scientific evidence were widely disseminated for use in the Latin American and the Caribbean countries. In January 2003, PAHO with the March of Dimes (MOD) and the Centers for Disease Control and Prevention (CDC) organized a second technical consultation to establish guidelines for recommended levels of fortification with folic acid and vitamin B12.

Following these two technical consultations, PAHO, CDC, MOD, UNICEF, and the Institute of Nutrition and Food Technology (INTA) of the University of Chile held a regional meeting with participants from 20 countries in the Americas. The purpose of this meeting was to translate current scientific knowledge into practice, by transferring the information for optimizing flour fortification into the hands of policy-makers and program implementers. The meeting provided a forum for participants representing the Ministries of Health, the regulatory or food control agencies, and flour millers in each country to exchange ideas, experiences, concerns, and needs. The discussions resulted in the recommendations by the countries on specific activities to improve food fortification programs.

One of the recommendations was in reference to the need for guidelines and mechanisms for assuring the quality of food premixes. With the growing number of commercial premix suppliers in the Region, both the public health authorities and food producers recognize the need to assure premix quality not only in terms of adequate types and levels of nutrients added but also in relation to hygiene, food safety, and good manufacturing practices, thereby assuring that the premix meets the minimum requirements for human consumption.

This Code of Practice for Food Premix Operations is the first response to a need raised by the implementers of food fortification programs. The first step to assuring premix quality will be the adoption of this Code by premix operators for their internal audit. The next steps will include developing a system of external auditing and certification of premix quality by regulatory agencies at the regional or sub-regional level. PAHO/WHO is pleased to produce the Code of Practice for Food Premix Operations and contribute to building effective food fortification programs to eliminate micronutrient deficiencies and improve the health and nutrition of populations.



INTRODUCTION

With this industry Code of Practice for Food Premix Operations, it shall be ensured that all types of food premixes are safe, that respective businesses operate in accordance with hygiene requirements harmonized at the regional level, and that traceability is improved.

In order to bring this Code in line with current food legislations and various activities at the national, industrial and/or association levels, it incorporates the principles of quality management and food safety as well as HACCP principles that are spelled out in:

- EN ISO 9001:2000, Quality management systems
- EU Commission's white paper on food safety
- Regulation (EC) No 178/2002 of the European parliament and of the council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority
- Relevant codes of practice of the Codex Alimentarius
- Principles of HACCP, re. Codex Alimentarius, General Principles of Food Hygiene, (CAC/RCP 1-1969, Rev. 3-1997, Amd. (1999), Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application), http://www.codexalimentarius.net/
- Good Manufacturing Practices as per the Code of Federal Regulations 21 CFR 110
- Standards of the American Institute of Baking
- Recommended International Code of Practice: General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)
- General Standard for Food Additives (Codex Stan 192-1995, Rev. 4-2003)
- ISO 15161:2001, Guidelines on the application of ISO 9001:2000 for the food and drink industry

The combination of these principles provides guidance for the food premix operators on what measures to implement and how to execute them in order to contribute to international food manufacturing and trade.

The aim of this Code is to provide a user-friendly document as background information and guidance for establishing industrial standard on reducing risk related to adulterated food premixes entering into the food chain. This Code is meant to be a guide to specify the general requirements.

An audit score sheet is included in the Appendix as a reference tool to provide detailed guidance to operators and for auditing compliance with this Code.

SECTION 1 SCOPE

This Code of Practice shall apply to food premix operators at all stages from the first placing of food premixes on the market. It also applies to food premixes imported from third countries.

This Code is structured following the general guidelines for quality management and food safety, taking into account the principles of various agencies and codes as stated in the introduction of this Code. Emphasis is taken on how to structure a Quality Management System, the Good Manufacturing Practices and corresponding prerequisite programs, and the HACCP system for food safety.

This Code establishes requirements for internal audit programs.

SECTION 2 TERMS AND DEFINITIONS

For the purpose of this Code:

Audit	A systematic examination involving professional judgment to determine whether food quality and safety activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Authorized personnel	Persons who have skills, permission and purpose as specified by e.g. job descriptions, process descriptions or management.
Calibration	The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.
Carry-over	The presence of an ingredient other than by direct addition following the guidelines established by the Codex Standard 192-1995. Cross-contamination is not considered under the definition of carry-over and should be eliminated by GMP.
Check/control	To monitor and measure processes and products against predetermined measurements related to product specifications, GMP, SSOP, HACCP or any other process oriented towards compliance with the quality standards of the operator.
Code of practice	It identifies the essential principles of food hygiene to ensure their safety for human consumption.
Contamination	The undesired introduction of impurities of a chemical or microbiological nature or of foreign matter, into or onto a raw material, intermediate, food additive or premix during production, sampling, packaging or repackaging, storage or transport.
Critical control point	A point in a step or procedure at which a control is to be applied to prevent or eliminate a hazard or reduce it to an acceptable level.
Critical limit	A value that separates acceptability from non-acceptability.
Cross-contamination	Contamination of a material or product with another material or product.
Food additive	Any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities (Codex Alimentarius).
Food hygiene	All measures and conditions necessary to control hazards and to ensure fitness of a food additive or a premix for human consumption, according to its intended use.
First placing on the market	The initial placing on the market of an additive after its manufacture or the import of an additive.

HACCP (Hazard Analysis and Critical Control Point)	A system that identifies, evaluates and controls hazards which are significant for food safety.
HACCP plan	A written document accepted by the regulatory authority that delineates the formal procedures for following the HACCP system that identifies, evaluates and controls hazards which are significant to food safety. It is based upon the Codex Alimentarius principles of HACCP and includes a generic hazard analysis for the process that results in a list of recognized hazards, which are then translated into a series of critical points and prerequisite programs to support the wholesome of the safety system.
Hazard	A biological, chemical or physical agent in the food chain with the potential to cause an adverse health effect for animals or consumers.
Hazard analysis	The process of collecting and evaluating information on hazards and conditions leading to their presence in all steps in the establishment or production operation, in accordance with the appropriate HACCP principles, to decide which are significant for food safety and therefore should be addressed in the HACCP plan and to elaborate the specific critical control point and critical limit for each hazard as defined by Codex Alimentarius.
Incoming material	A general term used to denote raw materials (starting materials, reagents and solvents), process aids, intermediates, and packaging and labeling materials.
Intermediate	Any product that has not yet been labeled as a final product, intended to be first placed on the market as a food additive.
Lot	A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a lot may correspond to a defined fraction of the production. A lot size may be defined either by a fixed quantity or the amount produced in a fixed time interval.
Lot number	A combination of numbers, letters and/or symbols which identifies a lot and from which the production and distribution history can be determined.
Manufacture/ production	All operations of receipt of materials, production, packaging, repackaging, labeling, re-labeling, quality control, release, storage, and distribution of food additives and premixes and the related controls.
Operator	Any unit of producing or manufacturing food premixes prepared from additives and any person, other than the manufacturer or the person producing for the exclusive requirements of his holding, who holds additives or premixes prepared from additives.
Placing on the market	Holding products for the purposes of sale, including offering for sale, or for the purposes of any other form of transfer, whether or not free of charge to third parties, and the sale and other forms of transfer themselves.
Plan	Establishes the objectives and processes necessary to deliver results in accordance with the organization's policies regarding quality and safety.
Premixes	Mixtures of food additives or mixtures of one or more food additives with food materials or water used as carriers, not intended for direct consumption by humans.

Procedure	Operations to be performed, precautions to be taken and measures to be applied directly or indirectly related to the manufacture of a material, food additive or premix.
Raw material	All materials which are in the final product.
Reworking	Any appropriate manipulation steps taken when the product does not comply with the specifications and when it is possible to follow corrective actions. The result of these actions must ensure a food additive or premix is conformed to specifications.
Risk	Exposure to a hazard that is likely or has a high possibility to occur.
Shall	It is a requirement to comply with the contents of the clause.
Should	When there is no requirement to comply with the contents of the clause, but compliance is recommended.
Specification	A list of tests, references to analytical procedures and appropriate acceptance criteria that are numerical limits, ranges or other criteria for the test described. It establishes the set of criteria to which a material should conform to be considered acceptable for its intended use. "Compliance to specification" means that the material, when tested according to the listed analytical procedures, meets the listed acceptance criteria.
SOP (Standard Operating Procedures)	Any manufacturing practice rule by commonly accepted operational practices for the particular process.
SSOP (Sanitation Standard Operating Procedures)	Operations to conduct cleaning and sanitation procedures as established by the Good Manufacturing Practices.
Verification	Application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.
Written documents	These may be substituted by electronic, photographic or other data processing systems provided that the data will be appropriately stored during the anticipated period of storage (archive) and can be made readily available in a legible form.

SECTION 3 QUALITY MANAGEMENT SYSTEM (QMS)

3.1 General Requirements

The operator shall establish, document, implement and maintain a quality and food safety management system in accordance with the requirements of this Code of Practice. It shall be continually adapted to regulatory developments.

The structure of the quality and food safety management system should be specific to the organization of the operator and includes policies, requirements and process documents that reflect the best practices of the operator. The system should ensure that all the activities within the operator that could impact on the quality and food safety of the product are consistently defined, implemented and maintained at all levels in the organization. ISO standards as well as other approaches may be used to define the Quality Management System (QMS). GMP, SOP and HACCP approaches shall be used to support the food safety activities.

The operator shall document that the quality system is working efficiently by planning, implementing and monitoring processes in order to demonstrate conformity of the products and conformity of the QMS. Monitoring processes includes collection of measurements, data analysis, drawing of conclusions, and, if relevant, issuing of procedures to improve the QMS.

3.2 Quality Policy

The operator shall have a properly defined and documented quality policy.

The policy shall provide a framework for establishing and reviewing quality objectives.

The policy shall state the operator's intention and commitment toward the production of quality and safe products, and the corresponding responsibility to its customers and employees. The policy shall be communicated throughout the organization and regularly reviewed to ensure business and legal requirements are achieved.

The policy should be understood by all supervisory staff and key personnel and implemented accordingly.

Management shall ensure that the policy is in compliance with the business goals of the organization, the statutory and regulatory requirements, and specific additional safety requirements from customers.

3.3 Quality Manual

The operator shall have a quality manual that states the organization's commitment to quality. The document should contain an outline of working methods and practices to achieve the requirements of this guideline.

The quality manual should be available to all personnel relevant to the operation.

The requirements established within the quality manual should be fully implemented.

The quality manual shall include:

- The scope of the QMS, GMP and food safety programs, including details of and justification for any exclusion;
- The documented procedures established for the QMS, GMP and food safety programs or reference to them; and

- A description of the interaction between the processes of the QMS, GMP and food safety programs.

3.4 Organizational Structure, Responsibility and Management Authority

Management shall be committed to the implementation of this Code of Practice in order to ensure quality and food safety. Documentary evidence shall be provided to demonstrate this.

Senior management shall appoint a member of management who shall have responsibility and authority that include:

- Ensuring that processes needed for the quality and food safety management systems are established, implemented and maintained;
- Reporting to top management on the performance of the quality and food safety management systems and any need for improvement; and
- Ensuring the promotion of awareness of customer requirements throughout the organization.

Management shall ensure that responsibility and authority are defined in written form and communicated within the organization, to ensure the effectiveness of the quality and food safety management systems implemented.

Senior management shall be responsible for the policies and objectives of the organization and shall provide adequate resources and investment to ensure product quality and safety.

Involvement of all persons relevant to the operation should be demonstrated.

Management shall ensure that levels of responsibility and accountability are clearly defined and assigned to key staff involved in product quality and safety. To this end, job descriptions should be available. Appropriate arrangements to cover positions/tasks in the absence of any key staff should be in place.

Management should regularly review its production and quality management system to ensure continued effectiveness and suitability. Formal reviews to appropriate intervals and actions documented shall be undertaken.

The staff appointed by senior management has the defined responsibility and authority to:

- Identify and record any problems with regard to the quality and food safety management system;
- Initiate corrective actions and control to these problems;
- Initiate actions to prevent the occurrence of non-conformities related to product quality and safety; and
- Appoint a HACCP team and team leader.

Management shall provide adequate resources for the implementation and control of the quality and food safety management systems.

3.5 Documentation Control

The operator shall ensure that all documents, records and data critical to the management of product quality and safety are in place and effectively controlled.

A master list of documents shall be in place, including the location and person responsible for updating the list.

Manufacturing records shall contain all relevant data that will permit investigation into the history of any product. The design and use of documents depend upon the operator.

Documents should have unambiguous contents. The title, scope and purpose should be clearly stated.

All documents should be approved, signed and dated by appropriate authorized persons, and kept up-to-date; correct versions should be readily available to appropriate staff.

No documents should be changed without authorization.

Any changes or amendments critical to the requirements of product quality or safety systems and procedures shall be documented.

Obsolete documentation should be rescinded and, if necessary, revised and replaced in a controlled manner.

Effective change control and investigation procedures should be implemented to manage both planned and unplanned deviations and documented.

The operator shall have a system of records and documentation that reflect all aspects of this Code of Practice.

3.6 Procedures

The operator shall have written instructive manuals, procedures and working instructions that thoroughly consider all operations critical to product quality and safety.

The procedures should be simple, structured and detailed to enable their correct application by appropriate staff, and should be readily available to key personnel when required.

Procedures should exist for notifying responsible management in a timely manner of a critical situation (critical complaints, recalls and audit findings) and documented.

All quality-related activities should be recorded immediately after they are performed, following the guidelines defined to ensure product quality and safety.

3.7 Product Control

3.7.1 Specifications

Up-to-date specifications shall exist for all:

- Raw materials including packaging materials;
- Finished products; and
- Intermediate products when appropriate.

All specifications shall be pertinent and thoroughly defined, and shall ensure compliance with the QMS and food safety guidelines of the organization as well as other regulatory requirements.

All specifications shall, when appropriate, be formally agreed to with customers or any other required person, company or organization.

The operator shall operate a specification review procedure for its customers and shall have all appropriate documentation relating to product quality and safety.

The operator shall determine statutory and regulatory requirements related to the product and requirements specified by the customer, including the requirements for delivery and post delivery activities.

Requirements not stated by the customer but necessary for specified or intended use of the premix shall be considered.

Each premix must have a written specification, which is amended when any change takes place.

Each product shall have a unique name or code.

Details of packaging, shelf life, storage requirements, special handling procedures, packaging weight and size, and labeling should be included in the specification.

Preservation of product:

- The organization shall establish the shelf life of a product and preserve the conformity of product during processing and delivery to the intended destination.
- This preservation shall include identification, handling, packaging, storage and protection.
- Preservation shall also apply to the constituent parts of a product.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. These changes shall be communicated to appropriate parties and customers.

3.7.2 Incoming materials

Requirements:

- Purchasing information shall describe the product to be purchased, including requirements for approval of product where appropriate.
- Selection and approval of all raw materials must consider their origin, transport, storage, processing and handling.
- Packaging shall comply with relevant food contact specifications. Supplier shall provide product data sheet and a written document assuring compliance with proper regulatory standards.
- Every raw material must be evaluated to ascertain any potential hazard arising from it.
- Each raw material must have a written specification, which is amended when any change takes place. In addition to the analytical characteristics, the specification must include, where appropriate, the risk of undesirable substances and those hazards or limitations that are considered in the HACCP process.
- There must be a list of internally approved suppliers, and each supplier must be subject to review periodically, at least annually. When annual review is not feasible, a tighter analytical control shall be implemented.

- The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Measures for non-compliance on key quality aspects shall also be established.

- Records of the results of evaluations and necessary actions arising from the evaluation shall be maintained.

- The raw materials must fulfill FCC and/or USP and/or Eu.P and/or any equivalent recognized food standard.

- Food additives shall be of food grade quality and shall comply with the recommendations of Identity and Purity recommended by the Codex Alimentarius.

Verification of incoming materials:

- Each supplier lot entering the site must be uniquely registered by means of a lot number, full name of product, date of receipt and quantity received.

- Visual inspection shall be practiced upon receipt of incoming materials to verify for the integrity of the material.

- Any damage must be reported to quality control.

- Incoming materials must be checked and formally approved according to written procedures prior to use.

- Proper handling of the received product according to its released status must be ensured.

- If incoming materials are rejected and not incorporated for reason of non-compliance with specification or any other reason connected with their quality or acceptability, their disposal, destination or return to supplier must be recorded.

3.7.3 Product manufacturing, packaging and labeling

Each manufactured premix shall have:

- Master formulae for each product;

- Operating instructions; and

- Control points for the particular process.

Each package must be labeled in a way that the batch to which it belongs can subsequently be identified and traced back.

The label shall clearly indicate and have the appropriate instructions for handling, storage and safe utilization of the product at later stages in the food chain.

Instructions for the use of equipment in the dispensing, blending and packaging sections must be delivered. They must be available for each mixing unit before the first lot of a premix to be commercialized is produced. The operating instructions should include:

- A list of all materials to be used for a specific premix with the name, code number and clearance, and quantity or percentage of the components;

- The operating capacity of the blender;

- The equipment used;
- The charging sequence of the ingredients in the premix;
- A detailed description of the mixing operations for each step (e.g. mixing time and agitator speed);
- The expected quantity of the finished product and its corresponding expected yield or equivalent; and
- Any special precautions to be taken.

The implementation of rules governing packaging:

- Where products are packaged, care must be taken to avoid contamination during the packaging process.
- The packaged products shall be correctly identified and labeled in compliance with the provisions of food regulations in force.
- Packaging must be appropriate to product type and to maintain contents for their intended shelf life.

3.7.4 Segregation

Physical segregation of raw materials, packaging and finished goods should be practiced.

Incompatible materials shall be stored in appropriate conditions to prevent contamination.

3.7.5 Stock rotation

All incoming raw materials and packaging shall be identifiable and traceable. Receipt documents and/or product labeling shall facilitate correct stock rotation.

Correct stock rotation should be such to ensure products are used in the correct order following first-in first-out procedures (FIFO) and within the allocated shelf life.

3.7.6 Product release

The operator shall carry out relevant checks of raw material in process and finished products to ensure compliance with the appropriate specifications.

The operator shall ensure suitable personnel are authorized to release product (raw materials and finished products), following examination of associated data and documentation.

All finished products should be inspected prior to dispatch, according to a written plan to ensure that they meet specification.

A retention sample should be taken of each batch and held until at least the expiry of that batch.

3.7.7 Cross-contamination

This special category of contamination usually consists of the unplanned and unsuitable presence in either gross or minute quantities of one active substance in the presence of another. It is often limited to the presence of one active ingredient in the presence of another bulk or formulated active material.

Cross-contamination usually occurs when common equipment or systems are used for the manufacturing and handling of different active substances. Improper cleaning procedures may contribute to this effect.

Often the absence of contaminants or cross-contaminants is assured by either testing, proof of process compliance or conformance to strict Good Manufacturing Practices and is indicated to the customer via the certificate of analysis or through a continuing guarantee.

Care must be maintained in all production operations to minimize and/or eliminate the risks of contamination and cross-contamination. Adherence to directives regarding Good Manufacturing Practices and Proof of Performance for Existing Processes provides a high degree of certainty that production processes will meet this requirement.

3.7.8 Carry-over

The operator shall comply with the Principle of Carry-Over as stated in the Codex Standard 192-1995:

Other by direct addition, an additive may be present in a premix, as a result of carry-over from a food ingredient, subject to the following conditions:

- An additive is permitted in the raw materials or other ingredient (including food additives) according to the Standards of the Codex Stan 192-1995.
- The amount of additive in the raw materials or other ingredient (including food additives) does not exceed the maximum amount so permitted.
- The premix into which the additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the ingredients under proper technical conditions or manufacturing practices.

Definition and acceptance criteria for carry-over must be based on a combination of customer discussion and customer acceptance. Determining acceptable levels of carry-over, as defined above will give operations maximum flexibility while still assuring that customers' needs are met.

3.8 Process Control

3.8.1 Quality control

The organization shall plan and carry out production and service provision under controlled conditions.

Production area shall be controlled thus that access for non-authorized personnel can be prevented.

All records relating to product processes, weighing, packing and labeling must be reviewed for conformance to specifications and local government guidelines.

Checks shall be carried out to demonstrate that packed contents conform to the predetermined requirements.

The frequency and methodology of checking quality shall meet the minimum requirements of legislations governing quality verification.

All equipment used for quality measurement shall be legally acceptable and checked regularly for accuracy.

3.8.2 Calibration

Measurement equipment used to monitor all predetermined control points shall be calibrated and traceable to a recognized national standard.

The organization shall establish processes to ensure that monitoring and measurement can be and are carried out in a consistent manner.

The organization shall take appropriate action on the equipment and any product affected.

Where necessary to ensure valid results, measuring equipment shall:

- Be calibrated or verified at specified intervals or, prior to use, against measurement standards traceable to international or national measurement standards; where no standards exist, the basis for calibration or verification shall be recorded;
- Be adjusted or re-adjusted as necessary;
- Be identified to enable the calibration status to be determined;
- Be safeguarded from adjustments that would invalidate the measurement result; and
- Be protected from damage and deterioration during handling, maintenance and storage.

The organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements.

Records of the calibration and verification results shall be maintained.

A documented maintenance program must be in operation in order to function in accordance with predetermined standards. A record must be kept of work carried out.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be verified. This shall be undertaken prior to initial use and reconfirmed as necessary.

3.8.3 Reference samples

Procedures should be in place for the collection of representative reference samples in line with a predetermined sampling plan, taking into account the nature of the product. These samples shall be stored under appropriate conditions.

Inspection and testing procedures should include examination protocols for reference samples during and at the end of shelf life.

3.8.4 Temperature and time control

When temperature control of raw materials or finished product is important to the quality and safety of the product, this shall be adequately controlled, monitored and recorded using the corresponding calibrated equipment.

3.8.5 Equipment validation

The operator shall have procedures that verify, on a routine basis, that the equipment employed is capable of producing consistently safe product with the desired characteristics.

In the case of an equipment failure, corrective actions must be followed and documented. The result of these actions shall provide guarantee of product safety prior to dispatch to the consumer.

3.8.6 Supervision

Appropriate level of training must be provided to all levels of supervision in order to assure that there is enough knowledge to judge possible risks during operational practices, take the corresponding preventive measures and corrective actions when required, and ensure effective overall supervision is in place.

3.8.7 Statistical techniques

The operator shall evaluate and identify the need for the use of statistical techniques where appropriate.

3.9 Internal Audit

The operator shall regularly audit those activities which impact upon product quality and safety. The audit should be scheduled and its style, depth and frequency shall cover the items stated in this Code of Practice.

The operator shall ensure that internal audits are performed to verify that the quality management system is:

- Effectively implemented and maintained;
- In compliance with regulatory and other defined requirements; and
- Internal audits may also be carried out to identify potential opportunities for improvements.

The schedule for conducting internal audits shall be documented and include planning, reports and improvements. The detailed auditing program should include as a minimum:

- Preparation and issuing of audit plans;
- Scope of the audits;
- Frequency of the audits;
- Methods for conducting the audits;
- Reporting of findings;
- Distribution of reports;
- Implementation of corrective actions and follow-up activities; and
- Selection and training of competent auditors.

Internal audits shall be carried out by trained auditors, where no compromise of their actual operating activities should arise.

Results of the internal audit shall be communicated to the proper personnel so that the root causes of any deviation can be prevented from occurring again.

Follow up must be performed as a result of corrective actions indicated by the auditing process.

There must be documentation identifying and prioritizing root causes along with corrective actions.

Guidelines for internal audits are included in Section 6 of this Code of Practice.

3.10 Control of Non-Conforming Products

The organization shall ensure procedures exist to investigate the cause of significant non-conformity against standards, specifications and procedures, which are critical to product quality and safety.

Corrective actions taken should be undertaken in a timely manner to prevent further occurrence of non-conformity and should be accurately documented, assigning responsibility and accountability.

The operator shall establish a documented procedure for dealing with products that do not comply with the intended requirements. This includes:

- Identification of product and batch code;
- Documentation;
- Evaluation of the cause;
- Segregation of batch or batches;
- Disposal of products; and
- Internal information of relevant parties.

The responsibility for review and disposal of the non-conforming product shall be defined and documented.

A non-conforming product shall be reviewed in accordance with documented procedures by one of the following ways:

- Rework;
- Reclassification or dispensation; or
- Rejection and subsequent destruction or disposal.

The archiving procedure following non-conforming responsive actions needs to be defined and the records kept accordingly.

The approval and use of reworks (e.g. from quality rejects, customer returns or spillage) must always be considered within the HACCP system. Potential reworks, which are not approved, become waste material and must be dealt with accordingly. The amount added as rework is controlled to assure that there is no compromise to product quality and safety.

If products and/or raw materials are rejected and not put into circulation for reason of non-compliance with specification or any other reason connected with their quality or acceptability, their disposal, destination or return to supplier must be recorded.

The operator shall ensure all non-conforming products are clearly identified, labeled and quarantined when appropriate.

All procedures regarding the administration of non-conforming products shall be readily available, and assurance of understanding shall be demonstrated.

3.11 Traceability

The operator shall have a procedure to be able to trace all steps in the manufacturing of all its products, including its raw and packaging materials.

The operator shall maintain a registry that contains:

- The names and addresses of manufacturers of incoming materials, additives or intermediaries. Incoming materials shall be verified according to point 3.7.2 of this Code of Practice.

- The nature and quantity of the additives and premixes produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture, and the name and addresses of the intermediaries, manufacturers or users to whom the additives or premixes have been delivered.

The operator shall indicate the nature and quantity of the additive or premix delivered and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous production.

3.12 Record Keeping

Records that confirm whether procedures are being followed and/or identify any deviation from the procedures must be kept. Procedures must be subject to regular critical appraisal to ensure that they continue to be effective.

A master production record and instructions for the use of equipment in the dispensing, blending and packaging sections must be delivered. Records shall be available for each mixing unit before the first lot of a premix to be commercialized is produced.

All records related to product quality and safety shall be legible, permanently recorded and should be authorized by appropriate staff.

Batch record shall be maintained. The batch record is a document showing conformity of the manufacturing process with the GMP, SOP and HACCP programs and the master production.

Batch records can be stored electronically or kept as hard copy. In case of computer controlled operations, batch records can be automatically stored if they comply with SOP, but will be write protected.

A record must be prepared for each batch processed and can consist of one or more pages.

The batch records must be checked by the plant supervisor or other designated individuals. Whenever the limits described in the SOP are not fulfilled, the plant manager must decide on how to proceed. The quality control department must be informed.

During processing, information should be recorded simultaneously with each action and after completion. The record must be dated and signed by the person responsible for the processing operation and by a plant supervisor.

For the weighing records, an additional check must be made.

The batch record must include:

- The premix name and code number;
- The date and time of production;
- Approval date of master batch records used;
- The equipment used, if multiple equipment exists;
- The batch/lot number of the premix;
- The list of raw materials and weighing protocols, with name and code number of the components;
- Quantity of compounds charged;
- List of all operations, if possible in chronological order;
- Any deviation from the requirements of the SOP and master batch record;
- The actual mixing time;
- The action taken on deviation; and
- A visa by the supervisor or his deputy confirming final examination of the batch record.

The batch record of the final packaging also includes:

- Packaging materials;
- Yield or quantities;
- Packaging sizes;
- Copy of label with imprinted lot number; and
- Label reconciliation.

3.13 Product Recall

The operator shall have an effective product recall procedure for all products.

The procedure shall be appropriate, formalized and be capable of being operated at any time. The procedure shall be reviewed regularly and, if necessary, revised to ensure it is up-to-date.

The procedure shall, where appropriate, be tested regularly, at least annually, to ensure effective cooperation and conformance with the quality management system. Such tests shall be documented and evaluated for improvements.

The recall procedure shall describe necessary actions to be conducted:

- Allocate the competency to the person responsible for the recall process and identify suitable deputies;
- Identify the non-conforming product and batch, including consequences to other products, batches or raw materials;

- Identify the destination of affected lots;
- Describe procedures for disposal of returned product/s, including segregation from other products;
- Describe maintenance of relevant registers that link the route from production to customers; and
- Include information of the authorities.

There must be an actualized list of personnel that can review a recall situation at any time. This list shall include title within the organization and phone numbers. There must be accessibility to a minimum of two (2) individual contacts 24 hours/7 days/week.

Records must indicate 100% of finished products and raw materials and be tracked to the first external customers within an appropriate period of time.

3.14 Complaint Handling System

A formalized documented program on complaint handling shall exist and include:

- Allocation of responsibilities for controlling complaints;
- Name of complaining customer;
- Product name and identification code;
- Cause of complaint; and
- Reply to customer.

Depending on the seriousness and frequency of the issue of complaint, corrective actions shall be carried out timely and effectively.

Where appropriate, complaint information shall be used to avoid recurrence and implement ongoing improvements to product quality and safety.

3.15 Supplier Audit Monitoring

Procedures for monitoring supplier performance shall be in place.

A list of approved suppliers for all ingredients must be available.

There must be sampling procedures and test methods and procedures for verifying compliance with specifications. A Certificate of Analysis (COA) on each specific ingredient lot is an acceptable alternative.

Testing and inspection procedures shall, where appropriate, include the evaluation of product suppliers, pertinent to quality and safety.

Procedures shall include the necessary action to be taken in the event of non-conformance, including rejection, acceptance by concession or alternative use. Any ingredient not meeting supplier requirements must be appropriately identified and should be segregated from accepted goods.

Documentation shall define how exceptions are handled, i.e., the use of product or services, where audit or monitoring has not been undertaken. In these circumstances, full traceability shall be maintained.

The suppliers must be reassessed on a regular basis. This comprises of a formal investigation as well as a periodical testing of samples.

Key suppliers should be routinely audited according to a defined program

3.16 Upper Management Responsibilities

Administrative levels of the organization shall provide guidance and follow-up on the following issues:

3.16.1 Review of contracts

The contract review must ensure that the customer is aware of the premix specifications, quantity, time frame, place and means of delivery, and the price and payment conditions.

New or modified formulations must be confirmed to the customer in writing. The new formulation must be checked for legal and technical feasibility aspects.

3.16.2 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to:

- Product information;
- Inquiries, contracts or order handling, including amendments; and
- Customer feedback, including customer complaints.

3.16.3 Provision of resources

The appointed responsible person shall identify and provide the necessary resources so that the manufacture of products is carried out in an efficient and safe manner. To accomplish this, the operator shall:

- Provide sufficient and appropriately designed equipment and premises;
- Employ sufficient and appropriately trained staff;
- Clearly assign the responsibility and authority for assuring compliance with regulatory requirements and industry codes of practice to competent persons;
- Issue, maintain and make available to the operator and external bodies an organizational chart and job descriptions; and
- Provide the necessary resources to meet the quality and safety objectives.

3.16.4 Management review

Management shall review, at defined intervals, the continuing suitability and effectiveness of quality and safety management systems. This review shall include assessing opportunities for improvement and the need for changes to the quality and safety management systems.

SECTION 4 GMP-PREREQUISITE PROGRAMS

4.1 Establishment: Design and Facilities

4.1.1 Location

Potential sources of contamination shall be considered to define the plant location.

Other protective measures, if necessary, should be in place to assure the production of safe and legal products.

4.1.2 Perimeter

The site should be enclosed to maintain its security. All grounds within the site should be finished and maintained according to function; all grass should be regularly tended and well maintained, and weeds should be controlled.

Where natural drainage is inadequate, external drainage shall be installed.

Outdoor storage should be kept to a minimum, and when it is necessary, items shall be protected from contamination and deterioration.

4.1.3 Layout/product flow

Premises and plant shall be designed, constructed and maintained to control the risk of contamination and to comply with all relevant legislation.

Premises shall allow sufficient working space and storage to enable all operations to be carried out properly under safe hygienic conditions.

There should be a controlled flow of product from raw material intake to finished product dispatch, with segregation of raw and processed materials.

The different stages of production must be carried out according to written procedures aimed at defining, checking and mastering the critical points in the manufacturing process and include details of necessary precaution to be taken to avoid cross-contamination and errors.

On-site laboratory facilities, where provided, shall be physically separated from production areas to minimize the risk of cross-contamination.

Facilities for tray and utensil washing and general purpose cleaning shall, where appropriate, be adequately segregated from production activities.

The dispensing area should be located in a designated room.

For the packaging of premixes, specifically designated areas are necessary. The packaging of two different premixes at the same time, in the same area, is not allowed.

4.1.4 Infrastructure/facilities

Walls: internal surfaces shall be suitable, smooth and, where appropriate, non-toxic, impervious, easily cleaned, able to be disinfected and maintained in good condition. It is highly recommended that wall/floor junctions and corners be covered.

Floors: should be designed to cope with the requirements of the processes being carried out. They should be constructed to allow adequate drainage and cleaning, and be maintained in appropriate sanitary conditions. Drainage should be designed to minimize the risk of contamination.

Ceilings/overheads: should be constructed, finished and maintained to prevent build up of dirt and condensation. They should be easy to clean. If false ceilings are used, they must be maintained in good condition and hygienic (free of pest activity), so an access to the ceiling gap shall be provided.

Windows/skylights: should preferably be non-opening, easy to clean and constructed to minimize the build up of dirt. Where they are designed to be opened for ventilation purposes, they shall be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed.

Doors: should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfected.

Working surfaces: those that come into direct contact with the product should be in good condition, durable and easy to clean, maintain and disinfect. They should be made of smooth non-absorbent materials and inert to the premixes, detergents and disinfectants under normal operating conditions.

Lighting: adequate lighting shall be provided for all work areas. All bulbs and strip lights within product handling areas shall be protected by shatterproof plastic diffusers or sleeve covers or fitted with fine mesh metal screen.

Ventilation: adequate ventilation should be provided in product storage and processing environments to produce satisfactory working conditions and to reduce humidity, condensation and temperature. The installation of dust extraction equipment for dry powder handling areas must be evaluated to assure personnel safety and avoid cross-contamination between products.

Water supply: As a minimum, potable water is to be used for all manufacturing operations (including cleaning) of premixes. Potable water should be as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard. Non-potable water (for use in, for example, fire control, steam production and other similar purposes where it would not contaminate the product) shall have a separate system that shall be identified and not connect with, or allow reflux into, potable water systems. When water is used as a starting material, additional quality standards should be defined to eliminate any potential risk for product safety. A regular monitoring program for water used in production must be followed.

4.1.5 Equipment

Equipment should be suitably designed for the intended purpose and shall be used so as to minimize the risk of contamination of product.

Equipment should be positioned so as to give access under, inside and around it for ease of cleaning and servicing.

Equipment, containers and all food-contact surfaces should be made of non-toxic materials and constructed to ensure they can be adequately cleaned, disinfected and maintained to avoid cross contamination.

4.1.6 Staff facilities and toilets

These should be designed, suitably located and shall be operated so as to minimize the risk of product contamination.

Toilet and hand washing facilities (with adequate means of drying hands) shall be available and sufficient and function properly as well as be maintained in a clean, hygienic and adequately ventilated condition.

Toilets should not be in direct contact with production, packaging or storage areas.

Additional hand cleaning facilities should be available at appropriate points within the production areas.

Changing facilities (locker rooms) shall be provided for all staff entering production areas. Suitable rest and catering facilities (lunchrooms) should be provided for employees and maintained in good order.

All restrooms, hand washing stations, lunchrooms and smoking areas should be posted with "Hand Wash" signs.

Admittance to the plant and dispensing areas must be restricted.

4.1.7 Waste/waste disposal

There shall be adequate systems for the collection of waste material. These systems should minimize the accumulation of waste in production areas. Effective effluent management systems should be in place.

External waste collection containers and compactors should be closed and/or covered.

All waste materials must be clearly identifiable and disposed of in accordance with local regulations and food safety.

Waste containers should be properly identified (or color coded) so they cannot be intended for any other use.

4.2 Personnel

4.2.1 Personal hygiene

Personal hygiene standards shall be documented and adopted by all personnel, including visitors and outside contractors.

Jewelry and watches shall not be worn, with the exception of a plain wedding ring. Perfume and makeup shall not be worn. Fingernails shall be kept short, clean and unvarnished.

Smoking, eating and drinking shall only be permitted in designated areas. No personal effects can be kept inside the production areas.

Hands shall be cleaned appropriate to the operation. The effectiveness of hand cleaning practice should be checked periodically.

Care must be maintained in all production operations to minimize and/or eliminate the risks of contamination and cross-contamination. Adherence to directives regarding Good Manufacturing Practices and Proof of Performance for Existing Processes provides a high degree of certainty that production processes will meet this requirement.

Steps should be taken to ensure that no person known or suspected to be affected by an infectious disease, or open lesions on exposed areas of the body, is engaged in the production area - where products are subject to open unprotected handling - until the condition presents no risk.

Direct contact between the operator and the exposed product should be avoided.

4.2.2 Protective clothing

To assure protection of the product from contamination, staff in production must be provided with protective clothing, appropriate to the operations involved. Clothing with no outside pockets, gloves, headgear, mouth and nose protection, appropriate footwear and goggles, as necessary, must be worn. Pockets must be completely emptied before working with exposed product or raw material.

A uniform policy should be written to assure that adequate and clean clothing is worn by all personnel at all times.

All hair, where appropriate, shall be fully contained to prevent product contamination.

4.2.3 Training

The organization shall ensure that appropriate competencies, qualifications, training and awareness are present to achieve conformity to product requirements, quality and food safety. The effectiveness of this training is important to assure that all personnel are aware of their responsibility in protecting the product from contamination.

The training should include all the organization's policies, especially those related to food safety and hygiene.

The operator should have documented training procedures, and completed training records should be maintained for all the staff. Training should be refreshed or reviewed on an annual basis.

Temporary personnel and contractors should be trained as part of the training system of the operator before they begin their work.

If the personnel must handle strong cleaning chemicals or other potentially hazardous chemicals (including raw materials), they should be instructed on specific techniques for safe handling.

The managers and employees shall have the necessary skills, qualifications and training to be able to execute their tasks.

The operators shall be trained in appropriate standards of hygienic behavior in order to contribute to overall food safety and as part of the food chain.

4.3 Pest Control

The operator shall be responsible for minimizing the risk of pest infestation and activity on the site. Suitable precautions should be taken to prevent pest access and to eliminate potential breeding sites.

There shall be a written plan for pest control, including description of periodic inspections at appropriate scheduled intervals to ensure pest control arrangements remain effective.

The operator shall either contract the services of a competent pest control organization or shall have trained personnel. Where the services of a pest control contractor are employed, the scope of the contract shall be clearly defined. All pest control activities must comply with local regulatory requirements.

Results of such inspections must be recorded, and follow up and corrective actions shall be implemented. It is highly recommended that the location of all pest control devices be identified on a plan/diagram of the site.

Details on any fumigation or use of chemicals such as pesticides must be recorded.

4.4 Maintenance

A system of planned and preventive maintenance shall be in place, covering all items of equipment that are critical to product safety, legality and quality.

The operator shall ensure that the product safety is not jeopardized during maintenance operations.

Outside contractors and all engineers shall be aware of and adhere to the hygiene standards in place.

Lubrication must be controlled to assure that only food-grade lubricants are used in the processing equipment. The lubricants and other chemicals used in maintenance must be stored securely in a separate area.

A maintenance security program must be in place to address possible contamination with foreign materials and lose parts after a equipment or process area had been serviced. Adequate cleaning by appropriate personnel must be completed before the restart of equipment for operation.

4.5 Hygiene/Cleaning

A high level of sanitation and hygiene should be practiced in every aspect of manufacture. The scope of sanitation and hygiene covers anything that could become a source of contamination to the product, i.e. personnel, premises, equipment, production materials, containers and cleansing agents.

Proper housekeeping is essential for obtaining premixes of high quality and safety. Therefore, the buildings must be cleaned on a regular basis, according to a defined procedure.

The equipment must be cleaned thoroughly and regularly according to a defined procedure to ensure hygienic conditions and to avoid contamination.

All procedures must be available in writing and should include the frequency and cleaning agents used. The cleaning agent used shall be a Food Industry Use Detergent or approved by the FDA; they shall be properly labeled and securely stored away from production or storage areas. This must be addressed as part of the hazard analysis, and all the material safety data sheets (MSDS) must be on file.

Cleaning and sanitation should be carried out in accordance with a cleaning schedule; any deviation shall not compromise product quality or safety. Cleaning and sanitation shall be verified by inspection, and the concentration of the chemicals must be checked periodically.

A microbiological monitoring program must be set up for the entire production area, including equipment and other food-contact surfaces.

4.6 Transport and Storage

4.6.1 Vehicles/transport

All shipping vehicles shall be maintained in good repair and clean. Where third party distribution or haulage is used, they must be selected based on safety and reliability. Third party vehicles and their operation must comply with regulations enforced for transportation of food and this Code of Practice.

For bulk deliveries, the transportation agent must provide a cleaning certificate and guarantee that a clean, empty, dry and

odorless cargo compartment is made available. The agent must provide information about the two previous loads and the means of cleaning and drying.

Product segregation during transportation shall maintain product safety, legality and quality. A distribution list shall be kept. The premixes cannot be transported with other non-food products. If the same vehicle is used for transporting different products or non-food products, it should to be cleaned between loads.

A visual inspection, paying special attention for hygiene and cleanliness, of the vehicle should be in place before any premix is loaded. A record of inspection must be kept.

A final inspection shall take place to ensure delivery of correct product.

4.6.2 Storage

All raw materials (included packaging material) and finished items should be protected from possible contamination (dirt, chemicals, toxic materials and water) during storage.

Access to stored raw materials and/or end product is restricted to authorized personnel only.

An appropriate distance for cleaning and monitoring pest activity must be maintained (at least 18 inches), between the stored products and walls and ceilings. The items shall be stored off the floor on pallets, slip sheets or racks.

Pallets must be serviceable, clean and dry. All pallets, which are returned, must be inspected and, if necessary, cleaned before re-use.

Finished product must be clearly identified and stored in clean dry conditions. Access to these materials is restricted to authorized personnel only.

Incoming materials, active substances, carrier substances and products that meet the specifications – and those that do not – must be stored in suitable containers in places designed, adapted and maintained in order to ensure good and appropriate storage conditions, and to exclude contamination and degradation of the active substances and the presence of harmful organisms.

Materials shall be stored in a way as to be easily identifiable, to avoid any confusion or cross-contamination and to prevent deterioration. A stock rotation system must be in place.

The storage environment must be set up in a way to minimize the risk of damage of packaging and spillage of material. When possible, packaging materials should be stored separate from finished products and raw materials.

SECTION 5 FOOD SAFETY

5.1 Foreign Material Control

The operator shall identify potential foreign material contaminants. Appropriate measures shall be implemented for their control and management.

Appropriate storage facilities shall be provided for the control and storage of chemicals (includes cleaning chemicals, pesticides, and other dangerous chemicals that might be used).

No glass material will be used in the production area.

The use of wood within raw material handling, processing, packaging and storage areas should be eliminated wherever possible.

Physical and chemical hazards are tested, monitored and documented against acceptable/specified limits.

The operator shall implement in-process methods such as:

- Metal control with the use of metal detectors, magnets and/or x-ray units;
- Other foreign material control with the use of sifters/screen and/or x-ray units; and/or
- Chemical control by isolation, proper storage, single use containers, adequate lubrication, and/or preventive maintenance.

5.2 HACCP Program

The operator shall establish a food safety management system to assure that all hazards are controlled. It is recommended to follow the HACCP system as specified in the Codex Alimentarius (Hazard Analysis and Critical Control Point System and Guidelines for its application, Annex to CAC/RCP 1-1969 (Rev. 4-2003). A specific HACCP by product or modular plans for several products shall be designed.

5.3 Design and Development

5.3.1 Development of new products and processes

The organization shall plan and control the design and development of products or processes related to its safety.

The safety of food additives shall be taken into account at each step of the development process of a new product. The implementation of HACCP rules during the development and before the implementation of the product shall ensure this safety.

Each raw material must have a written specification, which is amended when any change takes place. In addition to the analytical characteristics, the specification must include, where appropriate, the risk of undesirable substances and those hazards or limitations that are considered in the HACCP process.

Packaging must be appropriate to product type and to maintain contents for their intended shelf life. Packaging must be considered under HACCP analysis.

5.3.2 Change control

Design and development changes shall be identified, and records shall be maintained.

The changes in product formulation, processing methods, equipment or packaging shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on product safety and the HACCP program.

Records of the results of the review of changes and any necessary actions shall be maintained.

SECTION 6 AUDIT GUIDELINES

An audit score summary and sheet are included in Appendix 1 of this Code of Practice. The audit is designed to generate a score of the overall compliance with the defined QMS and food safety issues of this Code.

The auditor shall evaluate each of the items of the audit score sheet, according to the following general indications:

- 100 Score: All of the requirements of the particular item are fulfilled according to the auditor's judgment. All records required are available and up-to-date.
- 50 Score: It is the auditor's judgment that a minor deviation to the requirement is present in the particular item analyzed, which shall be corrected immediately, and directly affects the quality and safety of the operation. All records required are available and up-to-date.
- 25 Score: Major deviations to the requirements of the particular item are present. Most of the records required are available and up-to-date; no critical records are missing.
- 0 Score: There is no compliance to the requirement of this item. Major deficiencies are observed. Records with insufficient information and/or no records available.

Upon completion of the audit, a summary of results with the corresponding QMS, GMP and Food Safety Sections should be provided by the auditor in order to have a clear understanding of the requirements for overall compliance of this Code of Practice.

APPENDIX 1. AUDIT SCORE

AUDIT SCORE SUMMARY

Audit Date: _____

Company: _____

Plant Location: _____

CATEGORY	POSSIBLE POINTS	POINTS SCORED	ASSIGNED WEIGHT (%)	RATING (%)
1. Quality Management System	3200		40	
2. GMP-Prerequisite Programs	1500		30	
3. Food Safety	400		30	
Total	5100		100	
OVERALL RATING (%)				

AUDIT SCORE SHEET

NOTE: Guidelines for evaluating each of the items of the audit score sheet are included in Section 6 of this Code of Practice.

1. QUALITY MANAGEMENT SYSTEM	SCORE				COMMENTS
1.1 General Requirements	100	50	25	0	
1.2 Quality Policy	100	50	25	0	
1.3 Quality Manual	100	50	25	0	
1.4 Organizational Structure, Responsibility and Management Authority	100	50	25	0	
1.5 Documentation Control	100	50	25	0	
1.6 Procedures	100	50	25	0	
1.7 Product Control					
1.7.1 Specifications	100	50	25	0	
1.7.2 Incoming materials	100	50	25	0	
1.7.3 Product manufacturing, packaging and labeling	100	50	25	0	
1.7.4 Segregation	100	50	25	0	
1.7.5 Stock rotation	100	50	25	0	
1.7.6 Product release	100	50	25	0	
1.7.7 Cross-contamination	100	50	25	0	
1.7.8 Carry-over	100	50	25	0	
1.8 Process Control					
1.8.1 Quality control	100	50	25	0	
1.8.2 Calibration	100	50	25	0	
1.8.3 Reference samples	100	50	25	0	
1.8.4 Temperature and time control	100	50	25	0	
1.8.5 Equipment validation	100	50	25	0	
1.8.6 Supervision	100	50	25	0	
1.8.7 Statistical techniques	100	50	25	0	
1.9 Internal Audit	100	50	25	0	
1.10 Control of Non-Conforming Products	100	50	25	0	
1.11 Traceability	100	50	25	0	
1.12 Record Keeping	100	50	25	0	
1.13 Product Recall	100	50	25	0	
1.14 Complaint Handling System	100	50	25	0	
1.15 Supplier Audit Monitoring	100	50	25	0	
1.16 Upper Management Responsibilities					
1.16.1 Review of contracts	100	50	25	0	
1.16.2 Customer communication	100	50	25	0	
1.16.3 Provision of resources	100	50	25	0	
1.16.4 Management review	100	50	25	0	

POSSIBLE POINTS	**3200**
POINTS SCORED	

2. GMP-PREREQUISITE PROGRAMS	SCORE				COMMENTS
2.1 Establishment: Design and Facilities					
2.1.1 Location	100	50	25	0	
2.1.2 Perimeter	100	50	25	0	
2.1.3 Layout/product flow	100	50	25	0	
2.1.4 Infrastructure/facilities	100	50	25	0	
2.1.5 Equipment	100	50	25	0	
2.1.6 Staff facilities and toilets	100	50	25	0	
2.1.7 Waste/waste disposal	100	50	25	0	
2.2 Personnel					
2.2.1 Personal hygiene	100	50	25	0	
2.2.2 Protective clothing	100	50	25	0	
2.2.3 Training	100	50	25	0	
2.3 Pest Control	100	50	25	0	
2.4 Maintenance	100	50	25	0	
2.5 Hygiene/Cleaning	100	50	25	0	
2.6 Transport and Storage					
2.6.1 Vehicles/transport	100	50	25	0	
2.6.2 Storage	100	50	25	0	

POSSIBLE POINTS	**1500**
POINTS SCORED	

3. FOOD SAFETY	SCORE				COMMENTS
3.1 Foreign Material Control	100	50	25	0	
3.2 HACCP Program	100	50	25	0	
3.3 Design and Development					
3.3.1 Development of new products and processes	100	50	25	0	
3.3.2 Change control	100	50	25	0	

POSSIBLE POINTS	**400**
POINTS SCORED	