

FOOD SAFETY MANUAL

Goiasa Goiatuba Álcool LTDA.

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Manual

Segurança do Alimento



Created by
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1. PURPOSE

To establish guidelines to deploy, maintain, control and update the FSMS - Food Safety Management System ensuring the safe food production.

The main purpose of the Goiasa's Food Safety Management System is to identify the hazards related to consumer health that can be managed in our production, establishing control methods to ensure the safety of our sugar and the safety of the consumer.

The system complies with the following requirements:

- Codex Alimentarius Commission CAC/RCP 1 - 1969, Rev. 4 (2020);
- ABNT NBR ISO 22000:2019 (ISO 22000:2019);
- Esquema FSSC 22000 Versão 5.1;
- ABNT ISO/TS 22002-1:2012;
- Law Decrees, Ordinances, Resolutions and Normative Instructions applicable to Food Safety according to available legislation

2. FIELD OF APPLICATION

It applies to the sugar production areas, including employees, service providers, visitors, administrative area, raw materials, industrial inputs, and packaging.

3. DEFINITIONS

GMP - Good Manufacturing Practices These are the required and indispensable procedures for obtaining innocuous and healthy food.

Good Hygiene Practices - GHP Fundamental measures and conditions applied at any stage within the food chain to provide safe and suitable food.

Deviation: Failure to accomplish a critical limit or to follow a GHP procedure.

Supply: Packaging and auxiliary materials used in sugar production.

Hazard: A biological, chemical, or physical agent in food that may cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information about hazards identified in raw materials and other ingredients, environment, process, or food and conditions that lead to its presence to decide if such hazards are significant or not.

Disinfection: Reduction, by means of biological or chemical agents and/or physical methods, of the number of viable microorganisms on surfaces, in water or in air, to a level that does not compromise the safety and/or suitability of the food.

Primary production: the stages of the food chain up to and including the storage and, where appropriate, transportation of agricultural products. This would include growing crops, raising fish and animals, and harvesting plants, animals, or animal products from a farm or its natural habitat.

Acceptable level: Food safety hazard level not to be exceeded in the final product supplied by the organization.

Action criteria: Measurable or observable specification for monitoring a OPRP.

Audit: Independent, documented systematic process for obtaining audit evidence and objectively assessing it to determine the extent to which audit criteria are met.

- ✓ An audit can be internal (first part) or external (second or third part) and can be a combined audit (combining two or more disciplines).
- ✓ An internal audit is carried out by the organization itself or by an external party on its behalf.
- ✓ "Audit evidence" and "audit criteria" are defined by ABNT NBR ISO 19011.
- ✓ Relevant disciplines are, for example, food safety management, quality management, or environmental management.

Competency: Ability to apply knowledge and skills to achieve intended results.

Compliance: Fulfillment of a requirement.

Continuous improvement: recurring activity to increase performance.

Documented information: Information that requires control and maintenance by an organization and the medium in which it is stored.

- ✓ Documented information may be in any format and medium and may come from any source.

Batch: specified quantity of a product produced and/or processed and/or packaged under essentially the same conditions.

- ✓ The batch is defined by priorly established parameters by the organization and can be described by other terms, for example a whole bunch.
- ✓ The batch can be reduced to a single product unit.

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Food production chain: Sequence of steps in the production, processing, distribution, storage, and handling of food and its ingredients, from raw materials to consumption.

- ✓ In the food production chain is also included the production of materials intended to come into contact with food or its raw materials.
- ✓ The food production chain also includes service providers.

Cross-contact with allergen: the unintentional incorporation of a food or allergenic ingredient into another food that is not intended to contain that food or allergenic ingredient.

Cleaning: removal of soil, food residues, dirt, grease or other undesirable material.

Relevant authority: The government authority or official body authorized by the government that is responsible for establishing regulatory food safety requirements and/or the organization of official controls, including inspection.

Food Operating Company (FOC): The entity responsible for the operation of a business at any stage of the food chain.

Food handler: Any person who directly handles packaged or unpackaged food, equipment and utensils used for food, or surfaces that come into contact with food and are therefore expected to comply with food hygiene requirements.

Food hygiene: All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Food hygiene system: Prerequisite programmes, supplemented with control measures at CCPs as appropriate, that when taken as a whole, ensure that food is safe and suitable for its intended use.

Food suitability: Assurance that the food is acceptable for human consumption according to its intended use.

Sugar production/preparation: it is the set of all operations and processes carried out to obtain finished sugar.

Foreign bodies: Physical objects that are not part of the process and/or step.

ETGOI: Goiasa's technical specifications for raw material (sugar cane), crystal sugar, ethyl alcohol and electric energy.

PROCE: standard operating procedures.

INSTR: detailed instructions for task execution.

FORMU: records that provide evidence that the activities were carried out according to the procedures and work instructions.

MANUA: Goiasa's Management System manuals.

ETMA: technical specifications of materials.

ETSE: technical specifications of services.

ETEQ: technical specifications of equipments.

HACCP Plan: Documentation or set of documents, prepared in accordance with HACCP principles, to ensure the control of significant hazards in the food business.

Food Safety: Assurance that the food will not cause adverse health effects to the consumer when prepared and/or consumed in accordance with its intended use.

- ✓ Food safety is related to the occurrence of food safety hazards in the final products and does not include other aspects related to human health, such as malnutrition.
- ✓ It may not to be confused with the availability and access to food ("food security").

Study on Hazards to Food Safety: document prepared in accordance with HACCP principles to ensure the control of hazards that are significant to Food Safety in the production chain. In the Food Safety Plan are contemplated in the appendix: [PLAN-0051 - HACCP - Conventional and Organic Crystal Sugar](#), according to the applied methodology.

Control measure: Any action or activity that can be used to prevent or eliminate a hazard to the Food Safety or reduce it to an acceptable level.

Measurement: Process for determining a value, monitoring, determining the status of a system, a process, or an activity.

- ✓ To determine status, it may be necessary to check, supervise, or critically observe.
- ✓ In the context of food safety, monitoring is carrying out a planned sequence of observations or measurements to evaluate whether a process is operating as intended.
- ✓ Distinctions are made between the terms validation, monitoring, and verification:
- ✓ Validation is applied prior to an activity and provides information about the ability to deliver intended results;
- ✓ Monitoring is applied during an activity and provides information for action within a specified period of time;
- ✓ verification is applied after an activity and provides information for confirming compliance.

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Interested parties (preferable term) **stakeholder** (acceptable term): person or organization that can affect or be affected or to feel affected by a decision or activity.

Prerequisite program: Programs including Good Hygiene Practices, Good Agricultural Practices, and Good Manufacturing Practices, as well as other practices and procedures, such as training and traceability, which establish the basic environmental and operational conditions that lay the foundation for the implementation of an HACCP system.

Operational Pre-requirements Program (OPRP): control measure or combination of control measures applied to prevent or reduce a hazard significant to Food Safety to an acceptable level and where the criteria for action and measurement or observation allow effective control of the process and/or product.

Critical Control Point (CCP): Step in the process in which control measure(s) are applied to prevent or reduce a significant hazard to food safety to an acceptable level and set critical limits and measurement that allow corrections to be applied.

Potentially Unsafe Products: These are products made under conditions where the critical limits of the CCP(s) have been exceeded or when a loss of control occurs in any Operational Prerequisite Program.

Critical limit: Measurable value that separates acceptance from rejection.

- ✓ Critical limits are set to determine whether a CCP remains under control. If a critical limit is exceeded or not reached, the affected products are treated as potentially unsafe products.

Validation of control measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard for a specified outcome.

FSMS: Food Safety Management System.

Management System: The set of interrelated or interacting elements of an organization to establish policies, goals, and processes to achieve these goals.

- ✓ A management system can address a single discipline or several disciplines.
- ✓ The system elements include the organization structure, roles and responsibilities, planning, and operation.
- ✓ The scope of a management system may include the entire organization, specific, identified functions of the organization, specific, identified sections of the organization, or one or more functions within a group of organizations.
- ✓ Relevant disciplines are, for example, a quality management system or an environmental management system.

Non-conformance: Failure to meet an requirement, goal, outcome to be achieved.

- ✓ A goal may be strategic, tactical or operational.
- ✓ The goals may relate to different disciplines (such as finance, health and safety, and environmental goals) and can refer to different levels (such as strategic, organizational, project, product, and process).
- ✓ A goal can be expressed in other ways, for example, as an intended result, a purpose, an operational criterion, as a goal of the food safety management system, or by the use of words with similar meaning (e.g. Purpose, objective, or target).
- ✓ In the context of food safety management systems, goals are set by the organization, consistent with the food safety policy, to achieve specific results.

Correction: Action to eliminate a detected nonconformity.

Corrective action: Any action taken when a deviation occurs in order to restore control, segregate and determine the disposition of the affected product if any, and prevent or minimize the recurrence of the deviation.

Decision Tree: A logical sequence of questions and answers that assists in the rating of control measures for raw materials or process steps into prerequisite program (PRP), operational prerequisite program (OPRP), or critical control point (CCP).

FST - Food Safety Team: A multidisciplinary group of professionals responsible for the development and implementation of the HACCP Study and for deployment, maintenance and updating of the Food Safety Management System at Goiasa.

Monitoring: The act of carrying out a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.

Food safety hazard: A biological, chemical, or physical agent in food that may cause an adverse health effect.

- ✓ The term "hazard" is not to be confused with the term "risk," which in the context of food safety means a function of the probability of occurrence of an adverse health effect (e.g., getting sick) and the severity of this effect (death, hospitalization) when there is exposure to a specific hazard.

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- ✓ Food safety hazards include allergens and radiological substances.

Food Safety Plan: Set of documents for a certain product/process, which allow the planning and realization of safe products following the requirements of NBR ISO 22000:19, including: FSS, product and process description, input and process hazard analysis, establishing monitoring, verification and validation methodology for OPRP and CCP, and decision tree.

Risk: It is the combination of probability (possibility) and severity (consequence) of a hazard occurrence. It can be rated as high, medium or low.

Significant risk: a hazard identified by a risk analysis, with a reasonable probability of occurring at an unacceptable level in the absence of control, and for which control is essential given the intended use of the food.

Severity: Dimensioning the severity of a hazard as to the consequences resulting from its occurrence. It can be rated as high, medium or low.

Food Safety Policy: An organization's intentions and general guidelines concerning to Food Safety, formally expressed by Senior Management.

Flowchart: Schematic and systematic representation of the sequence and interactions of steps in the process.

Food Manufacturing (Category C): Sugar falls into category C of the food chain, because in this category we have the following processing activity "(d) Processing stable products at room temperature, production of food products from any source are stored and sold at room temperature, including canned foods, cookies, bread, slacks, oil, drinking water, beverages, pasta, flour, sugar, and edible salt".

Contaminant: Any biological, chemical, or physical agent, foreign matter, or other substance not intentionally added to food that may compromise the safety or suitability of the food.

Contamination: Introduction or occurrence of a contaminant, including a food safety hazard in a product or processing environment.

Control:

- when used as a noun: The state in which the correct procedures are being followed and any established criteria are being met.
- when used as a verb: Take all necessary actions to ensure and maintain compliance with the established criteria and procedures.

Efficiency: Extent to which the planned activities are carried out and the planned results are achieved in the end product that will not undergo any processing or transformation by the organization.

- ✓ A product that undergoes processing or transformation by another organization is a end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

Food: Substance (ingredient), processed, semi-processed or raw, intended for consumption, including beverages, chewing gum and any substance that has been used in the manufacture, preparation or treatment of the "food", excluding cosmetics, tobacco or substances (ingredients) used only as medicines.

Organization: A person or group of people who have their own roles, with responsibilities, authorities, and relationships to achieve their goals.

- ✓ The concept of organization includes, but is not limited to, individual entrepreneur, company, corporation, firm, enterprise, authority, partnership, charity, or part or combination thereof, whether incorporated or unincorporated, public or private.

Outsourcing: Making an arrangement where an external organization performs part of an organization's function or process

Performance: Measurable outcome

- ✓ Performance can relate to either quantitative or qualitative findings.
- ✓ Performance can relate to the management of activities, processes, products (including services), systems, or organizations.

Policy: Intentions and direction of an organization, as formally expressed by its Senior Management

Pre-requirements Program (PRP): Basic conditions and activities needed within the organization and along the food production chain to maintain food safety.

- ✓ PRPs depend on the segment of the food production chain in which the organization operates and the type of organization. Examples of equivalent terms are good agricultural practices (GAP), good animal husbandry practices (GAHP), good manufacturing practices (GMP), good hygiene practices (GHP), good handling practices (GHP), good distribution practices (GDP), and good selling practices (GSP).

Process: A set of interrelated or interactive activities that transform inputs into outputs.

Product: Output that is the result of a process

- ✓ An output can be a service.

Requirement: Need or expectation that is stated, usually implied or mandatory.

- ✓ "Generally implied" means that it is customary or common practice for the organization and stakeholders, so that the need or expectation under consideration is implied.

- ✓ A specified requirement is one that is stated, for example, as documented information.

Risk: Effect of uncertainty

- ✓ An effect is a deviation concerning to an expected condition - positive or negative.
- ✓ Uncertainty is the state, even if partial, of deficiency of information, understanding or knowledge, related to an event, its consequence or probability.
- ✓ Risk is often characterized by reference to potential "events" (as defined by ABNT ISO Guide 73:2009, 3.5.1.3) and "consequences" (as defined by ABNT ISO Guide 73:2009, 3.6.1.3), or a combination of them.
- ✓ Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ABNT ISO Guide 73:2009, 3.6.1.1) of such occurrence.
- ✓ Food safety risk is a probability function of an adverse health effect and the severity of such effect, resulting from hazards in food, as specified in the Codex Procedural Manual.

Significant hazard for food safety: A food safety hazard, identified by hazard analysis, that needs to be controlled by control measures.

Senior Management: Person or group of people who directs and controls an organization at the highest level.

- ✓ Senior Management has the power to delegate authority and provide resources in the organization
- ✓ If the scope of the management system covers only part of an organization, then Senior Management refers to those who direct and control this part of the organization.

Traceability: Ability to track the history, application, movement and location of an object through specified stage(s) of production, processing and distribution

- ✓ Movement may relate to the origin of materials, processing history, or food distribution.
- ✓ An object can be a product, a material, a unit, a piece of equipment, a service, etc.

Update

immediate and/or planned activity that ensures the application of the latest information

- ✓ Updating is different from the terms "maintain" and "retain":
- ✓ to maintain is to have something ongoing kept in good condition;
- ✓ to retain is to have something that is retrievable.

Validation: <food safety> obtaining evidence that the control measures (or combination of control measures) are capable of effectively controlling the significant food safety hazard.

- ✓ Validation is performed at the time a combination of control measures is designed or whenever changes are made to implemented control measures.
- ✓ Distinctions are made in this document between the terms validation, monitoring, and verification;
- ✓ Validation is applied prior to an activity and provides information about the ability to deliver intended results;
- ✓ Monitoring is applied during an activity and provides information for action within a specified time period;
- ✓ Verification is applied after an activity and provides information for confirming compliance.

Verification: Proof, by providing objective evidence, that specified requirements have been met.

- ✓ Distinctions are made in this document between the terms validation, monitoring, and verification;
- ✓ Validation is applied prior to an activity and provides information about the ability to deliver intended results;
- ✓ Monitoring is applied during an activity and provides information for action within a specified time period;
- ✓ Verification is applied during an activity and provides information for confirming compliance.

4. BACKGROUND

4.1 UNDERSTANDING THE ORGANIZATION AND ITS BACKGROUND

GOIASA's Board of Directors identified the internal and external issues that are pertinent to its purpose and strategic direction and that affect its ability to achieve the intended results of its Integrated Management System.

The SWOT analysis, [PLAN-0018 Strategic Plan/Unfolding Business Philosophy](#) recording these internal and external issues. Document approved by Board of Directors with controlled registration for two years.

The monitoring and critical analysis of information about internal and external issues are performed in periodic meetings by Senior Management.

4.2 UNDERSTANDING THE NEED AND EXPECTATION OF STAKEHOLDERS

GOIASA's Board of Directors has determined the stakeholders that are relevant to the Management System. The document of **Interested Parties**, is an integral part of [PLAN-0018 Strategic Plan/Unfolding Business Philosophy](#).

The monitoring and critical analysis of information about internal and external issues are performed in periodic meetings by Senior Management.

4.3 SCOPE

The scope of the Food Safety Management System was defined to Goiasa and is described on [MANUAL-0003 – Integrated Management System Manual](#).

In this scope, Goiasa has considered as dangers, those that can represent harm to the consumer's health.

Altered appearance resulting from the multiplication of spoilage microorganisms (mold and yeast).

Chemical hazards such as heavy metals, pesticide residues, etc.

Presence of foreign bodies obviously perceptible by the consumer: unidentified materials, pieces of plastic, hair, insects, etc.

The hazard analyses are described on [PLAN-0051 - HACCP - Conventional Crystal and Organic Sugar](#).

4.4 FSMS – FOOD SAFETY MANAGEMENT SYSTEM

Goiasa has established a Food Safety Management System for the Goiatuba unit in Goias State, Brazil, according to the requirements of FSSC 22000 Norm, in order to:

- Establish, implement, maintain, update, and continually improve the FSMS;
- Ensure that the Food Safety hazards considered in the scope are identified, evaluated, and controlled to ensure consumer safety;
- Communicate issues related to Food Safety in the production chain;
- Ensure communication regarding the development, deployment and updating of HSEMS throughout the organization to the extent necessary to ensure Food Safety;
- Periodically assess and update, when necessary, the FSMS to ensure that the system reflects the company's reality, as far as Food Safety assurance is concerned;
- The Brazilian system, Análise de Perigos e Pontos Críticos de Controle (APCC) is internationally known as Hazard Analysis and Critical Control Point - HACCP, and is used as the basis for the preventive system of control of Food Safety hazards developed and that meet the requirements established in the International Standard for Food Safety Assurance
- The HACCP system, established by the joint Commission of FAO (Food and Agriculture Organization of the United Nations) and WHO (World Health Organization) Codex Alimentarius, is a system implemented to guarantee the production of food that is safe for consumer health, applied to production, handling, packaging, storage, transport, quality assurance, shipping and handling
- Consistently provide food, product and service safety that meets customer and applicable statutory and regulatory requirements;
- Address the risks associated with its goals;
- Be able to demonstrate compliance with the specified FSMS requirements.

GOIASA uses document management software to establish, implement, maintain, update, and continually improve the FSMS.

4.4.1 FSMS PRINCIPLES

Food safety is related to the presence of hazards at the moment of consumption (by the consumer) that can occur, are adequately controlled, and are guaranteed with the combined efforts of all parties in the food production chain. This document specifies requirements for the FSMS that combine the generally recognized key elements:

- Interactive communication;
- Management system;
- Pre-requirements Program;
- Principles of Hazard Analysis and Critical Control Points (HACCP).

In addition, this document is based on the principles that are common to ABNT management system standards. The Management principles are:

- Focus on Customer;
- Leadership;
- People engagement;
- Process approach;

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- Improvement;
- Evidence-based decision making;
- Relationship Management.

4.4.2 PROCESS APPROACH

The process approach for FSMS is the same as established in the [MANUA-0003 – Manual of Integrated Management System](#) and involves the systematic definition and management of processes and their interactions to achieve the intended results in accordance with the Food Safety Policy and the strategic direction of the organization.

Processes and system management as a whole can be carried out using the PDCA cycle with a general focus on a risk-based mindset, aiming to take advantage of opportunities and prevent undesirable outcomes.

As illustrated on Figure 1, below, the process approach uses the concept of the PDCA cycle at two levels. The first covers the overall structure of the FSMS (Section 4, 7, 9 e 10 of ISO 22000:19) and the other level comprises operating processes (Section 8 of ISO 22000:19) within FSMS.

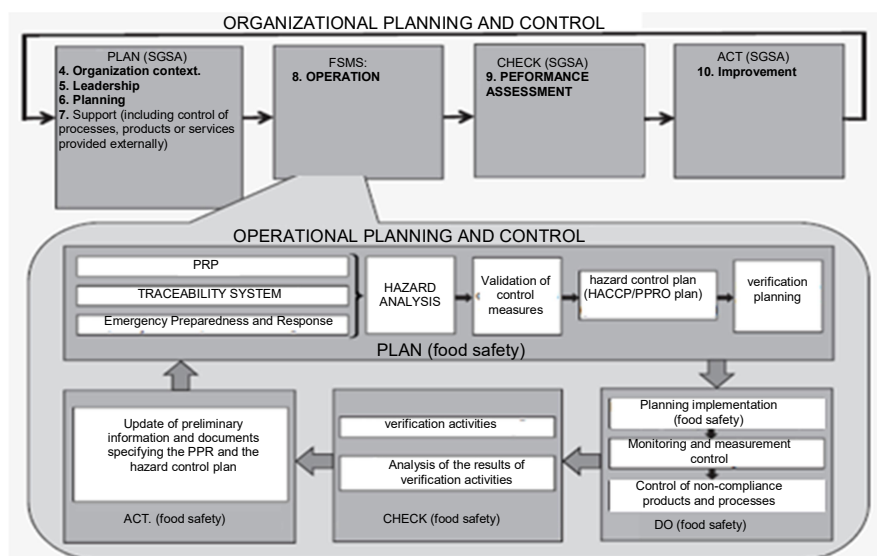


Figure 1 - Illustration of Plan-Do-Check-Act cycle in two levels.

The Management model, role of the customer in the organization, risk assessment and opportunities are defined in [MANUA-0003 – Manual of Integrated Management System](#).

In the context of operational risk management, it is performed according to HACCP principles and the required control measures to prevent or reduce hazards to acceptable levels are described in [PLAN-0051 - HACCP - Conventional and Organic Crystalline Sugar](#).

5. LEADERSHIP

Goiasa ensures that all relevant personnel are trained concerning to the importance of Food Safety Management System activities.

To implement the Food Safety Management System, the following Authorities and Responsibilities were defined, which are partly pointed out in the Integrated Management System Manual and also the following:

5.1 SENIOR MANAGEMENT

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Senior Management's commitment and policy towards the development, implementation, maintenance and continual improvement of the HSEMS is described in [MANUA-0003 – Manual of Integrated Management System](#), ensuring that:

- a) The Food Safety Policy and objectives are established for the FSMS and are compatible with the Strategic Direction of the Organization;
- b) The integration of the FSMS requirements into the organization's business processes;
- c) The required resources for the FSMS are available;
- d) The importance of an effective FSMS is communicated in accordance with applicable regulatory requirements and customer requirements;
- e) The SMSS is evaluated and maintained to achieve its intended results
- f) Directs and supports the person a for the effectiveness of the FSMS appoints the Food Safety Coordinator and the Food Safety Team.
- g) Continuous improvement is promoted;
- h) Supports other relevant management functions to demonstrate how their leadership applies to the areas under their responsibility.

Senior Management holds critical analysis meetings, on an annual basis, according to [PROCE-0017 Critical Analysis of Management System](#).

At Goiasa, Food Safety is understood as a priority and resources are made available according to Food Safety project openings, which are approved by senior management.

The Senior Management also approves the payment of bonuses upon the fulfillment of operational indicators related to Food Safety.

5.2 FSMS POLICY AND RELATED GOALS

The policy established by the Senior Management is pointed out in the document [ANNEX-0058 Goiasa's Business Philosophy](#). The goals that impact the Food Safety Management System are set out in the document [PLAN-0018 Strategic Plan/Unfolding Business Philosophy](#).

5.3 ORGANIZATIONAL FUNCTIONS, RESPONSIBILITIES AND AUTHORITIES .

5.3.1 SENIOR MANAGEMENT

It appoints the FST - Food Safety Team and the Team Coordinators. The names, positions and functions (members' contribution to the FST) are defined in the [ANEXO-0230 List of FST Key Contacts](#). This team has a shared management composed of Strategic Coordination and Operational Coordination.

5.3.2 FST

The company has a multidisciplinary team, the FST - Food Safety Team, which is responsible for:

- Establishing, implementing, maintaining and updating the Food Safety Management System;
- Performing activities as described in the [ANNEX-0116 Calendar of FST Activities](#);
- Ensure training or other actions to ensure the necessary competencies within each function (ESA, Internal Auditors, CCP and PPRO Monitors responsible for corrective actions, etc.) and awareness of the relevance and importance of the role of the people involved, described in the procedure [PROCE-0057 Training Procedure](#);
- Work as a communication channel for information related to Food Safety with their respective areas and customers;
- Report to Senior Management on the effectiveness and suitability of the FSMS at **Critical Analysis Meeting**.

The FST is linked to the Company's Superintendence, as shown in the organization chart available in the GIS manual [MANUA-0003 – Manual of Integrated Management System](#).

5.4 EMPLOYEEES

The Coordinators, Managers, Managers have responsibilities with the food safety culture (being an example to their subordinates), reporting deviations in the FSMS, collaborating with the investigation and analysis for problem solving and improvements related to Food Safety. Production Coordinators must perform verification activities through biweekly Food Safety inspections.

All employees have responsibilities to report problems related to Food Safety to their superiors and/or FST - Food Safety Team. I

The responsibilities for monitoring, verification, correction and corrective action of the PRPs are described in [MANUA-0002 Good Manufacturing Practices](#).

Responsibilities and authorities for persons involved in monitoring, verification, correction and corrective action activities for CCP, OPRP are described in the Monitoring and Verification Plans, available in the HACCP plans. Those responsible for each action necessary to correct and/or prevent nonconformities related to Food Safety must respond to the ESA Coordinator, and they will be aware of their actions through the pending beacon (Integrated Minutes).

5.5 TECHNICAL Responsible

Fábio Henrique Costa Batista de Oliveira (CRQ-XII under no. 04362469, Process no. 1175/14, according to Technical Function Note record no. 000079/2015).

6. PLANNING

6.1 ACTIONS FOR APPROACHING RISKS AND OPPORTUNITIES

As provided in [MANUA-0003 – Manual of Integrated Management System](#) GOIASA's Board of Directors analyzes and assesses the risks related to the internal and external issues (see 4.1) identified in the document **SWOT Analysis – GOIASA**.

From this analysis, the Board defines actions to address risks and opportunities. These actions are recorded in the [PLAN-0018 Strategic Plan/Unfolding Business Philosophy](#).

The effectiveness of these actions is evaluated in Critical Analyses by Management.

For stakeholder requirements (see 4.2), the risk analysis/assessment and the actions to address risks and opportunities are recorded also in the document [PLANO-0018 Strategic Plan/Unfolding Business Philosophy](#).

The identification of hazards and operational risks inherent to the activities in the existing production process related to Food Safety is included in the HACCP Plan, which is revised as necessary. GOIASA ensures the application of control measures to prevent hazards (PRP) and to control existing hazards (OPRP and CCP) according to the aspects of origin: physical, chemical, biological, allergenic, and radiological.

GOIASA releases among its employees the risks and impacts identified, inherent to its activities through forms for monitoring and verification of PRP, OPRP, and CCP, as well as through Food Safety Inspections.

6.2 FSMS' GOALS AND PLANNING TO ACHIEVE THEM

As set out in the [MANUA-0003 – Manual of Integrated Management System](#) GOIASA's Strategic Planning and Business Philosophy provide a framework for establishing the objectives of the GIS, which is the same adopted for the FSMS. GOIASA ensures that the objectives of the GIS/FSMS, including those necessary to meet product requirements, are established at all levels of the company.

6.3 CHANGE PLANNING

When GOIASA determines the need for changes in its Management System, the changes are carried out in a planned and systematic way.

The methodology for this planning is detailed in the [NMSMA-0006 Change Management](#).

7 SUPPORT

7.1 RESOURCES

7.1.1 OVERVIEW

Provided in the [MANUA-0003 – Manual of Integrated Management System](#) that the Chief Operating Officer and or the Superintendent approves the resources essential to ensure the maintenance of GIS, continuously improve its effectiveness, and increase customer, employee, and community satisfaction. Resources are as follows: human, specialized skills, organizational infrastructure, technology, and financial resources.

GOIASA considers:

- ☐ The existing internal resource capabilities and constraints;
- ☐ What needs to be obtained from external providers.

GOIASA ensures that all personnel performing activities affecting health, safety, quality, environment, and food safety possess appropriate competence, based on education, training, acquired skills and experience.

7.1.2 PEOPLE

GOIASA determines and provides the necessary people for the effective implementation of its Food Safety Management System and the operation and control of its processes.

7.1.3 INFRASTRUCTURE

GOIASA maintains the necessary infrastructure for the implementation of the FSMS, considering the equipment, materials, and facilities: agricultural, industrial, administrative offices, storeroom, living areas among others, computer network, and support services.

7.1.4 WORK ENVIRONMENT

GOIASA ensures the working environment conditions necessary to comply with the product and food safety requirements and to guarantee the health and safety of employees, conserve the environment, and ensure food safety. In addition, it has prevention and control programs that guarantee that all activities are carried out safely and avoid environmental impacts.

The work environments were designed to provide the required comfort and safety for good performance of employees working in the processes. The environment of agricultural, industrial, and office areas allows the integration of all employees who work there, ensuring safety and health of all workers.

Property security, maintenance, signaling and cleaning, as well as the necessary conditions for a good progress of the activities (lighting, ventilation, etc.) are planned and maintained in perfect conditions.

The social (non-discriminatory, calm and non-confrontational) and psychological (emotional protection) environment occurs as provided in [NMADM-0005 Code of Conduct](#).

7.1.5 ELEMENTS OF AN EXTERNALLY DEVELOPED FSMS

Not applicable, because there are no externally developed elements.

7.1.6 CONTROLLING OUTSOURCED PROCESSES, PRODUCTS OR SERVICES .

GOIASA ensures that any product or service that may have an impact on food safety has specified requirements and is managed according to the criteria for selection, approval, and monitoring of compliant suppliers [MANUA-0008 • Quality Manual for External Suppliers/Providers](#)

GOIASA keeps a documented procedure [PROCE-0067 Materials and Services Procurement](#), to ensure that the procurement of materials and services complies with specified requirements regarding product quality and safety, employee health and safety, and pollution prevention.

GOIASA maintains records of controlled materials, with their specifications, in order to guarantee that they can be clearly identified and have their requirements fully defined, according to the Technical Specifications of Materials - ETMA, Technical Specifications of Services - ETSE, and Technical Specifications of Equipment - ETEQ.

Materials are inspected upon receipt to the extent necessary to ensure that only materials in accordance with specifications.

Records are kept, both from suppliers and inspections are carried out on the material received, as a proof of the controls carried out.

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The procurement document, Purchase Order or Contract, contain all the data of the requested product or service and is released after critical analysis and approval by the person in charge or assigned by him/her.

GOIASA submits to the relevant suppliers of materials and equipments, related to FSMS, the ETMA - Material Technical Specification, to the relevant service providers, ETSE - Service Technical Specification, so that they are aware about the specifications, and to the relevant equipment suppliers, ETEQ - Material Technical Specification.

7.2 COMPETENCY

The Organization ensures competency, awareness and training of staff and personnel involved in activities that impact Food Safety by:

- Identification of the required competencies of the personnel involved in the activity that may impact the Food Safety, including personnel responsible for monitoring, corrections, and corrective actions are described in the Integrated Management System;
- The competency for in-house staff is defined in the job descriptions, and for outsourced staff in the ETSE (Technical Specification of Services).
- All Employees attend integration talks, according to the systematic defined in the recruitment and selection procedure, before they start their activities.
- Provision of Training or other actions to ensure the required competencies within each function (FST, Internal Auditors, CCP Monitors responsible for corrective actions, etc.), and awareness of the relevance and importance of the role of the people involved, described in the procedure [PROCE-0057 Training Procedure](#);
- Effective Communication about requirements;
- The Training sector will evaluate the effectiveness of the training of the OPRP and CCP monitors by applying a technical test.
- The company ensures that employees who work in control positions are submitted to training to ensure supervision for the application of Food Safety principles and practices related to their activities, as pointed out in the job descriptions prepared.

TABLE 01 Criteria for the formation of the coordinator and members of the Food Safety Team.

Competency:	Team Coordinator	Team Member
Skills/Education	As described in the Integrated Management System	As described in the Integrated Management System
Professional Experience	3 years of work experience 6 months of experience in the company	1 year of work experience 6 months of experience in the company
Experience in Food Safety	1 year working in the food area	6 months of experience in the company, in the specialty he represents in the team
Training	GMP HACCP FSSC 22000	GMP HACCP FSSC 22000

NOTE: The FST strategic coordinator assists in measures for FST's output actions, liaises between FST and Senior Management when necessary, and assists in the decision making when the Team needs to make a joint decision.

The FST Operational Coordinator has a university degree in an area related to the subject, and 3 years of professional experience and knowledge of FSMS. We use the criteria of 6 months of experience and 1 year working in Food Safety, both at Goiasa.

FST members have 1 year of professional experience in their portfolio, and 1 year of experience at Goiasa, being divided into 6 months of experience at Goiasa and more 6 months in the specialty that the member represents on the team, in order to ensure that he/she can represent his/her area and can add to the group's discussions.

Concerning to **experience in Food Safety** of FST members:

- Evidence of previous employment experience can be provided. For example: Through a letter of recommendation from the former employer, experience recorded in the portfolio, and a description of the activities previously performed in Food companies;
- Training certificates concerning to GMP, HACCP and FSSC 22000 are also accepted;

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- If a member has no experience in the area of Food Safety, he/she will attend the FST as an "FST Trainee" and after six months to be classified as a "FST Member".

7.3 AWARENESS

GOIASA ensures that anyone working for it or on its behalf is aware:

- ☐ About the GOIASA's Business Philosophy, in which the food safety policy is established;
- ☐ About the relevant Goals;
- ☐ About the significant Environmental Aspects and the actual or potential environmental impacts related to their work;
- ☐ Of the actual or potential SOS consequences of activities and behaviors;
- ☐ Their contribution to GIS effectiveness, including the benefits of improved performance;
- ☐ Of their roles, responsibilities, and the implications of not complying with GIS requirements, including not meeting legal and other requirements.

7.4 COMMUNICATION

GOIASA maintains an open and effective communication system, according to [PROCE-0056 - Organizational Communication](#), to disseminate GIS and FSMS information clearly and transparently to all employees, so that effective communication is understood by all personnel involved in activities that have an impact on food safety.

External communications with external suppliers, contractors, customers, statutory and regulatory authorities and other organizations, which have an impact on food safety, are also systematized in the compliance [PROCE-0056 - Organizational Communication](#).

In order to maintain the effectiveness of the FSMS, the organization must ensure that the FST-Food Safety Team is informed at the appropriate time of the following changes:

TYPE OF CHANGE	HOW FST IS INFORMED?
a) Products or new products	PROCE-0052 Critical Analysis on Supply e PROCE-0119 - Design and Development .
b) Raw materials, ingredients and services;	Through the consensus of the ETMA's and ETSE's.
c) Production systems and equipment;	PROCE-0119 - Design e Development and NMSMA-0006 Change Management .
d) Production facilities, equipment location, and surroundings;	PROCE-0119 - Design e Development and NMSMA-0006 Change Management .
e) cleaning and sanitation programs;	Through the consensus of the cleaning programs: PROCE-0007 - Hygiene of Product Contact Surface ; PROCE-0178 - Cleanliness and Conservation Goiasa
f) Packaging, storage and distribution systems;	Through the consensus of the ETMA.
g) Competences and/or designation of responsibilities and authorities;	PROCE-0056 - Organizational Communications
h) Applicable regulatory and statutory requirements;	PROCE-0123 Identifying, Meeting, and Evaluating Legal and Other Requirements
i) Knowledge related to food safety hazards and control measures;	PROCE-0123 Identifying, Meeting, and Evaluating Legal and Other Requirements
j) Customer, industry or other requirements observed by the organization;	Through acceptance of specification and contracts.
k) Relevant consultations and communications from external stakeholders;	NMADM-0003 - Organizational Communications
l) Complaints and alerts that impact food safety;	PROCE-0015 - Customer Manifestations .
m) Other conditions that may impact food safety.	PROCE-0056 - Organizational Communications

7.5 DOCUMENTED INFORMATION

7.5.1 OVERVIEW

The documented information to be kept (documents) required by GOIASA's FSMS are standardized and controlled according to the [PROCE-0014 Document Control Records](#).

The Food Safety System documentation consists of:

- a) FSMS policy and related goals;
- b) Manual do SGSA e BPF;
- c) Documents related to PRP/OPRP/CCP (including management);
- d) Description of the raw materials and ingredients and materials in contact with the product;
- e) Information relevant and raised by the team to perform the hazard analysis, and when applicable should be treated as documents of external and/or internal origin;
- f) Justifications for Danger;
- g) Acceptable level;
- h) End product features;
- i) Intended use;
- j) Reasonably expected handling of the end product, or any unintentional misuse or mishandling of the end product;
- k) Flowchart and verification of them;
- l) Control Measures and Operational Control Measures;
- m) Monitoring Plan for Operational Control Measures and Food Safety Management Plans;
- n) Critical limits;
- o) Rational for critical limit;
- p) Verification;
- q) Corrections and Corrective Actions;
- r) Team verification results;
- s) Records of regulatory and customer requirements.

7.5.2. CREATING AND UPDATING

GOIASA uses a document management tool (software) to standardize the processes of generating, updating, identifying, describing, forming, critically analyzing, and approving the documented information of the FSMS.

7.5.3. CONTROL OF DOCUMENTED INFORMATION

GOIASA uses a document management tool (software) to ensure that the information required by the ERP is controlled, available, appropriate for use, release, sharing, protection, and use of the company's knowledge, aiming to increase the agility and effectiveness in the execution of its internal processes. In addition, it provides simple and immediate access to documents by the areas at Goiasa, ensuring that up-to-date versions are available to the right people at the right time.

GOIASA establishes and maintains records to provide evidence of compliance with requirements for effective operation of the FSMS are kept legible, readily identifiable and retrievable.

Documents of GOIASA's GIS are related to the applicable records and are controlled through the [PROCE-0014 Control of Record Documents](#), which sets out guidelines for proper record keeping and defines the criteria for identification, storage, protection, retrieval, retention time, and disposal.

8 OPERATION

8.1 OPERATING PLANNING AND CONTROL

GOIASA maintains documented procedures with a purpose of identifying, planning, implementing, controlling, maintaining and updating the processes needed to meet the requirements for manufacturing safe products

The planning for the realization of the products is done by planning the activities as established in [MANUA-0003 – Manual of Integrated Management System](#).

GOIASA controls planned changes and critically analyzes the consequences of unintended changes, taking action to mitigate any adverse effects as stated in [NMSMA-0006 Change Management](#).

8.2 PRE-REQUIREMENTS PROGRAM (PRP)

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FST identifies prerequisite programs as appropriate to the nature of its products and processes, and the size and type of operation, to help control the likelihood of introducing food safety hazards through the work environment, avoiding biological, chemical, physical, allergenic and radiological contamination including cross contamination, to ensure the hazard levels in the products and in the work environment.

PRPs are approved by ESA through the document review flow, meet statutory and regulatory requirements, customer requirements and the CODEX Alimentarius commission's principles and codes of practice.

PRPs are set out, when applicable, to the company based on ISO TS 22002-1 Standard.

The Pre-Requirement Programs established by the company are addressed in documents such as [MANUA-0002 Good Manufacturing Practices](#), procedures and related documents of the implemented management system.

Product information and consumer awareness is set out in the product specifications: [ETGOI-0002 - Conventional Crystal Sugar](#) and [ETGOI-0005 Organic Crystal Sugar](#).

The verifications of the PRP are made through the **FSI-Food Safety Inspections** in the Production Coordinators Inspections, FST inspections, and through internal and external audits.

The company ensures that all services that may have an impact on food safety have requirements specified in contracts, and/or described in documents from the areas involved and are managed according to the criteria for selection, approval and monitoring of suppliers according to [MANUA-0008 • Quality Manual for External Suppliers/Providers](#)

8.3 TRACEABILITY SYSTEM

The company establishes and applies a traceability system that allows the identification of product batches and their relation to raw material batches (direct suppliers), processing, and release registration (initial distribution route of end product).

Traceability records are kept for a period of 02 years once this is the average consumption time of sugar by customers, it allows for the proper handling of potentially unsafe products and eventual product recall.

The records involved in the processing of organic sugar are kept on file for a period of 05 years, meeting an IBD - Biodynamic Institute - requirement.

The traceability scheme is described in [ANNEX-0445 - Identification and Traceability](#).

Care is taken to avoid possible cross-contamination when changing production from conventional to organic sugar, as provided for in the document [PROCE-0005 - Production of Organic Sugar](#), thus ensuring the necessary product traceability.

The effectiveness of the traceability system is tested through recall simulations as established in [PROCE-0064 - Product Recall](#).

8.4 PROMPT RESPONSE TO EMERGENCY

Senior Management's commitment and policy towards the development, implementation, maintenance and continuous improvement of the system is described in [MANUA-0003 – Manual of Integrated Management System](#).

Potential emergency situations and accidents that may impact Food Safety in the Organization or Supply Chain are managed according to the emergency response plan [PLANO-0011 - EAP - Emergency Assistance Plan](#).

Simulation exercises are conducted periodically, [ANEXO-0112 Annual Training Schedule / EAP Simulations](#), and cover escape situations, firefighting, first aid, and dealing with the sugar product are covered in the relevant scenarios.

Measures for emergencies and incidents, which impact Food Safety, are recorded in Minutes and for unforeseen emergencies we use the [PROCE-0019 - Nonconformity Control and Improvement](#) for assessment and definition of specific plans.

8.5 HAZARD ANALYSIS

8.5.1 PRELIMINARY STEPS TO ENABLE HAZARD ANALYSIS

8.5.1.1 CHARACTERISTICS OF THE RAW MATERIALS, INGREDIENTS AND MATERIALS IN CONTACT WITH THE PRODUCT.

Descriptions of ingredients, raw materials, packaging materials, and surfaces that come into contact with the product, to the extent necessary to conduct the hazard analysis, are covered in documents in the Hazard Studies: [PLAN-0051 - HACCP - Conventional and Organic Crystal Sugar](#).

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The description of the surfaces in contact with the product is described in [PROCE-0007 - Hygiene of Product Contact Surfaces](#).

The information about: product, origin, composition, characteristics, production methods, packaging and transport, storage and shelf life, methods for use, acceptance criteria and applicable legislation are described in the specifications (ETMA, ETSE and ETEQ).

The company ensures that all services, materials and equipment, which may have an impact on Food Safety, have specified requirements and are managed according to the criteria for selection, approval and monitoring of suppliers according to [MANUA-0008 • Quality Manual for External Suppliers/Providers](#)

8.5.1.2 END PRODUCT FEATURES

The characteristics of the final products are defined in the sugar specification - [ETGOI-0002 - Conventional Crystal Sugar](#) and [ETGOI-0005 Organic Crystal Sugar](#).

In the Studies on Hazards: [PLAN-0051 - HACCP - Conventional and Organic Crystal Sugar](#), are some product-specific descriptions with a focus on Food Safety.

In case of new product development FST is communicated as set out in the document [PROCE-0052 Critical Supply Analysis](#).

8.5.1.3 INTENDED USE

The intended use, including the reasonably expected handling of the end product and the unintended use of the end products are defined in the sugar specification - [ETGOI-0002 - Conventional Crystal Sugar](#) e [ETGOI-0005 Organic Crystal Sugar](#).

8.5.1.4 PROCESSES DESCRIPTION FLOWCHART

The flowcharts are established for the processes covered by the Food Safety Management System and are described in the Food Safety Management Plan. They provide the basis for hazard analysis related to supplies and process steps, pointing out:

- a) Sequence of steps for each process;
- b) Inputs to process steps in each flow;
- c) Outputs of final products, intermediate products and waste (relevant to Food Safety);
- d) Recirculation;
- e) External Processes.

The flowcharts are checked and confirmed on-site by FST members and records of the flowchart checks are kept in FST meeting minutes.

Parameters of processes or procedures that can influence food safety are described to the necessary extent in the Hazard Studies: [PLAN-0051 - HACCP - Conventional and Organic Crystal Sugar](#).

8.5.2 HAZARD ANALYSIS

8.5.2.1 OVERVIEW

FST is multidisciplinary and has the knowledge and experience to conduct the hazard analysis, aiming at the implementation and maintenance of the FSMS. Information must be collected and, if necessary, the participation of other collaborators can be requested to contribute with specific knowledge.

8.5.2.1.1 COMPANY IDENTIFICATION

Company Name: Goiasa - Goiatuba Álcool LTDA.

Address: Rod. GO 040 km 194 - Zona Rural.

City: Goiatuba

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State: GO
Zip Code: 75600--000
Phone: 64 3608 8800
Fax: 64 3608 8806
Corporate Taxpayer Registry Number (CNPJ): 02.773.950 / 0001-84
State Registration: 10.133.116 / 9
List of Prepared Products: [ETGOI-0002 - Conventional Crystal Sugar](#) and [ETGOI-0005 Organic Crystal Sugar](#).
Destination of Production: Domestic and Foreign Wholesale Market
FDA Registry 16548598454.

8.5.2.1.2 HACCP Foundations

The HACCP is a tool of preventive purpose and is based on recorded data about the causes of foodborne diseases and emphasizes critical operations where control is essential, thus simplifying the actions, indicating a few key operations of the processes that are fundamental to achieving Food Safety.

It considers the use of ingredients, supplies, processes, and subsequent use of the products.

It continuously monitors critical points to detect problems before they occur, enabling corrections and remedial actions to be taken immediately, i.e. it is a preventive system to ensure that the product at any stage of processing is not contaminated.

It is systematic because it is a complete plan, covering all operations, processes, and control measures, thus reducing the risk of foodborne diseases.

A Food Safety hazard study is specific to a particular product or product line and to a processing line. The method should be revised whenever new hazards are identified, equipment and/or process parameters undergo significant changes.

The HACCP system is based on the Seven Principles outlined in the *Codex Alimentarius*, which constitute the minimum set of activities or actions to be adopted so that food can be considered safe for consumption. They are:

Principle 1: Carrying out hazard analysis and preventive measures;

Principle 2: Determination of critical control points;

Principle 3: Establishing critical limits;

Principle 4: Establishing CCP control monitoring procedures;

Principle 5: Establishing corrective action;

Principle 6: Establishing verification procedures;

Principle 7: Establishing recording and documentation procedures.

The implementation of the principles should be carried out following a logical sequence of 12 steps. This sequence provides general guidelines for the practical application of the HACCP system and consists of:

- a) FST Groups (HACCP team/ Food Safety Team);
- b) Product description;
- c) Identification of the intended use of the product;
- d) Elaboration of the process flow diagram;
- e) Confirmation of the process flow diagram;
- f) Hazard analysis and preventive measures;
- g) Determination of critical control points;
- h) Establishing critical limits for all CCPs;
- i) Establishing monitoring procedures for all CCPs;
- j) Establishing corrective actions for all CCPs;
- k) Establishing verification procedures;
- l) Establishing recording and documentation procedures.

To ensure that the Food Safety Management System system is efficient, it is essential that prerequisite programs are in place. Good Manufacturing Practices (GMP) are some of the fundamental prerequisites for effective implementation of the Safety Management System. These prerequisite programs are established and managed separately from the Food Safety plans.

8.5.2.1.3 PLANNING AND PRODUCTION OF SAFE PRODUCTS

GOIASA ensures the effectiveness of planned activities for the production of safe products through prerequisite programs (PPR), operational prerequisites (OPRPs), and CCPs.

8.5.2.2 IDENTIFYING HAZARDS AND DEFINING ACCEPTABLE LEVELS

For each hazard identified, the acceptable level in the final product is defined, whenever possible.

The level determined takes into account regulatory requirements, standards, Goiasa's requirements, and supplier information, with the most restrictive parameters being adopted. In the absence of such information for the final product, historical data is taken into account whenever possible, and in some cases the acceptable hazard level established for the input is adopted.

To determine the maximum levels of microbiological contaminants (pathogens), the maximum levels established for indicators of hygienic conditions are taken as a basis. (Ex: total coliforms).

The hazards were surveyed, analyzing in detail all the stages of the production process.

Classification	Hazards
Biological	Pathogenic bacteria, viruses, pathogenic parasites, and protozoa.
Chemical	Natural toxins (ciguatoxins, paralytic, neurotoxic, amnesic, and diarrhetic toxins, among others), fungal, toxic metabolites of microbial origin, pesticides, herbicides, toxic inorganic contaminants, antibiotics, anabolic agents, toxic food additives and adjuvants, heavy metals, lubricants and paints, disinfectants, and so on.
Physical	Glass, metals, wood or objects that can cause an injury to the consumer (mouth injuries, broken teeth, and others that require surgical interventions for their removal from the consumer's body)
Radiological	Not applicable. Radiological hazards were assessed and not included in the PLANO-0051 - HACCP - Conventional and Organic Crystal Sugar , once: Goiasa does not use any irradiation source to increase the shelf life of sugar; Does not use any equipment that works with ionizing source within the productive process; No raw materials or inputs that undergo any type of irradiation are used, as set out in the FORMU-0131 - Supplier/External Provider Qualification Questionnaire .

8.5.2.3 HAZARD ASSESSMENT

The hazard analysis of inputs and process steps is conducted by FST in order to determine which hazards need to be controlled and what appropriate combination of control measures is required. The hazard analyses are recorded on specific forms.

The different types of hazards can cause consequences of varying severity for humans, resulting in different degrees of severity of pathologies. In our Plan we use the following assessments:

a) Probability Assessment:

Occurrence Probability Assessment	
High	The occurrence is frequent.
Medium	The occurrence is occasional.
Low	The occurrence is from time to time.

a) Severity

"A" = high (risk of death),

"M" = medium (hospitalization or sequelae),

"B" = low (in general does not lead to the need for hospitalization, and usually does not present sequelae).

b) Probability

"A" = high,

"M" = medium,

"B" = low.

c) Risk

"M" = major,

"m" = minor,

"C" = critical.

The probability of occurrence of the identified hazards is established considering information obtained in the preliminary steps of the hazard analysis, FST's experience and external information, and historical data and information obtained from the production chain.

b) Severity Assessment (Risk):

Each Food Safety hazard is evaluated according to its severity and the likelihood of its occurrence, according to the methodology indicated below.

The hazard's potential risk assessment took into account the frequency of its manifestation in consumers. Cross-referencing the Consequence Severity and Probability of Occurrence data provides the subjective estimation of Risk, i.e. whether it is minor, major, negligible, or critical, as shown in the following table:

Significance Matrix

A Significance Matrix was developed from the modification of the PAHO- Pan American Health Organization and Tool Kit matrix, as follows:

Severity	Probability		
	Low	Medium	High
High	m	M	C
Medium	m	M	M
Low	m	M	M

KEYS:

Severity: "A" = high (risk of death), "M" = medium (hospitalization or sequelae), "B" = low (in general does not lead to the need for hospitalization, and in general does not present sequelae).

Probability: "A" = high, "M" = medium, "B" = low.

Risk: "M" = major, "m" = minor, "C" = critical.

For cases of high severity, but with low probability, FST, considering the process history and occurrences, classifies the risk as minor.

In summary, the hazard analysis performed could be subdivided into the following steps:

Detailed analysis of the possible hazards in the raw material to be processed;

Detailed analysis of the possible hazards in the process steps;

Assessment of applying the Good Manufacturing Practices for hazard prevention;

On-site observation of processing conditions;

Carrying out analysis (physical, chemical, microbiological) for guidance and data collection;

Final analysis of the results.

Important to note that critical materials are defined by the decision tree, to fulfill the additional requirement no. 05 of FSSC 22000.

8.5.2.4 SELECTION AND CLASSIFICATION OF CONTROL MEASURES

The identified control measures aim to prevent, eliminate, or reduce hazards to defined acceptable levels. The selected control measures are classified according to whether they need to be managed through PRPs, Pre-Requirement Programs, Operational Pre-Requirement Programs, or the HACCP Plan. Decision trees were used for this classification. At the first level of the decision tree a systemic approach to hazard assessment will be taken, and at the second level the assessment of control measure failure will be performed.

To increase the rigor of product safety, the company has opted to take all the established control measures to the tree, regardless of the risk identified in the assessment.

When the control measures are classified as minor they are managed as a Pre-Requirement Program. When the risk is perceived by FST as major or critical, the control measures will be classified as OPRP and CCP, as required, and possibility of monitoring.

However, FST can make different decisions than the tree-driven ones, depending on its experience and understanding of the needs to ensure the safety of the products.

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8.5.22/8.5.23

Document the risks relevant to food safety and decide what hazards are reasonably expected to occur in relation to the type of product and process and process environment (8.5.2.2.1)

First level - hazard assessment

Q1- Is there a significant hazard (probability x severity) at this stage? (8.5.2.3)

NO

Apply PRPs as appropriate.
STOP, proceed to the next step in the process.

YES

Q2- Is it necessary to apply control measures in this step? (8.5.2.2.2)

NO

In all cases, a control measure at a subsequent step in the processes or food chain will reduce the risk to an acceptable level.
Apply PRPs as appropriate.
STOP, proceed to the next step in the process.

YES

Q3- Are the control measures already in place?

NO

Implement control measures
(a) modifying your own process or
(b) have control measures in the supplier's process of its raw materials.
If (a) and (b) are not feasible:
inform your client (close to the process) of the possible presence of the hazard. (7.4.2 b 2)
STOP, proceed to the next step in the process.

Second level - assessment of control measures failures

8.5.2.4

Q4 - Is there any failure in the control measure with high risk (probability x severity) for product safety?

(8.5.2.4.1)

Includes the following:

- The effect on danger.
- Control measure applied specifically to reduce to an acceptable level?
- Any subsequent control measures?
- Single measure or control combination?

NO

Categorize the control measure as an OPRP.

1. Establish action criteria. (3.5.2.4.2)
2. Monitor (measure or observe) for faults.

The method and frequency must be proportional to the probability and severity of the failure. (3.5.2.4.1)

3. In case of failure assess the causes and consequences of the failure and when necessary, manage the affected product as potentially unsafe (correction). (3.9.2.3)

STOP, proceed to the next step in the process

YES

Q5- Is it possible to establish measurable critical limits and monitoring that allow timely detection of correction of all failures?
(8.5.2.4.2)

NO

Categorize the control measure as an OPPP.

1. Establish action criteria. (3.5.2.4.2)
2. Monitor (measure or observe) for faults.

The method and frequency must be proportional to the probability and severity of the failure. (8.5.2.4.1)

3. In case of failure assess the causes and consequences of the failure and when necessary, manage the affected product as potentially unsafe (correction), (3.9.2.3)

4. When possible, redesign the product, process or control.

5. Inform customers and/or consumers about the risk. (7.4.2 b 2)

6. Take steps to reduce the probability and severity of failure.

STOP, proceed to the next step in the process.

YES

Categorize the control measure as an PCC

1. Establish measurable critical limits (8.5.4.2)
2. Monitor (measure) to detect any failure to comply with critical limits (8.5.4.3)
3. In case of failure, manage the affected products as potentially unsafe (8.9.2.2)

STOP, proceed to the next step in the process.

8.5.3 VALIDATION OF THE CONTROL MEASURE(S) AND THE COMBINATION(S) OF CONTROL MEASURE(S)

The selected CCP or OPRP control measures and/or combinations thereof are validated to demonstrate that they are capable of achieving the required control for each type of hazard for which they have been designated. If this validation is not possible, the control measure and/or its combinations are modified and re-evaluated. Validations should be conducted by FST jointly with Engineering, Management, or other applicable areas when necessary.

The FST must validate that the selected control measures are able to achieve the expected control of the Food Safety hazard, to obtain final products that meet the defined acceptable levels.

It is important that in planning the tests for the validation of the control measures, the criteria, objectives, and all necessary steps for test completion, test completion, etc. are defined. The validation process may include:

- a) Experimental testing to simulate process conditions;
- b) Data collected on physical, chemical and biological hazards during normal operating conditions;
- c) Statistical research;
- d) Mathematical models
- e) Equipment manufacturer's reports, etc.

A list of the OPRPs and CCPs validation reports are shown below:

- ☐ [ANNEX-0161 - Pre-Evaporation Validation Report;](#)
- ☐ [ANNEX-0162 - Employee Health and Hygiene Validation Report;](#)
- ☐ [ANNEX-0163 - Cleaning Program Validation Report;](#)
- ☐ [ANNEX-0164 - Electromagnet Validation Report;](#)
- ☐ [ANNEX-0163 - Metal Detectors Validation Report;](#)
- ☐ [ANNEX-0167 - Magnetic Separation Validation Report;](#)
- ☐ [ANNEX-0163 - Sugar Screening Validation Report;](#)

8.5.4 HAZARD CONTROL PLAN (HACCP PLANS)

Goiasa establishes, implements and maintains a Hazard Control Plan that includes information for each control measure in all CCPs or OPRPs.

The identified OPRPs and CCPs are documented as to:

- a) Food Safety Hazard to be controlled and the control measures adopted in the Hazard Studies: [PLAN-0051 - HACCP - Conventional and Organic Crystal Sugar](#), of supplies and process steps.
- b) Monitoring and verification procedure that shows that the OPRP is implemented, the criteria for taking action (measurable or observable), the corrections and corrective actions in case of control failure, responsibilities and authorities, and monitoring records is described in the HACCP plan.
- c) Monitoring and verification procedure showing that the CCP is implemented, devices used, critical limits, procedures, corrections and corrective actions in case of control failure, responsibilities and authorities, and monitoring records is described in the HACCP plans.

The control measure is related to the hazard and can be classified as either OPRP or CCP according to the answer achieved by the decision tree.

In some cases, control measures were identified that support the control of the hazard classified as PRPs (classified in the decision tree, mainly related to infrastructure conditions).

The hazard study includes the following information for each identified PRP or CCP:

- a) Food safety hazards to be controlled;
- b) Control measures;
- c) Specified critical limits, or criteria for action (measurable or observable) and reason for their choice;
- d) Monitoring procedures;
- e) Corrections and corrective actions to be taken if critical limits are exceeded;
- f) Responsibilities and authorities;
- g) Monitoring records.

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When specified critical limits, or criteria for taking action (measurable or observable) are not met, the following actions must be taken and recorded on the monitoring and verification forms:

- a) Potentially unsafe products are not released;
- b) The cause of the nonconformity must be identified;
- c) The parameter(s) controlled at the CCP, or OPRP, are returned to critical limits or criteria for action;
- d) Recurrence must be prevented.

8.6 UPDATING OF THE PRP INFORMATION AND THE HAZARDS CONTROL PLAN

Goiasa ensures that the hazard control plan and the PRPs are updated as described in item 7.5 DOCUMENTED INFORMATION and the FST is kept updated as described in item 7.4 COMMUNICATION.

8.7 MONITORING AND MEASUREMENT CONTROL

The instruments used for monitoring CCP's, operational prerequisite programs and activities involved with their verification are kept calibrated as described [PROCE-0113 Control of Measuring and Monitoring Devices](#). If a non-compliant instrument is detected, those responsible for the calibration activity perform the necessary actions on the instrument and communicate to FST, in cases involving measurements that impact the safety of the produced product (OPRP and CCP measurements) to assess the need for action on the affected product.

8.8 VERIFICATION RELATED TO PPR'S AND HAZARD CONTROL PLAN

The verification planning for CCP's and OPRP's is described in the CCP verification plans and PRP/OPRP verification plan respectively. These plans contain information such as purpose, methods, frequency, responsibilities, corrections/corrective actions, and records related to the verification activities.

The checks of CCP's and OPRP's are performed within the HACCP plans.

The other verifications have the objective of confirming that

- a) PRP's are implemented;
- b) The inputs to hazard analysis are updated;
- c) The OPRP's and the elements of the HACCP Plan are implemented and effective;
- d) Hazard levels are within acceptable levels;
- e) And compliance with other procedures identified by the organization.

These verifications, FSI - Food Safety Inspections, are carried out monthly by FST members. The verification results are noted on forms established by the organization and are used for FST's analysis of the results of verification activities. The forms to be used are:

[FORMU-0771 Food Safety Inspection - Sugar Factory;](#)

[FORMU-0853 Food Safety Inspection - Sugar Warehouse;](#)

[FORMU-0854 Food Safety Inspection - WTP - Capture, Recirculation Dist. And Water Treatment;](#)

[FORMU-0855 Food Safety Inspection - Evaporation;](#)

.

[FORMU-0857 Food Safety Inspection - Juice Treatment;](#)

[FORMU-0868 Food Safety Inspection - Alcohol Production;](#)

[FORMU-1013 Food Safety Inspection - Agriculture;](#)

[FORMU-1044 Food Safety Inspection - Kiosk;](#)

[FORMU-0394 Food Safety Inspection - Cafeteria;](#)

FST performs a critical analysis of the Food Safety Management System on an annual basis according to the [ANNEX-0116 - Calendar of FST Activities](#), prior to the critical analysis by senior management, regarding to assess the adequacy and effectiveness of the food safety

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management system, to identify trends indicating a higher incidence of potentially unsafe products, to provide evidence that corrections and corrective actions are effective, and to establish information for planning the internal audit program.

Where verification comprises analysis of finished product and where such analysis shows non-compliance with the acceptable hazard level, the affected batches shall be treated as potentially unsafe.

Where verification demonstrates non-compliance with the planned arrangements, the organization shall take action to achieve compliance by reviewing

- a) Existing procedures and communication channels;
- b) Hazard analysis, control measures;
- c) Food Safety Management System;
- d) Pre-requirements Program;
- e) The effectiveness of human resource management and training activities.

The FST coordination reports the relevant actions on the Food Safety Management System to the Senior Management, in order to keep it informed that it should take actions to achieve the required compliance, among them review of existing procedures, communication channels, HACCP plans, OPRP's, PRP's, and human resources management. If the necessary actions are not within his competence, he will take it to the Senior Management.

FST members report information to their areas as established in Critical Analysis meeting minutes and if necessary incorporate information into sector meeting minutes. The meetings are formalized by means of an attendance list and minutes. The results of the critical analyses may include corrective and preventive actions, which are handled accordingly [PROCE-0019 - Nonconformity Control and Improvement](#). Immediate actions can still be generated that are recorded in the meeting minutes.

The person responsible for the coordination of the FSMS will communicate the relevant information previously evaluated, to the Top Management according to the procedure [PROCE-0017 - Critical Analysis of the Management System](#), in the frequency established in the same.

8.9 CONTROL OF PRODUCT AND PROCESS NONCONFORMITIES

When CCP monitoring results show non-compliance with the established critical limits or there is a loss of control of the PPRO, corrections and planned corrective actions are taken to regain process control and product safety. Such corrections and corrective actions are predefined and described in the HACCP plans.

GOIASA ensures that when the critical limits for CCP's and/or the criteria for taking action for OPRP's are reached, the affected products are identified and treated as potentially unsafe products.

The system used for the treatment of potentially unsafe products is defined in the [PROCE-0019 - Nonconformity Control and Improvement](#).

Potentially unsafe products are addressed by taking action to prevent them from entering the food production chain unless it can be assured that:

- a) Food Safety hazards have been reduced to acceptable levels;
- b) Food Safety hazards will be reduced to acceptable levels before they enter the food production chain;
- c) The product still meets acceptable levels.

Products affected by a non-conforming situation will be kept under the organization's control until they have been evaluated for release. Such assessment should be based on evidence other than the monitoring system that shows that the control measures have been effective, or evidence that shows that the combined effect of the control measures meets the desired performance, and the results of sampling, analysis, and other verification activities show that the lot of affected product meets the identified acceptable levels. After such assessment, if it is deemed safe, they can be released. The data must be evaluated by people who are competent and in authority, and all documented information must be retained.

If products are deemed to be unsafe they must be treated in a way that ensures that they are not made available for consumption. The same can be: reprocessed, redirected to another use, destroyed or disposed of, or even if they are no longer under the organization's control, the collection must be initiated according to the [PROCE-0064 Product Recall](#). Documented information on the disposition of nonconforming products, including identification of persons with approval authority must be retained.

9 PERFORMANCE ASSESSMENT

9.1 MONITORING, MEASUREMENT, ANALYSIS AND ASSESSMENT.

9.1.1 OVERVIEW

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GOIASA establishes measurement, monitoring, and analysis activities in the material receiving stages, through appropriate records. During the process, the monitoring of the PRP's are defined in procedures, and the monitoring of the OPRP's and CCP's in the Monitoring and Verification Annexes, which establishes the appropriate steps and forms of measurement. Final approval of the product is obtained through pertinent analyses. The results of these activities are analyzed and, where appropriate, improvement actions are indicated and implemented.

The compliance of the FSMS and its continuous improvement are ensured through the monitoring and analysis of internal audits and indicators. This data obtained is used as the basis for defining actions to improve the system and to set the appropriate priorities for the company.

Statistical methods and tools are recognized as fundamental means to achieve, control and improve processes and the FSMS itself. Appropriate techniques can be used, identified for each case such as: MASP, 8 Disciplines, Pareto chart, Histogram, Check Sheets, Flowcharts, Cause and Effect Diagram, The 5 Whys, etc.

9.1.2 ANALYSIS AND ASSESSMENT

GOIASA analyzes and assesses appropriate data and information from monitoring and measurement, including checks of PRPs, OPRPs, and CCPs. Analysis results are used to evaluate:

- ☐ The performance of the FSMS and whether planning has been implemented effectively;
- ☐ The need for improvements in the FSMS;
- ☐ Identify trends in order to prevent potentially unsafe products or process failures;
- ☐ Establish information for audit planning;
- ☐ Provide evidence of corrections and corrective actions.

9.2 INTERNAL AUDIT

Audits of the Food Safety Management System are performed according to [PROCE-0018 Internal Audits](#).

Audits are conducted to determine whether the Food Safety Management System conforms to planned arrangements and is effectively implemented and maintained.

The Quality (Audit) area is responsible for communicating the audit plan and also for disseminating the audit results to the audited areas.

The person responsible for the audited area takes corrective, preventive actions to eliminate the non-conformities detected in accordance with [PROCE-0019 - Nonconformity Control and Improvement](#).

The results of the internal audit are used as input for critical analysis of the system by the FST.

9.3 CRITICAL ANALYSIS BY BOARD OF DIRECTORS

Critical analysis of the FSMS occurs as described in [MANUA-0003 – Manual of Integrated Management System](#).

10 IMPROVEMENT

GOIASA pursues continuously improvement as described in [MANUA-0003 – Manual of Integrated Management System](#).

Senior Management ensures the improvement and effectiveness of the food safety management system by evaluating at planned intervals by FST, using internal and external communication, information regarding the relevance, adequacy and effectiveness of the Food Safety Management System, outputs of the analyses of the results of the verification activity and output of the critical analysis by Management, or whenever necessary.

11 RECORDS

The other records described in this document are controlled in specific documents for each operation mentioned, within procedures and work instructions.

HAZARD ANALYSIS					
IDENTIFICATION	STORAGE	PROTECTIO N	RECOVERY	RETENTION TIME	DISPOSAL

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.					
FORMU-0857 Food Safety Inspection - Juice Treatment	V:\Interno\ESA-Equipe de Segurança de Alimento\ANO VIGENTE\Inspeções Equipe	Backup	Chronological	2 years	Delete
FORMU-0855 Food Safety Inspection - Evaporation					
FORMU-0771 Food Safety Inspection - Sugar Factory					
FORMU-0853 Food Safety Inspection - Sugar Warehouse					
FORMU-0854 Food Safety Inspection - WTP - Capture, Recirculation Dist. And Water Treatment;					
FORMU-0868 Food Safety Inspection - Alcohol Production					
FORMU-1044 Food Safety Inspection - Kiosk					
FORMU-0394 Food Safety Inspection - Cafeteria;					
FORMU-1013 Food Safety Inspection - Agriculture					