ISO 22000:2017

DIS

Food Safety Management Systems Manual

[Preview]

[Company Name]

ADDRESS

Phone: *Phone:*
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Table of Contents

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4.2 Understanding the needs and expectations of interested parties

Interaction of [Company Name] with the interested parties (fig. 4.2-01) includes:

- defining interested parties relevant to the FSMS;
- monitoring and analysis of interested parties' needs and expectations.

Defining interested parties relevant to the FSMS is carried out in the management review (sec.9.3).

Monitoring and analysis of interested parties' needs and expectations is conducted on a regular basis in accordance with the diagram shown in Fig. 4.2-01.

Interested party	Basic Needs and Expectations of the Interested Party	Form of Information about Interested Parties Needs and Expectations
Owners Stakeholders	Minimization of risks and losses, including penalties. Increase of market capitalization	Shareholders (owners) Meetings minutes – reviewed by the Leadership
Customers	Absence of negative impact of food on the customers' health, including acute diseases.	Safety indicators results analysis tables (lab). Customer satisfaction review via conducting tastings, polls, Internet discussions (Marketing department).
State via Legislative and regulatory bodies (local, regional, state / provincial, national or international	Health of the Nation and longevity increasing as the State sustainable development component. Compliance with national laws and international standards	The legislative requirements for food safety are reviewed by the Department of Quality and Food Safety Management
Society	Improving human health, minimizing risks of poisoning.	External communication (sec.7.4.3)
Employees	Proper working conditions, reducing the incidence of	Internal communication (sec.7.4.2), internal and external training programs,

Interested party	Basic Needs and Expectations of the Interested Party	Form of Information about Interested Parties Needs and Expectations
	occupational injuries, infectious diseases.	medical examination of employees, health insurance program.
Organizations-customers	Obtaining of stable profits, long-term and reliable cooperation, minimizing the risk of supply disruptions.	Contracts, protocols of meetings, 'Provider-customer-provider' negotiations
Providers	Obtaining of profits, long-term and reliable cooperation	Contracts, ongoing analysis of cooperation (acts, protocols), protocols of meetings, negotiations

Fig.4.2-01. Monitoring and Analysis of Interested Parties Needs and Expectations Diagram

The two-way communication is carried out between the organization and the interested parties, that includes the transfer of information about the organization's activities and the FSMS.

The results of monitoring and analysis of the interested parties' needs and expectations are taken into account:

- when defining the scope of the FSMS (sec. 4.3.);
- when establishing the Food Safety Policy (sec. 5.2) and Objectives of the FSMS (sec. 6.2);
- in the Management Review (sec. 9.3);
- in operational planning and control (sec.8.1).

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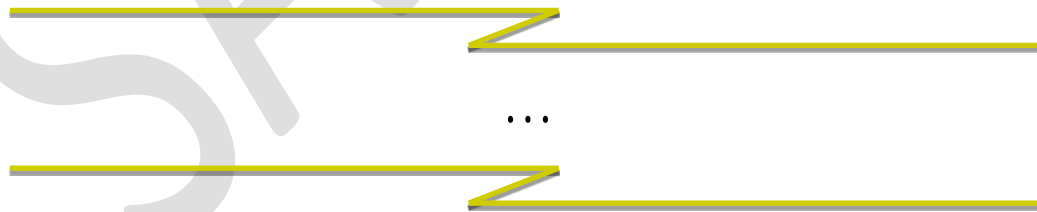
5.3 Roles, responsibilities, and authorities in the organization

[Company Name] Leadership ensures the responsibilities and authorities for the relevant roles were set, communicated, and understood within the organization.

Organizational structure of [Company Name] subdivisions that are in scope of the FSMS is provided in the fig. 5.3-01.

> *Place the chart of your organization's structure of subdivision that are included in scope of the FSMS*
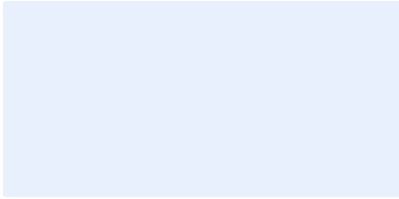
Figure 5.3-01. Organizational Structure of [Company Name] subdivisions that are in the scope of the FSMS

Responsibilities of [Company Name] top management is given in section 9.3.

Top management appoints the food safety team (FST) and the Food safety team leader (FST leader).

FST leader is responsible, among other things, for:

- ensuring that the FSMS conforms to the standard ISO 22000:2018 requirements;
- ensuring the FSMS is established, implemented, maintained and updated;
- coordination of FSMS processes, ensuring 'Communication' (sec.7.4), 'Corrective actions' (sec. 10.1), as well as responsibility for development, application and risk management structure support in the FSMS (sec.6.1);

- formation of FST from organization subdivisions' employees (sec.7.2);
- managing and organizing the work of the FST;
- ensuring relevant training of and competencies for the FST;
- coordination and control of the procedure incoming control of raw materials, components, ingredients, packaging materials etc. for further processing in the 'Production and service provision' process;
- organization of FSMS ongoing personnel training (sec.7.2);

- definition of competence requirements of external providers that can affect FSMS (sec.7.1.6, sec.7.2);
- providing training on FSMS, Food Safety Policy and Food Safety objectives for employees of contractors who work on site of the organization (sec.7.2);
- summarizing the information on changes (sec.7.4.3) for management review;
- protection against unintentional changes in records that are evidence of compliance (sec.7.5);

- ensuring PRP's development, appointment of a person responsible for PRPs control and establishing frequency of PRPs verification (sec.8.2);
- ensuring traceability system (sec.8.3);
- participation in development of the 'Plan for Localization and Elimination of Emergencies and Accidents' and the 'Annual PLEEA training sessions schedule' (sec.8.4);
- maintaining control copies of Hazard control protocols (sec.8.5);
- control over proper compliance with the developed verification activities related to PRPs and HACCP plan (sec.8.8);
- initiating the development of corrective actions in the event of exceeding critical limits for CCPs and / or failure to meet action criteria for PRPs (sec.8.9.2);
- creating commissions and proper implementation of correction in relation to potentially unsafe products, which were affected by exceeding critical limits for CCP or failure to meet action criteria for PRPs (sec.8.9.3);
- ensuring that products identified as potentially unsafe are under control until they are evaluated; and informing relevant interested parties (sec.8.9.4);

- participating in making decisions on nonconforming products actions (sec.8.9.4);
- ensuring complete and timely withdrawal or recall of the end product that has been identified as potentially unsafe (sec.8.9.5);
- analysis of the internal audits results by the FST (sec.9.2);
- effectiveness of corrective actions on the FSMS (sec.10.1);
- reporting to the top management on the FSMS effectiveness and suitability, including opportunities for FSMS improvement (sec.10.2, sec.10.3);
- communication with interested parties on matters relevant to the FSMS.

FST members:

- carry out ongoing monitoring of infrastructure objects food safety requirements (sec.7.1.3);
- participate in adaptation of externally developed FSMS elements to the processes and products of the organization (sec.7.1.5);
- provide accounting of information on changes (sec.7.4.3) when updating the FSMS;
- approve PRPs (sec.8.2);
- define legislative / regulatory food safety requirements and draft 'Description of raw materials, ingredients and product contact materials' protocol (sec.8.5.1.1) and the 'End-product description' protocol (sec.8.5.1.2);
- develop, validate and update process flow diagrams for each product type (sec.8.5.1.4.1; sec.8.5.1.4.2);
- describe processes and process conditions for each product type (sec. 8.5.1.4.3);
- conduct hazard analysis (sec. 8.5.2);
- conduct validation of control measures and combination of control measures (sec. 8.5.3);
- develop hazard control plan (HACCP plan) (sec. 8.5.3), including determination of critical limits, action criteria and actions when critical limits or action criteria are not met;
- update information that determines HACCP plan and PRPs (sec. 8.6);
- analyze previous measurement results when the equipment or work environment does not meet the requirements (sec.8.6);

- conduct verification relevant to PRPs and HACCP plan and evaluate verification plan individual results (sec. 8.8);
- participate in Commission for conducting correction with regards to the potentially unsafe products that were affected by exceeding critical limits at CCP or failure to meet action criteria for PRPs (sec.8.9.3);
- conduct identification, evaluation of hazards and distribution of control measures to prevent potentially unsafe products from entering the food chain (sec.8.9.4);
- analyze the criticality of end-products nonconformities, determine corrective actions to eliminate nonconformities (sec.8.9.4);
- develop corrective actions aimed at determining and eliminating the causes of identified nonconformities, preventing reoccurrence and proper process control after the nonconformity was eliminated (sec 10.1);
- evaluate FSMS and develop activities for its improvement (sec. 10.2).

Quality Management Department head is responsible, among other things, including conducting FSMS management review (sec.9.3), for:

- external communication with external providers on the quality of raw materials, components, ingredients, packaging materials (sec.7.4.2);
- marking the product with the appropriate information signs to ensure safe processing, storage, etc. (sec.7.4.2);
- FST communication on legislative/ normative FSMS requirements, including changes, as well as complaints, risks and warnings, indicating food safety hazard, relevant to end-product (sec.7.4.3);
- control of documented information (sec.7.5);
- ensuring system traceability (sec.8.3);
- ensuring control of proper observance of the developed verification activities related to the PRPs and HACCP plan (sec.8.8);
- initiation of corrective actions development in the event when critical limits exceeded at CCPs and / or action criteria are not met for PRPs (sec.8.9);
- participating in making decisions regarding handling the nonconforming products (sec.8.9.4);
- internal audit (sec.9.2);
- creating the program, conducting the 2nd party audits of suppliers and analysis of the audit results (sec.7.4.2).

Health officer is responsible for:

- ensuring hygiene of the personnel and sanitary condition of premises (sec.7.1.4);
- FST communication on cleaning and sanitation techniques, including changes (sec.7.4.3).

Microbiological laboratory head is responsible, among other things, for:

- microbiological control of the sanitary condition of industrial premises (sec.7.1.4);
- microbiological control of personnel hygiene (sec.7.1.4).

Production laboratory head is responsible, among other things, for:

- initiating the development of corrective actions based on the results of monitoring at CCP related to the equipment operation (sec.8.9);
- participating in making decisions regarding handling the nonconforming products (sec.8.9.4).

HR manager is responsible, among other things, including FSMS management review (sec.9.3), for:

- organization of FST Regulations development containing a section with FST leader competence requirements and a section with FST members competence requirements (sec.7.2);
- inclusion of FSMS requirements for competence and responsibilities in the personnel job descriptions (sec.7.2);
- drafting and implementation of the Annual personnel training plan, that includes FSMS training (sec.7.2);
- FST communication about FSMS competence and distribution of personnel responsibilities, including changes (sec.7.4.3).

Process owners are responsible for process operation and, above other, ensure:

- the completeness of process description;
- definition of responsibilities and authorities of process operators;
- sufficient resources within the process budget;
- definition of process criteria;
- compliance with the requirements for food safety in the process, including the requirements of ISO 22000:2018;

- analyses of trend and provision of information for management review;
- identification, analysis, and treatment of risks and opportunities (sec.6.1);
- activities to improve the process using process resources and (or) the initiation (and escalation to the leadership) of process improvement projects that require the budget of the organization (sec.6.2).

IT manager is responsible, among other things, for (sec.7.1.3; sec.8.7):

- validation of the software before; documenting validation results;
- timely software update;
- authorization and validation of software before use the whenever changes occur, including software configuration.

Product manager is responsible, among other things, including FSMS management review (sec.9.3), for:

- FST communication about the development of new types of products and changes in production technology, product characteristics, raw materials, components, ingredients, packaging and storage (sec.7.4.3);
- participating in making decisions regarding handling the nonconforming products (sec.8.9.4).

Maintenance manager is responsible, among other things, including conducting FSMS management review (sec.9.3), for:

- FST communication about changes in production equipment and renovation of industrial premises (sec.7.4.3).

Environmental Management Department head is responsible, among other things, including conducting FSMS management review (sec.9.3), for:

- FST communication about environmental management (sec.7.4.3).

Marketing manager is responsible, among other things, for:

- FST communication regarding customer requirements, complaints and warnings, that indicate food safety hazard, relevant to end-product (sec.7.4.3).

Sales manager is responsible, among other things, for:

- FST communication regarding customer requirements (sec.7.4.3).

Metrologist is responsible, among other things, for:

- FST communication on monitoring and measuring, including changes (sec.7.4.3).

All personnel are responsible for communicating information about problems in the field of FSMS (sec.10.1)

Responsibilities and authorities of personnel of subdivisions that are in scope of the FSMS are distributed and documented on in the corresponding sections of job descriptions.

Responsibilities and authorities of [Company Name] employees, defined on different levels, are agreed with each other and communicated to each employee.

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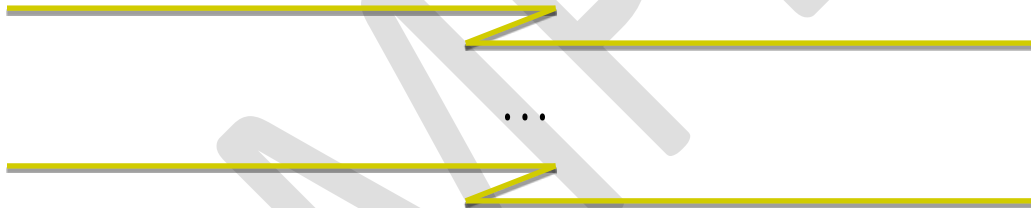
7.1.4 Work Environment

In *[Company Name]* the activity to define, ensure and maintain the work environment and to achieve compliance with FSMS requirements includes (fig. 7.1-01):

- Ensuring the hygiene of personnel and sanitary condition of production premises
- occupational health and safety provision;
- environmental management (ecology).

Work Environment		
Ensuring the hygiene of personnel and sanitary condition of production premises	Occupational health and safety provision	Environmental management (ecology)
Prevention or reduction of biological, chemical and physical contamination of products	Prevention of work-related injury and/or ill health	Prevention or mitigation of adverse environmental impacts

Fig. 7.1-01 The scheme of the components of the work environment

Normative requirements for the work environment are defined by:

- state sanitary norms and rules;
- state legislation on the production of high-quality and safe food products;
- legal requirements for occupational health and safety provision;
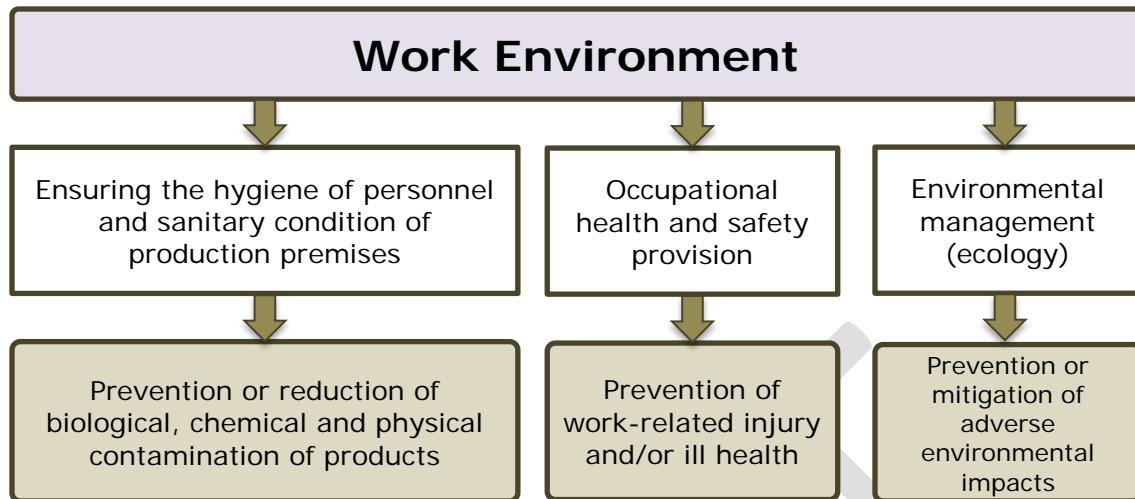- compliance obligations for environmental management.

Normative requirements are being updated and are available in accordance with 'Control of documented information' (sec.7.5).

a) Health officer is responsible for *Ensuring the hygiene of personnel and sanitary condition of production premises.*

Ensuring the hygiene of personnel and sanitary condition of production premises includes:

- Verification on job applicants' health status upon hiring, including the absence of infectious diseases;
- Conducting introductory briefings on hygiene and sanitation, when hiring employees;
- Conducting medical checkup of employees with a fixed periodicity;
- Daily monitoring of the production subdivisions' personnel at the beginning of work: observance of personal hygiene (proper passage into the clean zone through the shower, etc.); proper appearance of employees (according to the developed visualizations); examinations of the open surfaces of the body of workers (employees with pustular skin diseases,

suppuration cuts, burns, abrasions, as well as with catarrhs of the upper respiratory tract are not allowed to work);

- Daily monitoring of personnel for infectious diseases.
- Daily clean up and disinfection of industrial, common, storage facilities;
- Daily clean up and disinfection of sanitary units;
- Daily washing and disinfection of production equipment in accordance with sanitary regulations for each equipment type, noting the work performed in the journals.
- Daily selective monitoring by the microbiological laboratory of personnel hygiene by swabbing the hands and clothing of personnel;
- Daily selective monitoring by the microbiological laboratory of the sanitary condition of the production premises - the quality of equipment cleaning and the cleanliness of the air in the production area.

Commission is appointed by the order of the director to monitor the sanitary condition of industrial, domestic, storage facilities. The commission carries out weekly sanitary checks. The results of the check ups are recorded by the protocol. In case of a non-conformity, a nonconformity protocol is drafted and corrective actions are taken (sec 10.1).

b) Deputy director for labor protection is responsible for <u>occupational health and safety (OH&S) provision</u>.

OH&S laboratory measures the following occupational health and safety indicators:

- microclimate - temperature, humidity, speed of air movement in the working area;
- dustiness;
- noise;
- luminosity;
- microbiological indicators.

<u>Four-step monitoring</u> of OH&S activities efficiency includes:

- Monthly inspections of OH&S activities – are conducted before the start of work by the process operator (supervisor) independently. The results of the inspection are recorded in the Monthly OH&S status verification journal and are managed by the OH&S commissioner in the subdivision. Identified nonconformities are registered in the protocol (sec.10.2).

- Weekly inspections of OH&S activities in structural subdivisions – are conducted by a commission chaired by the process owner (structural subdivision leader). Commission composition is approved by the order for the structural subdivision. Based on the inspection results, an order is issued for the structural subdivision.

- Complex monthly inspections of OH&S activity, fire safety and environmental management are conducted by a commission chaired by the OH&S Department head. Commission composition is approved by the order for the organization. Based on the inspection results an act is drafted and an order is issued for the organization.

- Target inspections of working conditions, fire safety and environmental management are carried out by the OH&S Department, in accordance with the approved schedule, chaired by the OH&S Department head. Based on the inspection results, an act is drafted.

c) Environmental management department head is responsible for environmental management (ecology).

Environmental indicators criteria are established based on analysis of existing compliance obligations. The criteria are used to evaluate:

- fuel, electricity and heat consumption;
- operation of gas treatment and dust collection facilities;
- water consumption (drainage);
- quality and quantity of discharged sewage;
- amount of waste, packaging materials and containers.

The state of environmental protection in structural subdivisions is monitored at regular intervals shift based, daily, weekly and monthly:

- Shift supervisor conducts shift based* monitoring of the environmental state before the shift begins. Results are recorded in the daily inspection journal of the production subdivision.
- Structural subdivision leader (or a deputy) and environmental management department employee conduct daily monitoring of the environmental state. Monitoring covers entire territory of the production

subdivision and all its sections. The results are recorded in the daily inspection journal of the production subdivision.

- In all structural subdivisions in scope of the FSMS, a Commission conducts complex monthly monitoring of the environmental state, labor protection, and fire safety. Commission members are approved by the order of the director. The results are recorded in the act.

Unscheduled measurements of environmental characteristics are conducted in the following cases:

- if environmental characteristics exceed the permissible level,
- in the event of an emergency,
- when complaints are received from legal entities, organizations, or the public,
- on written request of the environmental management department head, senior management and structural subdivision leaders.

Based on the results of measurements of the environmental characteristics, the environmental laboratory prepares a report and sends it to the Environmental management department. Environmental management department head provides analysis of the results.

Results of the activity to define, ensure and maintain the work environment are analyzed by top management (sec.9.3).

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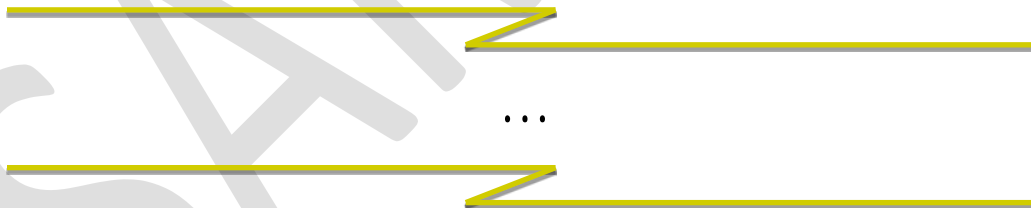
7.4.3 Internal communication

Internal communication of the personnel is conducted via:

- workshops at different levels;
- FST meetings;
- use of the corporate intranet;
- communication of managers with workers at the work sites.

FST coordinates internal communication on the FSMS issues, including changes, as per table 7.4-01.

Table 7.4-01

FSMS issues internal communication diagram

Type of communication	Form of communication	Responsible for communication	Frequency of communication
Development of new types of products and changing product characteristics	FST meeting information	Product manager	
Changes in raw materials, components, ingredients	FST meeting information	Product manager	
Changes in production technology	FST meeting information	Product manager	
Changes in production equipment	FST meeting information	Maintenance manager	
Production facilities renovation; change of production equipment location	FST meeting information	Maintenance manager	
Changes in environmental management	FST meeting information	Environmental Management Department head	
Changes in cleaning and sanitation techniques	FST meeting information	Health officer	
Changes in packaging and storage	FST meeting information	Product manager	
Changes in competence or authority	FST meeting information	HR manager	
Changes in legal / regulatory requirements	FST meeting information	Quality Management Department head	
Information on food safety risks of and the methods their management	FST meeting information	FST Leader	
Customer requirements communication	FST meeting information	Sales manager/ Marketing manager	
Information on external interested parties	FST meeting information	According to figure 4.2-01	
Complaints, risks and warnings indicating food	FST meeting information	Quality Management Department	When changes were made

Type of communication	Form of communication	Responsible for communication	Frequency of communication
safety hazards relevant to the end product		head/ Marketing manager	
Changes in monitoring and measurements	FST meeting information	Metrologist	

FST ensures recording of information (Table 7.4-01) when FSMS is updated.

FST Leader summarizes the information (Table 7.4-01) for management review (sec. 9.3).

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