ISO 22000 2018
Plain English Food Safety Terms and Definitions

We've translated ISO 22000 2018 food safety management definitions into Plain English in order to make them easier to understand.

Acceptable level - Action criteria - Animal food - Audit - Competence
Conformity - Contamination - Context - Continual improvement - Control
Correction - Corrective action - Critical control point - Critical limit
Documented information - Effectiveness - End product - Feed - Flow diagram - Food
Food chain - Food contact materials - Food defense - Food fraud - Food safety
Food safety hazard - Food safety hazard analysis - Food safety management system
Interested party - Lot - Management review - Management system - Measurement
Monitoring - Nonconformity - Objective - Operational prerequisite programme
Organization - Outsource - Performance - Policy - Prerequisite programme
Procedure - Process - Product - Requirement - Risk - Risk assessment
Risk criteria - Significant food safety hazard - Top management
Traceability - Update - Validation - Verification

If you like our Plain English approach, please consider Purchasing our Plain English Products.

Acceptable level

This term refers to the level of a food safety hazard. An *acceptable safety hazard level* is the level that end products must not exceed. Organizations must consider customer, statutory, and regulatory requirements when acceptable safety hazard levels are specified. They must also use control measures, critical limits, and action criteria to ensure that these levels aren't exceeded.

Action criterion

Action criteria are measurable or observable specifications that are defined in order to determine whether or not operational prerequisite programmes (OPRPs) are in control and still operating as intended.

Animal food

The term *animal food* refers to both single and multiple products that are fed to non-food-producing animals (such as pets) and can be raw, processed, or semi-processed.

Audit

An *audit* is an evidence gathering process. Evidence is used to evaluate how well audit criteria are being met. Audits must be objective, impartial, and independent, and the audit process must be both systematic and documented. Audits can be either internal or external.

Internal audits are referred to as first-party audits while external audits can be either second or third party. They can also be combined audits (when two or more management of different disciplines are audited together at the same time).

Audit evidence includes records, factual statements, and other verifiable information that is related to the audit criteria being used. Audit criteria may be thought of as a reference point and include policies, requirements, and other forms of documented information. They are compared against audit evidence to determine how well they are being met. Audit evidence is used to determine how well policies are being implemented and how well requirements are being followed.

For more information about auditing, see our ISO 19011 Auditing Guide at https://www.praxiom.com/19011.htm

Competence

Competence means being able to apply knowledge and skill to achieve intended results. *Being competent* means having the knowledge and skill that you need and knowing how to apply it. Being competent means that you're qualified to do the job.

Conformity

To conform means to meet a requirement. Since there are many kinds of requirements, conformity can take many forms. You can conform (or comply) with mandatory requirements like laws and regulations or with voluntary requirements such as contracts, agreements, codes, and standards.

In the context of food safety management systems, you can conform (or comply) with (or to) the ISO 22000 requirements (or obligations) and to any additional food safety management requirements (or obligations) that your organization establishes for itself.

Contamination

A *contaminant* is a polluting or poisonous substance that makes something impure and *contamination* refers to the occurrence of a contaminant in a product or processing environment or the introduction of a contaminant into a product or processing environment.

Context of the organization

An organization's *context* is its business environment. It includes all of the internal and external factors and conditions that affect its products and services, have an influence on its FSMS, and are relevant to its purpose and strategic direction.

An organization's *external context* includes all of the needs and expectations of interested parties, as well as its social, cultural, legal, technological, regulatory, and competitive environment. An organization's *internal context* includes its values, culture, knowledge, and performance.

Continual improvement

In the context of this FSMS standard, *continual improvement* is a set of recurring activities that organizations use to enhance their safety performance. Continual improvements can be achieved by carrying out audits, self-assessments, and management reviews. They can also be realized by collecting data, analyzing information, setting objectives, and taking corrective actions.

Control measure

Control measures are actions or activities that are used to manage significant food safety hazards. Control measures must be capable of preventing or eliminating hazards or reducing them to acceptable levels.

Correction

A *correction* is any action that is taken to eliminate a nonconformity. In the context of ISO 22000, a *correction* is any action that is taken to deal specifically with potentially *unsafe* products (nonconforming products). *Corrections* may include the following types of actions: reprocessing or further processing of potentially unsafe products, assigning them to a different use, or simply destroying them.

Corrective action

Corrective actions are steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence. The corrective action process tries to make sure that existing nonconformities and incidents don't happen again.

Critical control point

A *critical control point (CCP)* is the point (or step) at which a control measure must be applied. It is a point that is critical or essential to safety. It is the point where a control measure can be used to prevent or eliminate a food safety hazard or to reduce it to an acceptable level.

Critical limit

A *critical limit* is a criterion or boundary that is used to distinguish between what is acceptable (safe) and what is unacceptable (unsafe). A critical limit is a value of a parameter or variable. Critical limits or values are used to ensure that a process produces safe products.

When critical limits are violated or exceeded, products are deemed to be potentially unsafe. Critical limits are established at critical control points (CCPs). They are used to determine whether or not a CCP is still under control. Whenever critical limits are violated or exceeded, CCPs are out of control and the associated products are considered to be potentially unsafe.

Documented information

The term *documented information* refers to information that must be controlled and maintained and its supporting medium. Documented information can be in any format and on any medium and can come from any source.

Documented information includes information about the management system and related processes. It also includes all the information that organizations need to operate and all the information that they use to document the results that they achieve (aka records).

Effectiveness

Effectiveness refers to the degree to which a planned effect is achieved. Planned activities are effective if these activities are actually carried out and planned results are effective if these results are actually achieved.

End product (or end-product)

An *end product* is a finished product. It requires no further processing or transformation. However, an end product for one organization could be an ingredient or raw material for another (customer) organization.

Feed

The term *feed* refers to both single and multiple products that are fed to food-producing animals and can be raw, processed, or semi-processed.

Flow diagram

A flow *diagram* is a schematic representation of a series of steps. It shows how steps are sequentially arranged and specifies how they interact. Flow diagrams usually consist of boxes and ovals (steps) connected with lines or arrows.

Food

The term *food* refers to raw, processed, or semi-processed substances and ingredients that are intended for consumption by humans and animals. It also includes any substance or ingredient that is used in the manufacture, preparation, or treatment of food. It does not, however, include cosmetics or tobacco; nor does it include substances and ingredients that are used only as drugs.

Food chain

The *food chain* consists of the entire sequence of stages and operations involved in the creation and consumption of food products. This includes every step from initial production to final consumption. It includes the production, processing, distribution, storage, and handling of all food and food ingredients.

The *food chain* also includes organizations that do not directly handle food. These include organizations that produce feed for animals that produce food and organizations that produce feed for animals that will be used as food. It also includes organizations that produce materials that will eventually come into contact with food or food ingredients.

Food contact materials

Food contact materials are objects that come into contact with food, such as bottles, cans, cartons, knives, forks, cups, and plates.

Food defense

Food defense refers to the protection of food products and ingredients from intentional contamination or adulteration by biological, chemical, physical, or radiological agents.

Food fraud

Food fraud is the intentional misrepresentation or adulteration of food products or ingredients for economic gain.

Food safety

The basic *food safety* concept is this: food will not cause adverse health effects so long as intended use guidelines are followed when it is prepared or eaten. Conversely, food is potentially harmful whenever it has been exposed to hazardous agents and intended use guidelines have not been followed.

Food safety hazard

A *food safety hazard* is an agent or condition that could potentially cause an adverse human health effect. Agents can be either biological, chemical, or physical, and can be either in or on food. Plus, the condition of the food itself could be hazardous. Food safety hazards can also be found in or on animal feed and feed ingredients. Since these may be transferred to food through the consumption of animal products, they can also cause adverse human health effects.

Organizations that do not directly handle food and feed may also compromise food safety. These include producers of packaging materials, cleaning agents, and other products that come into contact with food or feed. If such products have been exposed to hazardous agents and they come into contact with food or feed, adverse human health effects can occur.

Food safety hazard analysis

A *food safety hazard analysis* is done in order to determine which hazards need to be controlled, how much control is needed, and which combination of control measures should be used in order to make sure that food is safe. In the context of ISO 22000, a food safety hazard analysis is carried out in the following way:

1. Identify your organization's food safety hazards.
2. Pinpoint where each hazard may be introduced.
3. Specify acceptable hazard levels for each hazard.
4. Assess each hazard and decide how to control it.
5. Select control measures to control your hazards.
6. Use OPRPs and CCPs to manage your hazards.

Food safety management system (FSMS)

A *food safety management system (FSMS)* is one part of a larger management system and is a set of interrelated or interacting elements that organizations use to meet their food safety compliance obligations, to address their food safety hazards, and to manage their food safety risks and opportunities. These elements include programs, procedures, practices, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, techniques, technologies, and resources.

NOTE: In spite of the fact that it is all about establishing a food safety management system, ISO 22000 does not formally define this concept. As a result, we've given it a try.

Interested party

An *interested party* is any person, group, or organization who can affect, be affected by, or believe that they are affected by a decision or activity. In the context of this ISO 22000 standard, an interested party is anyone who can affect, be affected by, or believe that they are affected by the food safety performance of an organization.

Lot

A *lot* (or batch) is a defined quantity of a specific product that is produced, processed, or packaged under essentially the same basic conditions.

Management review

The purpose of a *management review* is to evaluate the overall performance of an organization's food safety management system (FSMS) and to identify improvement opportunities. Management reviews are carried out by the organization's top managers and are done regularly.

Management system

A *management system* is a set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved. These elements include structures, programs, procedures, practices, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.

There are many types of *management systems*. Some of these include quality management systems, environmental management systems, financial management systems, information security management systems, business continuity management systems, emergency management systems, disaster management systems, food safety management systems, and health and safety management systems.

The scope or focus of a *management system* could be restricted to a specific function or section of an organization or it could include the entire organization. It could even include a function that cuts across several organizations.

Measurement

Measurement is a process that is used to determine a value. In most cases this value will be a quantity.

Monitoring

To *monitor* means to determine the status of an activity, process, or system at different stages or at different times. In order to determine status, you need to supervise and to continually check and critically observe the activity, process, or system that is being monitored.

Nonconformity

Nonconformity is a nonfulfillment or failure to meet a requirement. A requirement is a need, expectation, or obligation. It can be stated or implied by an organization or interested parties.

Objective

An *objective* is a result you intend to achieve. *Objectives* can be strategic, tactical, or operational and can apply to an organization as a whole or to a system, process, project, product, or service. Objectives may also be referred to as targets, aims, goals, or intended outcomes.

Operational prerequisite programme (OPRP)

Operational prerequisite programs (OPRPs) are control measures or combinations of control measures that are used to control significant food safety hazards.

OPRPs, observations, measurements, and action criteria are used to prevent food safety hazards or to reduce the likelihood that products will be exposed to such hazards, that they will be contaminated, and that hazards will proliferate. They are also used to reduce the likelihood that the processing environment will be exposed to significant hazards, that it will be contaminated, and that such hazards will proliferate in that environment.

Organization

An *organization* can be a single person or a group that achieves its objectives by using its own functions, responsibilities, authorities, and relationships. It can be a company, corporation, enterprise, firm, partnership, charity, association, or institution and can be either incorporated or unincorporated and be either privately or publicly owned. It can also be an operating unit that is part of a larger entity.

Outsource

When an organization makes an arrangement with an outside organization to perform part of a function or process, it is referred to as *outsourcing. To outsource* means to ask an external organization to perform part of a function or process normally done inhouse. While an outsourced organization is beyond the scope of your FSMS, the outsourced process or function itself falls within your scope.

Performance

According to ISO, the term *performance* refers to a *measurable result.* It refers to the measurable results that activities, processes, products, services, systems and organizations are able to achieve. Whenever they *perform well* it means that acceptable results are being achieved and whenever they *perform poorly*, unacceptable results are achieved.

Policy

A *policy* is a general commitment, direction, or intention and is formally stated by top management. A *quality policy statement* should express top management's commitment to the implementation and improvement of its quality management system and should allow managers to set quality objectives.

Prerequisite programme (PRP)

Prerequisite programs (PRPs) are the conditions that must be established throughout the food chain and the activities and practices that must be performed in order to ensure that food products are safe. PRPs must be suitable and be capable of producing safe end products and providing food that is safe for human consumption.

In order to select the most suitable PRPs, organizations must consider their type of organization and their own unique circumstances, as well as the capabilities of their suppliers and service providers. They must also consider customer needs and expectations; they must consider statutory and regulatory requirements; they must consider good practices in their segment of the food chain; and they must consider all relevant standards and guidelines.

Procedure

A *procedure* is a way of carrying out a process or an activity. Procedures may or may not be formally documented.

Process

A *process* is a set of activities that are interrelated or that interact with one another. *Processes* use resources to transform inputs into outputs. Processes are interconnected because the output from one process often becomes the input for another process.

While *processes* usually transform inputs into outputs, this is not always the case. Sometimes inputs become outputs without transformation.

Organizational processes should be planned and carried out under controlled conditions. An effective process is one that realizes planned activities and achieves planned results.

Product

A *product* is a tangible or intangible output that is the result of a process. Products can be either tangible or intangible (a service can be a product).

Requirement

A *requirement* is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. A specified requirement is one that has been stated (in a document for example), whereas an implied requirement is a need, expectation, or obligation that is common practice or customary.

There are many types of requirements. Some of these include customer requirements, safety requirements, safety management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements, and regulatory requirements.

Risk

ISO 22000 2018 (3.39) defines *risk* as the *"effect of uncertainty"*. This rather enigmatic definition is a shorted variation of the equally enigmatic version found in the ISO 31000 risk management standard which defines *risk* as the *"effect of uncertainty on objectives"*. ISO 31000 goes on to say that an effect is a positive or negative deviation from what is expected.

This definition recognizes that all of us operate in an uncertain world. There's always the chance that things will not go according to plan. Every step has an element of risk that needs to be managed and every outcome is uncertain.

While the official definition thinks of *risk* as the "*effect of uncertainty"*, a note to this ISO 22000 definition actually seems to reject it. It says that *"Food safety risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to (a) hazard(s) in food"*. This more traditional definition starts with a "hazard in food" and then asks: what is the probability that this hazard will cause an adverse health effect and how severe would this effect be?

While ISO 31000 defines risk in a new and unusual way, the two definitions are largely compatible. Both definitions talk about the same phenomena but from two different perspectives. ISO 31000 provides a conceptual definition of risk while the more traditional ISO 22000 formulation operationalizes this general definition: it explains how to quantify risk. It argues that the amount or level of risk can be calculated by combining probability and severity.

For more on risk management, please see: https://www.praxiom.com/31000.htm

Risk assessment

Risk assessment is a process that is made up of three separate processes: risk identification, risk analysis, and risk evaluation. *Risk identification* is a process that is used to find, recognize, and describe the risks that could affect the achievement of objectives. *Risk analysis* is a process that is used to understand the nature, sources, and causes of the risks that you have identified and to estimate the level of risk. It is also used to study impacts and consequences and to examine the controls that exist. *Risk evaluation* is a process that is used to compare risk analysis results with risk criteria in order to determine whether or not a specified level of risk is acceptable or tolerable.

Risk criteria

Risk criteria are terms of reference and are used to evaluate the significance or importance of your organization's risks. They are used to determine whether a specified level of risk is acceptable or tolerable. Risk criteria should reflect your organization's values, policies, and objectives, should be based on its external and internal context, should consider the views of stakeholders, and should be derived from standards, laws, policies, and other requirements.

Significant food safety hazard

A *food safety hazard* is an agent or condition that could potentially cause an adverse health effect. A food safety hazard is considered to be *significant* when a hazard assessment has concluded that control measures need to be applied.

Top management

The term *top management* normally refers to the people at the top of an organization. It refers to the people who provide resources and delegate authority and who coordinate, direct, and control organizations.

However, if the scope of a management system covers only part of an organization, then the term *top management* refers, instead, to the people who direct and control that part of the organization.

Traceability

Traceability is the ability to identify and trace the history, movement, location, and application of objects. A *traceability system* records and follows the trail as objects come from their source and on through to production, processing, and final distribution.

Update

An update is an immediate or planned activity. Its purpose is to ensure that the most recent information is being applied.

Validation

Validation is a process that is used to ensure that food safety control measures are capable of controlling significant food safety hazards. The *validation process* uses evidence to determine whether control measures are actually effective.

Verification

Verfiication is a process that uses objective evidence to confirm that specified requirements have been met.

If you like our Plain English approach, please consider Purchasing our Plain English Products.

Praxiom Research Group Limited
First Edmonton Place 14 Floor 10665 Jasper Ave
Edmonton, Alberta, Canada, T5J 3S9 780-461-4514
info@praxiom.com info@praxiom.org praxiom@gmail.com

We ship worldwide. Our products are used in over 100 countries.