

新 版 ISO22000

新版 ISO22000 学习

Introduction

引言

The adoption of a food safety management system is a strategic decision for an organization that can help to improve its overall performance in food safety. The potential benefits to an organization of implementing a food safety management system based on this document are:

采用食品安全管理体系应该是组织的一项**战略性**决策，可以帮助组织改进其食品安全的整体绩效。对于根据本标准实施食品安全管理体系的组织来说，潜在的收益是：

a) the ability to consistently provide safe foods and relevant products and services that meet customer and applicable statutory and regulatory requirements;

稳定提供满足顾客要求和法律法规要求的产品和服务的能力；

b) addressing risks associated with its objectives;

应对与其目标相关的风险

c) the ability to demonstrate conformity to specified food safety management system requirements.

证实符合食品安全管理体系特定要求的能力。

This document employs the process approach (see 0.3), which incorporates the Plan - Do - Check - Act(0.3.2) cycle and risk - based thinking (0.3.3).

本标准采用过程方法，包括策划-实施-检查-改进（PDCA）循环和基于风险的思维

This process approach enables an organization to plan its processes and their interactions.

过程方法使组织能够策划组织的过程及其相互作用。

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

PDCA 循环使组织能够确保其过程得到充分的资源和管理，并确定和实施改进机会。

Risk - based thinking enables an organization to determine the factors that could cause its processes and its food safety management system to deviate from the planned results, and to put in place preventive controls to minimize negative effects

基于风险的思维能够使组织确定可能导致其过程和食品安全管理体系偏离所策划的结果的因素，采取预防性控制，以最小化负面影响

In this document, the following verbal forms are used:

本标准中采用了以下动词形式：

- “shall” indicates a requirement;

“shall” 表示要求；

- “should” indicates a recommendation;

“should” 表示建议；

- “may” indicates a permission;

may” 表示允许；

- “can” indicates a possibility or a capability.

“can” 表示可能性或能力

Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

标注为“注”的信息是理解或说明相关要求的指南。

Food safety is related to the presence of food safety hazards at the time of consumption (intake by consumer). As the introduction of food safety hazards can occur at any stage of the food chain, adequate control throughout the food chain is **essential**. Thus, food safety is ensured through the combined efforts of all the parties in the food chain. This document specifies the requirements for a food safety management system that combines the following generally recognized key elements:

食品安全与食品在消费环节（由消费者摄入）食源性危害的存在有关。由于在食品链的任何阶段都有可能引入食品安全危害，因此，必需对整个食品链进行充分的控制，食品安全是要通过食品链中所有参与方的共同努力来保证。本标准规定了食品安全管理体系的要求，其结合了下列普遍认同的关键要素：

- interactive communication; 相互沟通；

- system management; 体系管理;
- prerequisite programmes;前提方案;
- hazard analysis and critical control points (HACCP) principles. HACCP 原理

In addition, this document is based on the principle to be common to the management system of ISO.

另外，本标准基于 ISO 管理体系相同的原则。

The management principles are: 管理原则包括:

- customer focus; 以顾客 为关注焦点
- leadership;领导力
- engagement of people;全员参与
- process approach; 过程方法
- improvement; 改进
- evidence - based decision making; 循证决策
- relationship management. 关系管理

0.3.1 General 总则

This document promotes the adoption of a process approach when developing and implementing a food safety management system and improving its effectiveness in order to enhance production of safe products and services and meet applicable requirements.

本标准鼓励在建立、实施食品安全管理体系以及改进其有效性时采用过程方法，以增强食品安全的生产和服务，以及满足适用的要求。

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the food safety policy and strategic direction of the organization.

将相互关联的过程作为系统进行理解和管理，会有助于组织实现其预期结果的**有效性和效率**。过程方法运用系统的定义，和管理过程及其相互作用，以期实现与组织的食品安全方针和战略方向一致的预期结果。

0.3.1 General 总则

Management of the processes and the system as a whole can be achieved using the PDCA cycle with an overall focus on risk - based thinking aimed at taking advantage of opportunities and preventing undesirable results.

将 PDCA 循环全面用于旨在利用机会优势和预防不期望的结果的基于风险的思维，能够实现对过程和整个体系进行管理。

The recognition of the organization's role and position within the food chain is **essential** to ensure effective interactive communication throughout the food chain.

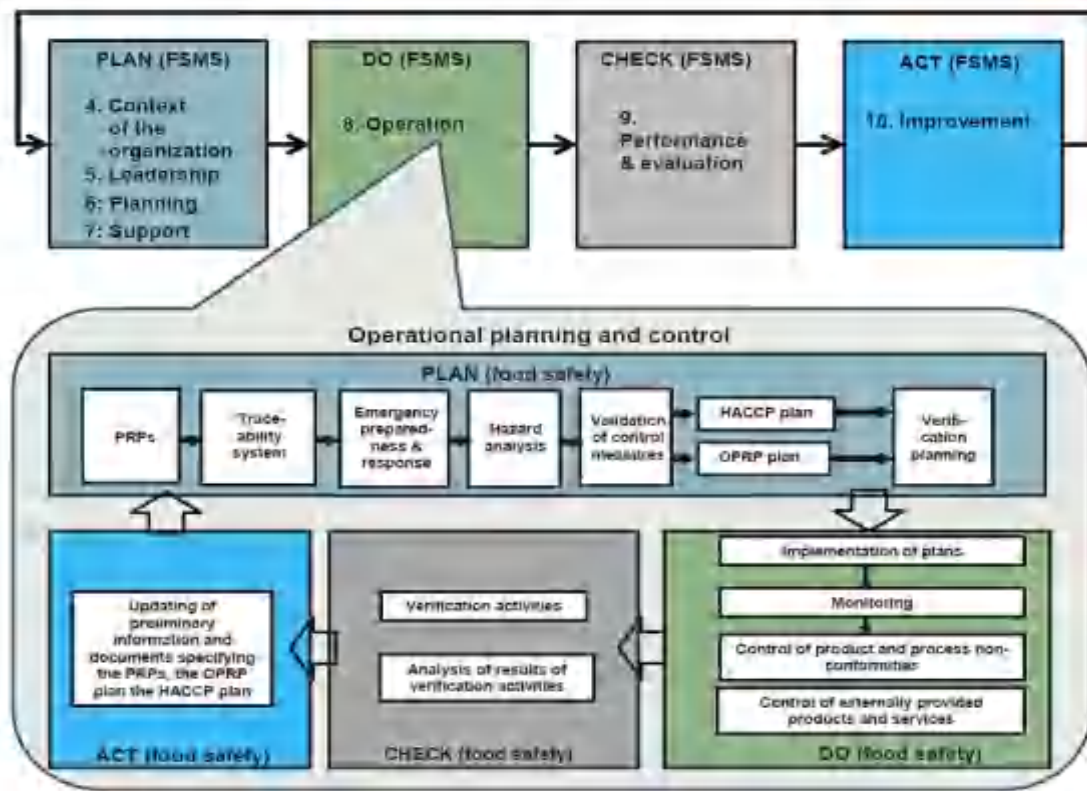
为了提供安全食品中给最终消费者，认识组织在食品链中的角色和位置对确保在食品链中有效的相互交通是必须的。

0.3.2 Plan - Do - Check - Act

The PDCA cycle can be described briefly as follows:PDCA 模式可以简要描述如下:

Plan: establish the objectives of the system and its processes and provide the resources needed to deliver the results and identify and address risks and opportunities;

策划: 建立体系目标及其过程的目标，以及提供结果所需的资源



Do: implement what was planned; 实施：实施所策划的安排

Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

检查：根据方针、目标、要求和策划的活动，对过程、产品和服务进行监视和测量（适用时），并报告结果；

Act: take actions to improve performance, as necessary.

处置：必要时，采取措施，以改进过程绩效。

0.3.2 Plan - Do - Check - Act

In this document and as illustrated in Figure 1, the process approach embraces two PDCA cycles. One cycle covers the overall frame of the food safety management system (Clause 4 to Clause 7 and Clause 9 to Clause 10). The other cycle covers the operational processes within the food safety as described in Clause 8. This means that communication between the two cycles is essential.

Figure 1 – Illustration of the two Plan - Do - Check - Act cycles

0.3.3 Risk - based thinking

Risk - based thinking is **essential** for achieving an effective food safety management system. In this document risk - based thinking is also addressed in two levels like the ones described in 0.3.2.

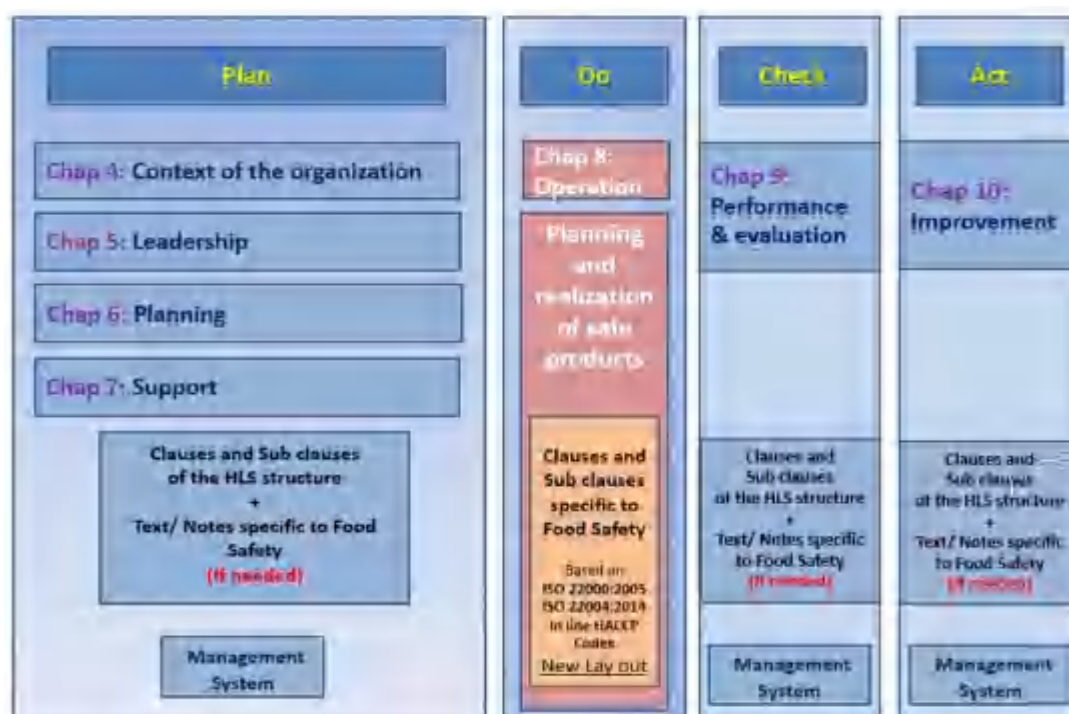
基于风险的思维对于达到有效的食品安全管理体系是必须的。

0.3.3.1 Organizational risk management

Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

To conform to the requirements of this document, an organization plans and implements actions to address organizational risks (see Clause 6). Addressing risks establishes a basis for increasing the effectiveness of the food safety management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or



improve productivity.

0.3.3.2 Hazard analysis – operational processes

The concept of risk - based thinking at the operational level has been implicit in ISO 22000 based on HACCP principles. The subsequent steps in the HACCP process can be considered as the necessary measures to prevent or reduce hazards to acceptable levels to ensure food is safe at the time of consumption (see Clause 8).

Decisions taken in the application of the HACCP should be based on science, free from bias and documented. The documentation should include any key assumptions in the decision making process.

This document is developed within the ISO High Level Structure (HLS). The objective of the HLS is to improve alignment between the ISO management system standards. This document enables a ganization to use the process approach, coupled with the PDCA cycle and risk based thinking, to align or integrate its food safety management system approach with the requirements of other management systems and supporting standards.

本标准采用 ISO 制定的 HLS 框架，以提高与其它管理体系标准的兼容性。本标准使用组织能够使用过程方法，并结合 PDCA 和基于风险的思维，将其食品安全管理体系要求与其它管理体系标准要求协调或整合。

This document is the core principle and framework for food safety management systems. It sets out the specific food safety management system requirements for organizations throughout the food chain. Other food safety related guidance, specifications and/or requirements specific to food sectors can be used together with this framework.

本标准是食品安全管理体系的核心原则和框架。本标准为食品链组织制定了特定的食品管理体系要求，可以在此框架上增加其它指南、规范和要求，以支持食品链的通用指南或特定领域的规范和要求。

The ISO/TS 22002 series specifies requirements and guidance for establishing, implementing and maintaining prerequisite programmes (PRPs) to assist in controlling food safety hazards.

These Technical Specifications are:

- ISO/TS 22002 - 1 Prerequisite programmes on food safety - Part 1: Food manufacturing
- ISO/TS 22002 - 2 Prerequisite programmes on food safety - Part 2: Catering
- ISO/TS 22002 - 3 Prerequisite programmes on food safety - Part 3: Farming
- ISO/TS 22002 - 4 Prerequisite programmes on food safety - Part 4: Food packaging manufacturing
- ISO/TS 22002 - 6 Prerequisite programmes on food safety - Part 6: Feed and animal food production.

Furthermore, the ISO 22000 family includes the following publications:

- ISO/TS 22003 Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems
- ISO 22004 Food safety management systems – Guidance on the application of ISO 22000
- ISO 22005 Traceability in the feed and food chain – General principles and basic requirements for system design and implementation.

1 Scope

范围

This document specifies requirements for a food safety management system to enable an organization:

标准规定的对食品安全管理体系的要求，使组织能够：

a) to plan, implement, operate, maintain and update a food safety management system aimed at providing products that, according to their intended use, are safe for consumers;

策划、实施、运行、保持和更新食品安全管理体系，确保提供的产品按预期用途对消费者是安全的；

b) to demonstrate compliance with applicable statutory/regulatory food safety requirements;

证实符合适用的食品安全法律法规要求；

c) to evaluate and assess food safety customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety;

评价和评估顾客要求，并证实其符合双方商定的、与食品安全有关的顾客要求；以增强顾客满意；

d) to effectively communicate food safety issues to interested parties within the food chain;

与供方、顾客及食品链中的其他相关方在食品安全方面进行有效沟通；

e) to ensure that the organization conforms to its stated food safety policy;

确保组织符合其声明的食品安全方针；

f) to demonstrate conformity to relevant interested parties; and

证实符合其他相关方的要求；

g) to seek certification or registration of its food safety management system by an external organization, or make a

self - assessment or self - declaration of conformity to this document.

寻求由外部组织对其食品安全管理体系的认证或注册，或进行符合性的自我评估，或自我声明符合本标准。

All requirements of this document are generic and are intended to be applicable to all organizations in the food chain regardless of size and complexity. This includes organizations directly or indirectly involved in one or more steps of the food chain. Organizations that are directly involved include, but are not limited to, feed producers, animal food producers, harvesters of wild plants and animals, farmers, producers of ingredients, food manufacturers, retailers, food services, catering services, organizations providing cleaning and sanitation services, transportation, storage and distribution services. Other organizations that are indirectly involved include, but are not limited to, suppliers of equipment, cleaning and disinfectants, packaging materials, and other food contact materials.

本准则所有要求都是通用的，旨在适用于在食品链中的所有组织，无论其规模大小和复杂程度如何。直接介入食品链中的组织包括但不限于饲料加工者，收获者，农作物种植者，辅料生产者，食品生产者，零售商，食品服务商，配餐服务组织，提供清洁和消毒服务、运输、贮存和分销服务的组织；其他间接介入食品链的组织包括但不限于设备、清洁剂、包装材料以及其他与食品接触材料的供应商。

This document allows any organization, including small and/or less developed organizations (e.g. a small farm, a small packer - distributor, a small retail or food service outlet) to implement externally developed elements in the food management system.

本准则允许组织，如小型和/或欠发达组织（如小农场，小分包商，小零售或食品服务商）实施外部开发的食品安全管理体系的要素。

The means of meeting any requirements of this document can be accomplished through the use of internal and/or external resources.

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■ 3 Terms and definitions 术语和定义

For the purpose of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

ISO Online browsing platform: available at <http://www.iso.org/obp>

IEC Electropedia: available at <http://www.electropedia.org/>

3 Terms and definitions 术语和定义

3.1 acceptable level 可接受水平

3.2 action criterion 行动准则

3.3 audit 审核

3.4 competence 能力

3.5 conformity 符合

3.6 contamination 污染

3.7 continual improvement 持续改进

3.8 control measure 控制措施

3.9 correction 纠正

3.10 corrective action 纠正措施

3.11 critical control point 关键控制点 CCP

3.12 critical limit 关键限值

3.13 documented information 文件化信息

3.14 effectiveness 有效性

3.15 end product 终产品

3.16 feed 饲料

3.17 flow diagram 流程图

3.18 food 食品

3.19 food, animal

3.20 food chain 食品链

3.21 food safety 食品安全

3.22 food safety hazard 食品安全危害

3.23 food safety management system 食品安全管理体系

3.24 food safety policy 食品安全方针

3.25 interested party

3.26 lot 批

3.27 measurement 测量

3.28 monitoring 监视

3.29 nonconformity 不符合

3.30 objective 目标

3.31 operational prerequisite programme , OPRP

3.32 organization 组织

3.33 outsource (verb) 外包

3.34 performance 绩效

3.35 prerequisite programme 前提方案

3.36 process 过程

3.37 product 产品

3.38 requirement 要求

3.39 risk 风险

3.40 significant food safety hazard 显著危害

3.41 top management 最高管理者

3.42 traceability 可追溯性

3.43 update 更新

3.44 validation 确认

3.45 verification 验证

3.1 acceptable level 可接受水平

level of a food safety hazard (3.22) not to be exceeded in the end product (3.15) provided by the *organization* (3.32)
提供的终产品中的危害不能超出的水平

3.2 action criterion 行动准则

measurable or observable specification for the monitoring (3.28) of an OPRP (3.31)

设定的用于监视如操作性前提方案的控制措施的可测量的或可观察的准则。

Note 1: An action criterion is established to determine whether an OPRP (3.31) remains in control, and distinguishes between what is acceptable (criterion met or achieved means the OPRP is operating (criterion met or achieved means the OPRP is operating as intended) and unacceptable (criterion not met nor achieved means the OPRP is not operating as intended).

备注 1：一个行动准则用来表明是否 OPRP 处于受控状态，并区分什么是可接受（满足或达到意味着 OPRP 按预期运行）和不可接受的（未满足或未达到意味着控制措施未按预期运行）。

3.3 audit 审核

systematic, independent and documented *process* (3.35) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

系统地、独立的和文件化的过程(3.35)，通过获取审核证据和评价，客观地判定审核准则实现的程度。

Note 1: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines such as food safety management, quality management or environmental management).

Note 2: An internal audit is conducted by the organization itself, or by an external party on its behalf.备注 2：内部审核由组织自身或代表组织外部相关方实施。

Note 3 : The terms “audit evidence” and “audit criteria” are defined in ISO 19011.

3.4 competence 能力

ability to apply knowledge and skills to achieve intended results

应用知识和技能实现预期结果的本领

3.5 conformity 符合

fulfilment of a requirement (3.38)

满足要求

3.6 contamination 污染

introduction or occurrence of a contaminant including food safety hazard (3.22) in product (3.37) or product environment
在食品或食品环境中引入或产生危害

3.7 continual improvement 持续改进

recurring activity to enhance *performance* (3.34) of the food safety management system

提高食品安全管理体系绩效的循环活动

3.8 control measure 控制措施

<food safety> action or activity that is essential to prevent a significant food safety hazard (3.22) or reduce it to an acceptable level (3.1) (see definition on significant food safety hazards (3.40))

经过确认和用于监视的，<食品安全> 能够用于防止食品安全危害（3.3）或将其降低到可接受水平的行动或活动，

Note 1: Control measures are identified by the hazard analysis

3.9 correction 纠正

action to eliminate a detected *nonconformity* (3.29)

为消除已发现的不合格所采取的措施。

Note 1: A correction includes the handling of potentially unsafe products, and can therefore be made in conjunction with a corrective action (3.10).

纠正与潜在不安全产品的处理有关，所以可以连同纠正措施（3.14）一起实施。

Note 2: A correction may be, e.g. reprocessing, further processing, and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).

3.10 corrective action 纠正措施

action to eliminate the cause of a nonconformity (3.29) and to prevent recurrence

为消除已发现的不合格或其他不期望情况的原因所采取的措施。

Note 1: There can be more than one cause for a nonconformity.

注 1：一个不合格可以有若干个原因。

Note 2 : Corrective action includes cause analysis and is taken to prevent recurrence.

注 2：纠正措施包括原因分析

3.14 corrective action 纠正措施

为消除已发现的不合格或其他不期望情况的原因所采取的措施。[GB/T19000-2000，定义 3.6.5]

action to eliminate the cause of a detected nonconformity or other undesirable situation

注 1：一个不合格可以有若干个原因。

NOTE 1: There can be more than one cause for a nonconformity. [ISO 9000:2000, definition 3.6.5]

注 2：纠正措施包括原因分析和采取措施防止再发生。

NOTE 2: Corrective action includes cause analysis and is taken to prevent recurrence.

3.11 critical control point 关键控制点 CCP

step in the process at which control measure(s) (3.8) is (are) applied, critical limit(s) (3.12) is (are) defined, and where measurement (3.27) enables effective control of the product (3.36)

过程中的步骤，在其应用控制措施，并有规定的关键限值，通过测量能够有效控制产品。

ISO22000:2005

(食品安全) (能够施加控制，并且该控制对防止或消除食品安全危害（3.3）或将其降低到可接受水平是所必需的某一步骤。

〈food safety〉 step at which control can be applied and is essential to prevent or eliminate a food safety hazard (3.3) or reduce it to an acceptable level

注：改编自文献[11]。NOTE: Adapted from Reference [11].

3.12 critical limit 关键限值

measurable value which separates acceptability from unacceptability

区分可接受和不可接受的判定值。

Note 1: Critical limits are established to determine whether a CCP (3.11) remains in control. If a critical limit is exceeded or violated, the products affected are to be handled as potentially unsafe product

注 2：设定关键限值保证关键控制点（CCP）受控。当超出或违反关键限值时，受影响产品应视为潜在不安全产

品进行处理。

[SOURCE: CAC/RCP 1 - 1969]

3.13 documented information 文件化信息

information required to be controlled and maintained by an *organization* (3.32) and the *medium* on which it is contained
组织需要控制和保持的信息及其载体

Note 1: Documented information can be in any format and media, and from any source. 形成文件化信息的可以是任何格式和载体存在，并可来自任何来源

Note 2 : Documented information can refer to: 文件化信息可包括：

- the *food safety management system* (3.23), including related processes (3.36);
食品安全管理体系，包括相关过程；
- information created in order for the organization to operate (documentation);
为组织的运行产生的信息（文件）
- evidence of results achieved (records). 结果实现的证据（记录）

3.14 effectiveness 有效性

extent to which planned activities are realized and planned results achieved
完成策划的活动并得到策划结果的程度

3.15 end product 终产品

product (3.36) that will undergo no further processing or transformation by the organization (3.32)
组织不再进一步加工或转化的产品。

Note 1: A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

备注 1：需其他组织进一步加工或转化的产品，是该组织的终产品或下游组织的原料或辅料。

3.16 feed 饲料

any single or multiple products, whether processed, semi - processed or raw, which is intended to be fed to food producing animals

饲喂给食用动物的单一或复合产品，可以是加工品、半加工品或原料。

Note 1

- Food (3.18) in this document is intended for consumption by humans and animals and includes feed and animal food;
- Feed (3.16) is intended to be fed to food producing animals;
- Animal food (3.19) is intended to be fed to non - food producing animals, like pets.

[SOURCE: CAC/GL 81 - 2013, modified – The word “materials” changed to “products” and “directly”]

3.17 flow diagram 流程图

schematic and systematic presentation of the sequence and interactions of steps
依据各步骤之间的顺序及相互作用以图解的方式进行系统性表达。

3.18 food 食品

any substance (ingredient), whether processed, semi - processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs

用于食用的物质，包括饮料、口香糖和任何作为“食品”生产、制备或处理的物质，可以是加工品、半加工品或原料，但不包括化妆品、烟草或只作为药用的物质。

Note 1:

- Food (3.18) in this document is intended for consumption by humans and animals and includes feed and animal food;
- Feed (3.16) is intended to be fed to food producing animals;
- Animal food (3.19) is intended to be fed to non - food producing animals, like pets.

[SOURCE: Codex procedural manual, modified - The word “human” has been deleted]

3.19 food, animal

any single or multiple products, whether processed, semi - processed or raw, which is intended to be fed to non - food producing animals

Note 1 :

- Food (3.18) in this document is intended for consumption by humans and animals and includes feed and animal food;
- Feed (3.16) is intended to be fed to food producing animals;
- Animal food (3.19) is intended to be fed to non - food producing animals, like pets.

[SOURCE: CAC/GL 81 - 2013, modified - The word “materials” changed to “products”, “non” added and “directly” deleted]

3.20 food chain 食品链（修改）

sequence of the stages in the production, processing, distribution, storage and handling of a food (3.18) and its ingredients, from primary production to consumption

从初级生产直至消费的各环节的顺序，涉及食品及其辅料的生产、加工、分销、贮存和处理。

Note 1: This includes the production of *feed (3.16) and animal food (3.19)*.

包括饲料和动物食品的生产；

Note2: The food chain also includes the production of materials intended to come into contact with food or raw materials.

食品链也包括用于食品接触材料或原材料的生产；

Note 3: The food chain also include service providers.

食品链包括服务供应商。

3.21 food safety 食品安全

assurance that food will not cause adverse health effect to the consumer when it is prepared and/or consumed according to its intended use

食品在按照预期用途进行制备和（或）食用时不会对消费者健康有不良影响的保证。

Note 1: Food safety is related to the occurrence of *food safety hazards (3.22)* in end products (3.15) *and does not include other* health aspects related to, for example, malnutrition.

食品安全与食品安全危害（3.3）的发生有关，但不包括其他与人类健康相关的方面，如营养不良。

Note 2 : It is not to be confused the availability of, and access to, food (food security).

Note 3 : This includes feed and animal food.其包括饲料和动物食品。

[SOURCE: CAC/RCP 1 - 1969, modified - The word “concept” changed to “assurance”, “harm” changed to “adverse” health effect and Notes have been added]

3.22 food safety hazard 食品安全危害（修改）

biological, chemical or physical agent in food (3.198) with the potential to cause an adverse health effect

食品中所含有的对健康有潜在不良影响的生物、化学或物理因素

3.22 food safety hazard 食品安全危害

Note 1: The term "hazard" is not to be confused with the term "risk" (3.39) which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (death, hospitalization etc.) when exposed to a specified hazard.

备注 1：术语“危害”不应和“风险”混淆，对食品安全而言，“风险”是食品暴露于特定危害时对健康产生不良影响的概率（如生病）与影响的严重程度（死亡、住院、缺勤等）之间形成的函数。风险在 ISO/IEC 导则 51 中定义为伤害发生的概率和严重程度的组合。

Note 2 : Food safety hazards include allergens and radiological substances.

食品安全危害包括过敏原和放射物质

Note 3 : In the context of feed and feed ingredients, relevant food safety hazards are those that may be present in and/or on feed and feed ingredients and that may through animal consumption of feed be transferred to food and may thus have the potential to cause an adverse health effect to the human consumer. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, disinfectants, etc.), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food when used as intended (see 8.5.1.3).

在饲料和饲料配料方面，相关食品安全危害是那些可能存在或出现于饲料和饲料配料内，继而通过动物消费饲料转移至食品中，并由此可能导致人类不良健康后果的成份。在不直接处理饲料和食品的操作中（如包装材料、清洁剂等的生产者），相关的食品安全危害是指那些按所提供产品和（或）服务的预期用途可能直接或间接转移到食品中，并由此可能造成人类不良健康后果的成分。

Note 4 : In the context of animal food, relevant food safety hazards are those that are hazardous to animal species for which the food is intended.

[SOURCE: CAC/RCP 1 - 1969, modified - The text “or condition of” has been deleted from the definition

3.23 food safety management system

食品安全管理体系

set of interrelated or interacting elements of an organization (3.32) to establish food safety policies (3.24) and objectives (3.30) and processes (3.36) to achieve those objectives

组织建立食品安全方针和目标，以及实现这些目标的过程的相互关联或相互作用的一组要素。

Note 1: A management system can address a single discipline or several disciplines (quality management system, environmental management system, etc.).

备注 1：一个管理体系可以针对单一领域或几个领域

Note 2: The system elements include the organization's structure, roles and responsibilities, planning and operation.

体系要素包括组织的机构、岗位和职责、策划和运行

Note 3: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organizations, or one or more functions across a group of organizations.

管理体系的范围可能包括整个组织，组织中可被明确识别的职能或可被明确识别的部门，以及跨部门的单一职能或多职能的团队

3.24 food safety policy 食品安全方针

intentions and direction of an organization (3.32) related to food safety (3.21) as formally expressed by its top management (3.41)

由最高管理者正式发布的与食品安全有关的组织的宗旨和方向

3.25 interested party

person or organization (3.32) that can affect, be affected by, or perceive itself to be affected by a decision or activity

3.26 lot 批

a definitive quantity of a *product (3.36) produced and/or processed or packaged essentially under the same conditions*
在相同条件下生产和或加工或包装的商品的一定数量

Note 1: The lot is determined by parameters established beforehand by the organization and may be described by other terms, e.g. batch.

批是组织事先确定的参数决定的

Note 2 : The lot may be reduced to a single unit of product.

批可以减少到一个单一的产品单位

[SOURCE: CODEX STAN 1, modified – Reference to “processed and packaged” has been included in the definition and Notes to entry have been added]

3.27 measurement 测量

process (3.35) to determine a value

确定数值的过程

3.28 monitoring 监视

determining the status of a system, a process (3.35) or an activity

确定体系、过程或活动的状态

ISO22000:2005

为评价控制措施（3.7）是否按预期运行，**对控制参数实施**的一系列策划的观察或测量活动。

conducting a planned sequence of observations or measurements to assess whether **control measures (3.7)** are operating as intended

Note 1: To determine the status, there may be a need to check, supervise or critically observe.

备注 1：可能需要检查、监督或密切观察才可确定状态。

Note 2 : In the context of food safety, monitoring is conducting a planned sequence of observations or measurements to assess whether a process is operating as intended.

备注:2：对于食品安全来说，为评估过程是否按预期运行，监视是实施一系列观察或测量。

Note 3 :

- Validation (3.44) is applied prior to an activity and provides information about the capability to deliver intended results;
- Monitoring (3.28) is applied during an activity and provides information for action within specified time - frame;
- Verification (3.45) is applied after an activity and provides information for confirmation of conformity

3.29 nonconformity 不符合

non - fulfilment of a *requirement* (3.38)

未满足要求

3.30 objective 目标

result to be achieved

要实现的结果

Note 1: An objective can be strategic, tactical, or operational.

备注 1: 目标可以是战略的、战术的或操作层面的。

Note 2: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization - wide, project, product, and *process* (3.35))

备注 2: 目标可以涉及不同的战略（如财务的、职业健康的与安全的和环境的目标），并可应用于不同的层次（如：战略的、组织整体的、项目的、产品和过程）

Note 3: An objective can be expressed in other ways, e.g. as an intended result, a purpose, an operational criterion, as a food safety management system objective, or by the use of other words with similar meaning (e.g. aim, goal or target).

备注 3: 可以采用其他方式表述目标，例如：预期的结果、目的或操作规程，食品安全管理体系目标，或使用类似含意的词（例如：aim, goal, 或 target）。

Note 4: In the context of food safety management systems, objectives are set by the organization, consistent with the food safety policy, to achieve specific results.

备注 4: 在食品安全管理体系中，食品安全目标由组织制定，与食品安全方针一致，为实现特定结果而设 control measure(s) (3.8) or combinations of control measures having defined action criteria (3.2), where

3.31 operational prerequisite programme

操作性前提方案； OPRP

measurement (3.27) or observation enables effective control of the process (3.36) and/or product (3.37)

具有规定的行动准则的控制措施或其组合，测量和观察能有效地控制过程和或产品

ISO22000:2005

通过危害分析确定的、必需的前提方案 PRP (3.8)，以控制食品安全危害(3.3)引入的可能性和(或)食品安全危害在产品或加工环境中污染或扩散的可能性。

PRP (3.8) identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards (3.3) to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment

3.32 organization 组织

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives (3.30)

为实现其目标，由职责、权限和相互关系地区的那他们的身职能的一个人或一组人

Note 1: The concept of organization includes, but is not limited to sole - trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

备注 1: 组织的概念包括，但是不限于代理商、公司、集团、商行、企事业单位、行政机构、合营公司、社团、慈善机构或研究机构，或上述组织的部分或组合，无论是否为法人组织，公有的或私有的。

3.33 outsource (verb) 外包

make an arrangement where an external organization (3.32) performs part of an organization's function or process (3.35)
安排外部组织执行组织的部分职能或过程。

Note : An external organization is out side the scope of the food safety management system (3.23), although the outsourced function or process is within the scope.

备注：外包的职责或过程是在组织的食品安全管理体系范围外，尽管外方的职能或过程在范围内。

3.34 performance 绩效

measurable result

测量的结果

Note 1: Performance can relate either to quantitative or qualitative findings.

备注 1：绩效可能涉及及定量的或定性的结果。

Note 2 : Performance can relate to the management of activities, processes (3.36), products (3.37) (including services), systems or organizations (3.32).

备注 2：绩效可能涉及活动、过程、产品（包括服务）、体系或组织的管理。

什么是 PRP?

关于 PRP 您了解些什么?

在您所在的工作场所，您见到了哪些与 PRP 相关的内容?

3.35 prerequisite programme 前提方案

basic conditions and activities that are necessary to maintain food safety within the *organization* (3.32) and throughout the *food chain* (3.20)

对于在组织内和食品链中保持食品安全所必须的基本条件和活动。

Note 1: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. Examples of equivalent terms are: Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP).

备注 1：PRP 取决于组织所处的食品链环节和组织的类型。

Note 2: Where PRPs are used to control significant food safety hazards (3.40), they are control measure(s) (3.8), which will be categorized either as CCPs (3.11) or as OPRPs (3.31).

备注 2：当 PRP 用于控制显著食品安全危害，他们是控制措施。

3.35 PRP, prerequisite program 前提方案

ISO22000:2005

- <食品安全> 在整个食品链（3.2）中为保持卫生环境所必需的基本条件和活动，以适合生产、处置和提供安全终产品和人类消费的安全食品；

<food safety> basic conditions and activities that are **necessary** to maintain a hygienic environment throughout the food chain (3.2) suitable for the production, handling and provision of safe end products (3.5) and safe food for human consumption

3.36 process 过程

set of interrelated or interacting activities which transforms inputs to outputs

将输入转化为输出的相互关联或相互作用的一组活动。

3.37 product 产品

output that is a result of a *process* (3.35)

过程结果的输出

Note 1 : Product can be a service.

产品可以是服务。

3.38 requirement 要求

need or expectation that is stated, generally implied or obligatory

明示的、通常隐含的或必须履行需求或期望。

Note 1: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

备注 1: “通常隐含”是指组织和相关方的惯例 或一般做法，所考虑的需求或期望是不言而喻的。

Note 2 to entry: A specified requirement is one that is stated, for example in documented information.

备注 2: 规定要求是经明示的要求，如：在形成文件化信息中阐明。

3.39 risk 风险

effect of uncertainty

不确定性的影响。

Note 1: An effect is a deviation from the expected – positive or negative.

备注：影响是指偏离预期、可以是正面的或负面的。

Note 2: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

备注：不确定性是一种对某个甚至是局部的事件、结果或可能性缺乏信息上、理解或知识的状态。

Note 3 : Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73:2009, 3.5.1.3) and "consequences" as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.

备注：风险通常以潜在事件(ISO Guide 73:2009, 3.5.1.3 定义)和后果(ISO Guide 73:2009, 3.6.1.3 定义)或其组合为特征

Note 4 : 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 ISO Guide 73:2009, 3.6.1.1) of occurrence.

备注 4: 风险通常表达为事件(包括环境的变化)的后果和发生可能性(ISO Guide 73:2009, 3.6.1.1 定义)的组合

Note 5: 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* (3.22) (as defined in *Codex Procedural Manual*).

食品安全风险是有害健康影响的可能性与该影响 严重程度的函数，是危害的结果。

3.40 significant food safety hazard 显著危害

food safety hazard (3.22), identified through the hazard assessment, which needs to be controlled by control measures (3.8)

通过危害分析识别的，需要通过控制措施控制的食品安全危害。

3.41 top management 最高管理者

person or group of people who directs and controls an organization (3.32) at the highest level

在最高层指挥和控制组织的一个人或一组人。

Note 1: Top management has the power to delegate authority and provide resources within the organization.

备注：最高管理者在组织内有授权和提供资源的权力。

Note 2 : If the scope of the food safety management system (3.23) covers only part of an organization, then top management refers to those who direct and control that part of the organization

备注：如果食品安全管理体系的范围仅覆盖组织的一部分，则最高管理者是指管理和控制组织的这部分的一个人或一组人。

3.42 traceability 可追溯性

ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution

追溯客体经历特定生产、加工和配送阶段的历史、应用情况、移动和所处位置的能力

Note 1: Movement can relate to the origin of the materials, processing history or distribution of the feed or food(3.18)..

移动可涉及饲料或食品原材料的来源、加工历史或配送。

Note 2 : An object can be a product (3.37), a material, a unit, equipment, a service etc.

客体可以是一个产品、原料、单元、设备、服务等。

[SOURCE: CAC/GL 60 - 2006, modified – Notes to entry have been added]

3.43 update 更新

immediate and/or planned activity to ensure application of the most recent information.

为确保应用最新信息而进行的即时和（或）有计划的活动。

Note 1:

- Maintain - to keep something on - going / to keep in good condition,
- Retain – to keep something that is retrievable,
- Update – immediate and/or planned activity to ensure application of the most recent information

3.44 validation 确认

〈food safety〉 obtaining evidence that a control measure (3.8) (or combination of control measures), will be capable of effectively controlling the significant food safety hazard (3.40)

〈食品安全〉 获得控制措施或控制措施组合能够有效的证据， 以控制显著食品安全危害。

Note 1 : This definition is more useful for the field of food safety (3.21) than the definition given in ISO 9000.

此定义在食品安全领域比在 ISO9000 里的定义更有用。

Note 2 : Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures.

当设计控制措施组合时，或当变更已实施的控制措施时要进行确认。

Note 3 :

- Validation (3.44) is applied prior to an activity and provides information about the capability to deliver intended results;

确认在活动之前进行的，提供实现预期结果的能力的信息；

- Monitoring (3.28) is applied during an activity and provides information for action within a specified time - frame;

监视在活动中进行的，提供一个指定的时间框架内活动的信息；

- Verification (3.45) is applied after an activity and provides information for confirmation of conformity.

验证在活动后进行的，提供符合的认定

3.45 verification 验证

confirmation, through the provision of objective evidence, that specified requirements (3.39) have been fulfilled
通过提供客观证据对规定要求已得到满足的认定。

Note 1:

- Validation (3.44) is applied prior to an activity and provides information about the capability to deliver intended results;

确认在活动之前进行的，提供实现预期结果的能力的信息；

- Monitoring (3.28) is applied during an activity and provides information for action within a specified time - frame;

监视在活动中进行的，提供一个指定的时间框架内活动的信息；

- Verification (3.45) is applied after an activity and provides information for confirmation of conformity.

验证在活动后进行的，提供符合的认定。

4 Context of the organization

组织环境

4.1 Understanding the organization and its context

理解组织及其环境

4.2 Understanding the needs and expectations of interested parties organization

理解相关方的需求和期望

4.3 Determining the scope of the food safety management system

确定食品安全管理体系的范围

4.4 Food safety management system

食品安全管理体系

4.1 Understanding the organization and its context 理解组织及其环境

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended results of its food safety management system.

组织应确定与其宗旨有关的，且影响质量管理体系实现其预期结果的能力的内部和外部情况。

The organization shall monitor and review information related to these external and internal issues.

组织应监视和评审有关内部和外部情况的信息。

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

注 1：情况可能是正面或负面的因素或要考虑的状况；

NOTE 2 Understanding the context can be facilitated by considering issues not limited to legal, technological, competitive, market, cultural, social, economic environments and food fraud, food defence and intentional contamination, whether international, national, regional or local.

注 2：可以通过考虑源于国际、国家、地区或本地的法律法规、技术、竞争、市场、文化、社会和经济环境的情况，促进对外部环境的了解

4.2 Understanding the needs and expectations of interested parties 理解相关方的需求和期望

To ensure that the organization has the ability to consistently provide products and services that meet applicable statutory/regulatory and customer requirements with regard to food safety, the organization shall determine:

为确保组织持续提供满足顾客和适用的法律法规要求的产品和服务的能力，组织应确定：

a) the interested parties that are relevant to the food safety management system;

与食品安全管理体系有关的相关方；

b) the relevant requirements of the interested parties that are relevant to the food safety management system.

与食品安全管理体系有关的相关方的要求。

The organization shall monitor and review information related to the interested parties and their relevant requirements.

组织应监视和评审有关相关方及其有关要求的信息。

4.3 Determining the scope of the food safety management system 确定食品安全管理体系的范围

The organization shall determine the boundaries and applicability of the food safety management system to establish its scope. The scope shall specify the products or product categories, processes and production sites that are addressed by the food safety management system.

组织应确定食品安全管理体系的边界和适用性来建立其范围。范围应说明食品安全管理体系所覆盖的产品和产品类别，过程和生产场所。

When determining this scope, the organization shall consider:

在确定质量管理体系范围时，组织应考虑：

a) the external and internal issues referred to in 4.1;

在 4.1 中涉及的外部 and 内部情况

b) the requirements referred to in 4.2.

在 4.2 中涉及的有关相关方要求；

The scope shall be available and maintained as documented information.

范围应可获取并保持文件化信息。

4.4 Food safety management system

食品安全管理体系

The organization shall establish, implement, document, maintain, update and continually improve a food safety management system, including the processes needed and their interactions, in accordance with the requirements of this document.

组织应按本标准的要求建立、实施、保持和持续改进食品安全管理体系，包括食品安全管理体系所需的过程及其相互作用，以符合本标准的要求。

5 Leadership

领导力

5.1 Leadership and commitment

领导力和承诺

Top management shall demonstrate leadership and commitment with respect to the food safety management system by:

最高管理者应通过以下方面证实其领导力和对食品安全管理体系承诺：

a) ensuring that the food safety policy and the objectives of the food safety management system are established and are compatible with the strategic direction of the organization;

确保食品安全方针和食品安全管理体系目标得到建立，并与组织的战略方向和组织环境保持一致；

b) ensuring the integration of the food safety management system requirements into the organization's business processes;

确保将食品安全管理体系要求融入组织的业务过程；

c) ensuring that the resources needed for the food safety management system are available;

确保获得食品安全管理体系所需的资源;

d) communicating the importance of effective food safety management and of conforming to the food safety management system requirements, statutory/regulatory requirements, and customer requirements related to food safety;

传达有效的食品安全管理以及满足食品安全管理体系、立法/执法和与食品安全相关的顾客要求的重要性;

e) ensuring that the food safety policy is communicated, understood and applied within the organization;

确保在组织内沟通、理解和应用食品安全方针;

f) ensuring that the food safety management system is evaluated and achieves its intended results;

确保食品安全管理体系得到评估和实现其预期的结果;

g) directing and supporting persons to contribute to the effectiveness of the food safety management system;

指导和支持员工为食品安全管理体系的有效性做出贡献;

h) promoting continual improvement;

增强持续改进;

i) supporting other relevant management roles to demonstrate their food safety leadership as it applies to their areas of responsibility;

支持其他相关管理者在其负责的区域证实其领导力。

j) assessing the effectiveness of the food safety management system.

评估食品安全管理体系的有效性;

NOTE Reference to “business” in this document can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence.

注: 本标准中的“业务”从广义上解释为对于组织的存在而言具有核心价值活动。

5.2 Food safety policy 食品安全方针

5.2.1 Establishing the food safety policy

Top management shall establish, implement and maintain a food safety policy that:

最高管理者应建立、实施和保持食品安全方针, 方针应:

a) is appropriate to the purpose and context of the organization;

与组织的宗旨和环境相适应;

b) provides a framework for setting and reviewing the objectives of the food safety management system;

提供制定食品安全管理体系目标的框架

c) includes a commitment to satisfy applicable food safety requirements including statutory/ regulatory requirements and mutually agreed food safety requirements of customers;

5.2.1 Establishing the food safety policy

包括对满足适用的食品安全要求, 包括立法/执法和双方认可的顾客的食品安全要求的承诺;

d) addresses internal and external communication;

应对内部和外部沟通;

e) includes a commitment to continual improvement of the food safety management system;

包括对持续改进食品安全管理体系的承诺;

f) addresses the need to ensure competences related to food safety.

应对与食品安全相关的能力的需要。

5.2.2 Communicating the food safety policy 沟通质量方针

The food safety policy shall:

质量方针应：

a) be available and maintained as documented information;

可获得并作为文件化信息加以保留；

b) be communicated, understood, implemented and maintained at all levels within the organization;

在组织内各层次沟通、理解、实施和保留；

c) be available to relevant interested parties, as appropriate.

适当时，可为相关方所获取。

5.3 Organizational roles, responsibilities and authorities 组织角色、职责和权限

5.3.1 Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

最高管理者应确保相关角色的职责和权限在整个组织得到规定、沟通和理解。

Top management shall assign the responsibility and authority for:

最高管理者应规定职责和权限以：

a) ensuring that the food safety management system conforms to the requirements of this document; 确保食品安全管理体系符合本标准的要求；

b) reporting on the performance of the food safety management system to top management; 向最高管理者报告食品安全管理体系绩效和改进机会；

c) appointing the food safety team and food safety team leader.

任命食品安全小组和食品安全小组组长。

5.3.2 The food safety team leader shall be responsible for:

食品安全小组组长应负责：

a) ensuring the food safety management system is established, implemented, maintained and updated;

确保食品安全管理体系的建立、实施、保持和更新；

b) managing and organising the work of the food safety team; and

管理和组织食品安全小组的工作；和

c) ensuring relevant training of and competences for the food safety team (see 8.5.1).

确保食品安全小组成员的相关培训和能力；

All personnel shall have responsibility to report problem(s) with the food safety management system to identified person(s). Designated personnel shall have defined responsibility and authority to implement and document action(s).

所有人员应有向指定人员汇报食品安全管理体系问题的职责。指定的人员应有规定的职责和权限实施和记录行动。

6 Planning

策划

6.1 Actions to address risks and opportunities

风险和机会的处理措施

6.2 Objectives of the food safety management system and planning to achieve them

6.3 Planning of changes

变更的策划

6.1 Actions to address risks and opportunities

应对风险和机遇的措施

6.1.1 When planning for the food safety management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

策划食品安全管理体系时，组织应考虑 4.1 的因素和 4.2 的要求，并确定需要应对的风险和机会以：

a) give assurance that the food safety management system can achieve its intended results;

确保食品安全管理体系能够实现其预期的结果；

b) prevent, or reduce, undesired effects;

预防或减少非预期的影响；

c) achieve continual improvement.

实现持续改进。

NOTE In the context of this document, the concept of risks and opportunities is limited to events and their consequences relating to the performance and effectiveness of the food safety management system. Organizations are not required to directly address public health risks which are under the responsibility of the competent authorities. However, they are required to manage food safety hazards (see 3.22) and the requirements related to this process are laid down in clause 8.

备注：在本标准中，风险和机遇概论仅限于与食品安全管理体系绩效和有效性有关，而不是公众健康风险。

6.1.2 The organization shall plan:组织应策划：

a) actions to address these risks and opportunities;

应对风险和机会的措施；

b) how to: to 如何：

1) integrate and implement the actions into its food safety management system processes;

在食品安全管理体系过程中融入和实施这些措施；

2) evaluate the effectiveness of these actions.

评价这些措施的有效性。

6.1.3 The actions taken by the organization to address risks and opportunities shall be proportionate to:

组织采取的应对风险和机遇的行动应与以下相适应：

a) the potential impact on food safety requirements, and;

食品安全要求的潜在影响，和；

b) the conformity of food products and services to customers, and;

顾客产品和服务的符合性，和；

c) requirements of interested parties in the food chain.食品链中相关的要求；

NOTE Options to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or accepting the presence of risk by informed decision.

备注：应对风险和机遇的选择可以包括：避免风险、为获取机会而接受风险、消除风险源、改变可能性或结果、分担风险或经过决策而保留风险。

6.2 Objectives of the food safety management system and planning to achieve them

食品安全管理体系目标及实施方案

6.2.1 The organization shall establish objectives of the food safety management system at relevant functions and levels.

组织应在食品安全管理体系所需的相关职能、层次和过程上建立目标。

The objectives of the food safety management system shall:

食品安全管理体系目标应：

a) be consistent with the food safety policy;

与食品安全方针保持一致；

b) be measurable (if practicable); 可测量（可行时）；

c) take into account applicable food safety requirements including statutory/regulatory requirements;

考虑适用的食品安全要求，包括立法/执法要求；

d) be monitored and verified;

得到监视和验证；

e) be communicated;

得到沟通；

f) be updated as appropriate.

适当时进行更新。

The organization shall retain documented information on the objectives of the food safety management system.

组织应保持食品安全管理体系目标的文件化信息。

6.2.2 When planning how to achieve its objectives of the food safety management system (see 6.2), the organization shall determine:

策划如何实现其食品安全管理体系目标时，组织应确定：

a) what will be done;要做什么；

b) what resources will be required;需要什么资源；

c) who will be responsible;由谁负责；

d) when it will be completed;什么时候完成；

e) how the results will be evaluated.如何评价结果。

6.3 Planning of change 变更的策划

When the organization determines the need for changes to the food safety management system, including personnel changes, the changes shall be carried out in a planned manner. The organization shall consider:

当组织确定了食品安全管理体系变更的需求时（见 4.4），应按策划的、系统化的方式进行变更。组织应考虑：

a) the purpose of the changes and their potential consequences for the supply and maintenance of safe food production;

提供和维护安全食品生产变更的目的及其潜在后果；

b) the integrity of the food safety management system;食品安全管理体系的完整性

c) the availability of resources to effectively implement the changes;

有效实施变更资源的获得；

d) the allocation or re-allocation of responsibilities and authorities.

职责和权限的分配与再分配；

7 Support

支持

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, updating and continual improvement of the food safety management system.

组织应确定和提供为建立、实施、保持、更新和持续改进食品安全管理体系所需的资源。

The organization shall consider:

组织应考虑：

a) the capability of and any constraints on existing internal resources; and

现有内部资源的能力和制约；和

b) what is required from external resources.

需要的外部资源。

7.1.2 People 人员

The organization shall determine and provide the persons that are necessary to operate and maintain the food safety management system.

组织应确定并提供运行和保持食品安全管理体系所需的人员。

Where the assistance of external experts is used for the development, implementation, operation or assessment of the food safety management system, evidence of agreement or contracts defining the competency, responsibility and authority of external experts shall be retained as documented information.

当需要外部专家帮助建立、实施、运行和评估食品安全管理体系时，应在签订的协议或合同中对这些专家的能力、职责和权限予以规定。

7.1.3 Infrastructure 基础设施

The organization shall provide the resources for the determination, establishment and maintenance of the infrastructure necessary to achieve conformity of end products.

组织应提供资源以确定、建立和维护满足终产品符合性的基础设施。

NOTE Infrastructure can include:基础设施包括：

- land, vessels, buildings and associated utilities,
土地、船舶、建筑和相关设施
- equipment, including hardware and software;
设备，包括硬件和软件；
- transportation resource, 运输资源
- information and communication technology.
信息和通讯技术。

7.1.4 Work environment 工作环境

The organization shall determine, provide and maintain the resources for the establishment, management and maintenance of the work environment necessary to achieve conformity of end products.

组织应确定、提供和维护建立、管理和维护工作环境所需的资源，以达到产品的符合性。

7.1.5 Externally developed elements of the food safety management system 食品安全管理体系的外部的要素

When an organization establishes, maintains, updates and continually improves the food safety management system by

using externally developed elements of a food safety management system including PRPs and the hazard control plan, the organization shall ensure that the provided elements are:

当组织通过利用食品安全管理体系的外部要素包括 PRP 和危害控制计划，来建立、维护、更新和持续改进食品安全管理体系，组织应确保提供的要素是：

a) developed in conformance with requirements of this document;

以满足本标准的要求建立；

b) applicable to the sites, processes and products of the organization;

适合于组织的场所、过程和产品

c) specifically adapted, by the food safety team to the processes and products of the organization; and,

适合时，由食品安全小组根据组织的过程和产品进行专门的调整；和

d) implemented, maintained and updated as required by this document;

根据本标准的要求实施、运行和更新。

e) retained as documented information.

作为文件化信息加以保留。

NOTE Externally developed elements of a food safety management system can be used by any organization, however, they are primarily intended for use by small and/or less developed organizations.

组织可使用外部建立的食品安全管理体系要素，但主要服务于小型和或发达组织

7.1.6 Control of externally provided products or services 外部提供产品或服务的控制

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

组织在与外部供方沟通前，应确保要求是充分的。

The organization shall ensure that externally provided elements do not adversely affect the organization's ability to consistently deliver the specified products and services to its customers.

组织应确保外部提供的要素对于组织向顾客提供规定的产品和服务的能力，不会产生负面影响。

The organization shall establish and apply criteria for the evaluation, selection, monitoring of performance, and re - evaluation of external providers, based on their ability to provide elements in accordance with the requirements. The organization shall ensure that external providers conform to the established criteria.

组织应根据外部供方按要求提供要素的能力，对于外部供方的评估、选择、绩效监视和再评估确定评价准则并实施。

The organization shall retain documented information of these activities and any necessary actions as a result of the evaluations.

组织应保留这些活动和任何必要的作为评估结果的行动的文件化信息。

7.2 Competence 能力

The organization shall:组织应

a) determine the necessary competence of person(s) doing work under its control that affects its food safety performance and effectiveness of the food safety management system;

确定其控制范围内人员所需的能力，这些人员人事的工作影响食品安全绩效和食品安全管理体系的有效性；

b) ensure that these persons, including the food safety team, are competent based on the application of knowledge and skills;

基于适用的知识和技能，确保这些人员包括食品安全小组是有能力的；

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

可行时，采取措施获得所面的能力，并评价采取措施的有效性；

d) retain appropriate documented information as evidence of competence.

保留适当的作为能力证据的文件化信息。

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re - assignment of currently employed persons; or the hiring or contracting of competent persons.

备注：采取的适当措施可包括对在职人员进行培训、辅导或重新分配工作，或者招聘具备能力的人员等。

7.3 Awareness 意识

The organization shall ensure that relevant persons doing work under the organization's control shall be aware of:

组织应确保其控制范围内的相关工作人员到：

a) the food safety policy;食品安全方针；

b) the food safety management objectives relevant to their task:

与其任务相关的食品安全管理目标；

c) their contribution of their individual activities to the effectiveness of the food safety management system, including the benefits of improved food safety performance;

他们个人的活动对食品安全管理体系有效性的贡献，

d) the implications of not conforming with the food safety management system requirements.不符合食品安全管理体系要求的后果。

7.4 Communication

7.4.1 General

The organization shall determine the internal and external communications relevant to the food safety management system, including:

组织应确定与食品安全管理体系相关的内部和外部沟通，包括：

a) on what it will communicate; 沟通什么

b) when to communicate;何时沟通

c) with whom to communicate;和谁沟通

d) how to communicate; 如何沟通

e) who communicates; 谁来沟通

The organization shall ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on food safety.

组织应确保有效沟通的要求得到其活动对食品安全有影响的全部人员的理解。

7.4.2 External communication 外部沟通

7.4.2.1 The organization shall ensure that sufficient information is communicated externally and available throughout the food chain.

组织应确保在食品链中能够获得食品安全方面的充分信息和外部沟通。

The organization shall establish, implement and maintain effective communications with: 组织应建立、实施和保持与以下各方有效的沟通：

a) suppliers and contractors; 供方和承包方

b) customers or consumers;顾客或消费者；

c) statutory/regulatory authorities, and 立法和执行部门，和

d) other organizations that have an impact on, or will be affected by, the effectiveness or updating of the food safety management system.

对食品安全管理体系的有效性或更新具有影响或将受其影响的其它组织。

7.4.2 External communication 外部沟通

7.4.2.2 Communication with customers or consumers shall include:

与顾客或消费者的沟通应包括：

a) product information to enable the safe handling, display, storage and preparation and use of the product within the food chain or by the consumer;

安全处置、展示、贮存和制备产品信的产品信息，和食品链或顾客的产品使用

b) contractual arrangements, enquiries and orders including their amendments; and

协议、询问和订单，包括其修改；和

c) customer feedback including customer complaints.

顾客反馈，包括顾客投诉。

7.4.2 External communication 外部沟通

External communication shall provide appropriate information on food safety aspects of the organization's products that may be relevant to other organizations in the food chain.

外部沟通应提供组织的产品在食品安全方面适宜的信息，其可能与食品链中其他组织相关。

NOTE Communication within the food chain can include known food safety hazards that need to be controlled by other organizations.

在食品链中的沟通可以包括由其他组织控制的已知的食品安全危害。

Designated personnel shall have defined responsibility and authority for the external communication of any information concerning food safety. Where relevant, information obtained through external communication shall be included as input for updating the food safety management system (see 4.4) and management review (see 9.3).

指定人员应具有规定的职责和权限以进行有关食品安全信息的对外沟通。相关时，通过外部获得的信息应作为体系更新 (see 4.4) 和管理评审的输入(see 9.3).

Evidence of external communication shall be retained as documented information.

外部沟通的证据应作为文件化信息加在保留。

7.5 Documented information 文件化信息

7.5.1 General 总则

The organization's food safety management system shall include:

组织的食品安全管理体系应包括：

a) documented information required by this document;

本标准要求的文件化信息；

b) documented information determined by the organization as being necessary for the effectiveness of the food safety management system;

组织确定的为确保食品安全管理体系有效运行所需的文件化信息。

c) documented information required by statutory/regulatory authorities and customers;立法执法部门和顾客要求的文件化信息；

d) food safety requirements from statutory/regulatory authorities and customers.

立法执法部门和顾客的食品安要求。

NOTE The extent of documented information for a food safety management system can differ from one organization to another due to:

不同组织的食品安全管理体系文件化信息的程度可以因以下方面而不同：

— the size of organization and its type of activities, processes, products and services;

组织的规模、活动、过程、产品和服务的类型；

— the complexity of processes and their interactions;

过程及其相互作用的复杂程度；

— the competence of persons.

人员的能力。

7.5.2 Creating and updating 编制和更新

When creating and updating documented information, the organization shall ensure appropriate:

在编制和更新文件时，组织应确保适当的：

a) identification and description (e.g. a title, date, author, or reference number);

标识和说明（例如：标题、日期、作者、文件编号等）；

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

格式（例如：语言、软件版本、图示）和媒介（例如：纸质、电子）；

c) review and approval for suitability and adequacy.

评审和批准以确保适宜性和充分性。

7.5.3 Control of documented information 文件化信息的控制

7.5.3.1 Documented information required by the food safety management system and by this document shall be controlled to ensure:

应对食品安全管理体系和本标准所要求的文件化信息进行控制，以确保：

a) it is available and suitable for use, where and when it is needed;

在需要处和需要时，能获得并且适用；

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

得到充分地保护（如防止泄密、使用不当、缺损）。

7.5.3 Control of documented information

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

适用时，组织应实施以下活动对文件化信息进行控制：

a) distribution, access, retrieval and use;

分发、获取、检索和使用；

b) storage and preservation, including preservation of legibility;

储存、保护，包括保持清晰；

c) control of changes (e.g. version control);

更改的控制（如：版本控制）；

d) retention time and disposition. 保留和处置。

Documented information of external origin determined by the organization to be necessary for the planning and operation of the food safety management system shall be identified, as appropriate, and controlled.

组织所确定的策划和运行食品安全管理体系所需的外来文件化信息应得到适当的识别和控制。

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

注：获取是指有关文件化信息浏览许可的决定，或浏览和更改文件化信息的许可和权力。

8.1 Operational planning and control

The organization shall plan, implement, control and update the processes needed for the realization of safe products to meet requirements, and to implement the actions determined in 6.1 by:

组织应通过以下措施，策划、实施、控制和更新满足要求的安全产品所必需的过程，并实施 6.1 所确定的措施：

a) establishing criteria for the processes;

为过程建立准则；

b) implementing control of the processes in accordance with the criteria;

按照准则实施过程控制；

c) keeping documented information to the extent necessary to have the confidence to demonstrate that the processes have been carried out as planned.

保留文件化信息，其程度为证实过程已经按策划进行。

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

组织应控制策划的更改，评审非预期变更的后果，必要时，采取措施减少不利影响。

The organization shall ensure that outsourced processes are controlled.

组织应确保外包过程得到控制。

8.2 前提方案（PRP(s)）

8.2.1 The organization shall establish, implement and maintain PRP(s) to control:

组织应建立、实施和保持前提方案（PRP(s)），以助于控制：

a) the likelihood of introducing contaminants (including food safety hazards) to the product through the work environment;

污染物（包括食品安全危害）通过工作环境进入产品的可能性；

b) the biological, chemical and physical contamination of products, including cross contamination between them, and; 产品的生物、化学和物理污染，包括产品之间的交叉污染；

c) and facilitate the control of contaminants (including food safety hazards) in the products and product processing environment.

有助于产品和产品加工环境污染物（包括食品安全危害）的控制

8.2.2 The PRP(s) shall:前提方案应：

a) be appropriate to the organization and its context with regard to food safety;

与组织和其在食品安全方面的环境相适宜；

b) be appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled; 与运行的规模和类型、制造和（或）处置的产品性质相适宜；

c) be implemented across the entire production system, either as general programmes or as specific programmes for a particular product or process; and

无论是普遍适用还是适用于特定产品或过程，前提方案都应在整个生产系统中实施；

d) be approved by the food safety team.

获得食品安全小组的批准

8.2.2 The PRP(s) shall:前提方案应：

NOTE PRPs should be established and designed before proceeding to the hazard analysis. However updating of the PRPs and other parts of the food safety management system may identify the need for changes or improvements to the PRPs.

PRP 应在进行危害分析前建立和设计。但更新 PRP 和食品安全管理体系其它部分时，可识别 PRP 变更和改进的需求。

8.2.3 When selecting and/or establishing PRP(s), and in addition to statutory/regulatory requirements, the organization shall consider:

当选择和（或）建立前提方案时，组织应考虑：

a) applicable Technical Specification of the ISO/TS 22002 - series;

适用 ISO/TS 22002 系列技术规范；

b) customer requirements;

客户要求；

c) applicable codes of practice and guidelines.

适用的法典和指南。

8.2.4 The organization shall consider, when establishing PRPs, the following:

当制定这些方案时，组织应考虑如下：

a) construction and lay - out of buildings and associated utilities;

建筑物和相关设施的布局和建设；

b) lay - out of premises, including workspace and employee facilities;

包括工作空间和员工设施在内的厂房布局；

c) supplies of air, water, energy and other utilities;

空气、水、能源和其他基础条件的提供；

d) supporting services, including pest control, waste and sewage disposal;

支持服务，包括虫害控制，废物和污水处理；

e) the suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance;

设备的适宜性，及其清洁、保养和预防性维护的可实现性；

f) supplier approval and assurance process (e.g. raw materials, ingredients, chemicals and packaging);

供应商批准和保证过程（如原料、辅料、化学品和包装材料）

g) receiving of incoming materials, storage, transportation and handling of products

到货物料的接收、贮存、运输和产品的处置；

h) measures for the prevention of cross contamination;

交叉污染的预防措施；

i) cleaning and sanitizing;

) 清洁和消毒；

j) personnel hygiene; 人员卫生；

k) product information/consumer awareness;

产品信息和消费者意识；

l) others as appropriate. 其他适用的方面。

The organization shall effectively implement and update established PRPs.

组织应有效地实施和更新 PRP。

Documented information should specify how activities included in the PRP(s) are managed.

文件宜规定如何管理前提方案中包括的活动。

8.3 Traceability system

The traceability system shall be able to uniquely identify incoming material from the immediate suppliers and the initial distribution route of the end product. The organization shall implement, establish and apply the following:

可追溯性系统应能够识别直接供方的进料和终产品首次分销途径。

组织应建立、实施和适用以下：

a) the relation of batch/lot of received materials, intermediate and end products, including rework;

与原料批次、中间产品和终产品的关系，包括返工；

b) compliance to statutory/regulatory and customer requirements.

符合法律法规和顾客要求。

Documented information as evidence of the traceability system shall be retained for a defined period (includes as a minimum shelf - life of the product).

应在一定期间内保留作为追溯系统证据的文件化信息（包括最少的产品保质期）。

The organization shall verify and test the effectiveness of the traceability system.

组织应验证和测试追溯系统的有效性。

NOTE Where appropriate, the verification of the system is expected to include the reconciliation of quantities of end products with the quantity of ingredients as evidence of effectiveness.

备注：适当时，验证系统包括作为有效性证据的终产品和原料数量的相一致。

8.4 Emergency preparedness and response

应急准备和响应

8.4.1 General

Top management shall establish, implement and maintain procedures to manage potential emergency situations and accidents that may have an impact on food safety and which are relevant to the role of the organization in the food chain.

最高管理者应建立、实施并保持程序，以管理能影响食品安全的潜在紧急情况和事故，该程序应与组织在食品链中的作用相适宜。

8.4.2 Handling of emergencies and accidents 紧急情况和事故的处置

The organization shall:组织应

a) respond to actual emergency situations and accidents by:

通过以下方式响应实际发生的紧急情况和事故：

1) complying with statutory/regulatory requirements, where applicable;

适用时，符合法律法规要求；

2) communicating internally; 对外沟通；

3) communicating externally (e.g. suppliers, customers, law enforcement, governmental agencies, media);

对内沟通（例如，供应商，顾客，执法部门，政府机械，结体）

b) take action to reduce the consequences of the emergency situation, appropriate to the magnitude of the emergency or accident and the potential food safety impact;

采取措施减少紧急情况的后果，该措施要适于紧急情况或事故的程度及对食品安全可能的影响；

8.3 Traceability system

8.4.2 Handling of emergencies and accidents

c) periodically test procedures where practical;

可行时，对程序进行定期地测试；

d) review and, where necessary, revise the procedure, in particular, after the occurrence of any accident, emergency situation or tests.

必要时评审和修订程序，特别是在事故、紧急情况或测试发生后；

NOTE 1 Examples of emergency situations that can affect food safety and/or production are natural disasters, environmental accidents, bioterrorism, workplace accidents, public health emergencies and other accidents like interruption of essential services such as water, electricity or refrigeration supply.

备注 1：可以影响食品安全和或生产的紧急情况是自然灾害、环境事故、生物恐怖、工作场地事故、公共卫生事件和其它事故，和其它必要服务的中断，如断水、断电或冷气供应中断。

本条款目的是为实施危害分析提供必要的准备，以确保危害分析的充分性。7.3.1 是本条款的总原则，规定了通过采取预备步骤所获得的信息应形成文件，且收集、保持和更新这些信息后形成的文件应是受控的。应保持收集、保持和更新这些信息的记录。

8.5.1 Food safety team 食品安全小组

The food safety team shall ensure that all preliminary information needed for hazard analysis is collected, updated and maintained as documented information. This shall include but not be limited to:

食品安全小组应确保收集、更新和保持危害分析所需的全部基本信息，并形成文件化信息。这些信息包括但不限于：

a) the organization's products, processes, equipment; and

组织的产品、过程、设备；

b) food safety hazards within the scope of the food safety management system.

食品安全管理体系范围内的食品安全危害。

8.5.2 Characteristics of raw materials, ingredients and product contact materials

The organization shall ensure that all applicable statutory/regulatory food safety requirements are identified for all raw materials, ingredients and product contact materials.

组织应确保识别与原料、辅料与产品接触材料有关适用食品安全法律法规的要求。

The organization shall maintain documented information concerning all raw materials, ingredients and product contact materials to the extent needed to conduct the hazard analysis (see 8.5.6), including the following, as appropriate:

组织应保留所有原料、辅料和与产品接触的材料的文件化信息，其详略程度为实施危害分析所需（见 8.5.6）。适用时，包括以下方面：

a) biological, chemical and physical characteristics, including known allergens;

生物、化学和物理特性，包括已知的过敏原；

b) composition of formulated ingredients, including additives and processing aids;

配制辅料的组成，包括添加剂和加工助剂；

c) source, origin or provenance, as applicable (see the note);

来源，起源或出处，适用时（见备注）；

d) method of production;

生产方法；

e) packaging and delivery methods;

包装和交付方式；

f) storage conditions and shelf life;

贮存条件和保质期；

g) preparation and/or handling before use or processing;

使用或生产前的预处理；

h) food safety - related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended use.

与采购材料和辅料预期用途相适宜的有关食品安全的接收准则或规范。

NOTE When the organization determine origin, it should consider the place of provenance and source (e.g. animal origin, plant origin).

备注：当组织确定来源，应考虑起源和出处的位置（例如，动物来源，植物来源）

8.5.3 Characteristics of end products

终产品特性

The organization shall ensure that all applicable statutory/regulatory food safety requirements are identified for all the end products intended to be produced.

组织应确保识别与预期生产的终产品有关的适用的食品安全法律法规的要求。

The characteristics of end products shall be described in documents to the extent needed to conduct the hazard analysis (see 8.5.6), including information on the following, as appropriate:

组织应保留终产品特性文件化信息，其详略程度为实施危害分析所需（见 8.5.6）。适用时，包括以下方面：

a) product name or similar identification;

产品名称或类似标识；

b) composition;

成分；

c) biological, chemical and physical characteristics relevant for food safety;

与**食品安全**有关的化学、生物和物理特性；（

d) intended shelf life and storage conditions;

预期的保质期和贮存条件；

e) packaging;

包装；

f) labelling relating to food safety and/or instructions for handling, preparation and usage;

与食品安全有关的标识和（或）处理、制备及使用的说明书；

g) method(s) of distribution.

分销方法。

8.5.4 Intended use

The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documented information to the extent needed to conduct the hazard analysis (see 8.5.6).

应考虑终产品的预期用途和合理的预期处理，以及非预期但可能发生的错误处置和误用，并应将其在文件化信息

描述，其详略程度为实施危害分析所需（见 8.5.6）。

Where appropriate, groups of consumers/users shall be identified for each product, and consumer groups/users known to be especially vulnerable to specific food safety hazards shall be assessed.

适用时，应识别每种产品的消费和使用群体；并应考虑对特定食品安全危害的易感消费群体。

8.5.5 Flow diagrams and description of processes 流程图和过程描述

8.5.5.1 Preparation of the flow diagrams 流程图的准备

The food safety team shall establish, maintain and update flow diagrams as documented information for the product categories and all processes.

食品安全小组应建立、保留和更新文件化信息方式的所有产品类别和过程的流程图。

The flow diagrams shall be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase or introduction of food safety hazards.

流程图应为评价食品安全危害可能的出现、增加或引入提供基础。

Flow diagrams shall be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams shall, as appropriate, include the following:

流程图应清晰、准确和足够详尽，其详略程度为实施危害分析所需。适当时，流程图应包括：

a) the sequence and interaction of all steps in the operation;

操作中所有步骤的顺序和相互关系；

b) any outsourced processes and subcontracted work;

源于外部的过程和分包工作；

c) where raw materials, ingredients, processing aids, packaging materials and intermediate products enter the flow;

原料、辅料和中间产品投入点；

d) the description of process parameters; 过程参数的描述；

e) where reworking and recycling take place; 返工点和循环点；

f) where end products, intermediate products, by-products and waste are released or removed. 终产品、中间产品和副产品放行点及废弃物的排放点。

8.5.5.2 On-site confirmation of flow diagrams 流程图的现场证实

The food safety team shall confirm on-site the accuracy of the flow diagrams, update where appropriate and retain as documented information.

食品安全小组应现场证实流程图的准确性，适当时更新作为文件化信息进行保留

8.5.5.3 Description of processes and environment 过程和环境描述

The food safety team shall describe, to the extent needed to conduct the hazards analysis, and update:

食品安全小组应描述和更新，其详略程度为实施危害分析所需。

a) layout of premises including food and non-food handling areas, processing equipment and contact materials, processing aids and flow of materials;

工厂平面图，包括食品和非食品加工区，过程设备和接触材料，加工助剂和物流；

b) the existing PRPs, process parameters, control measures if any and/or the strictness with which they are applied, or procedures that may influence food safety;

现有的 PRP，过程参数，控制措施（如果有）和（或）它们应用的严格程度，或者可以影响食品安全的程序；

c) the external requirements (e.g. from regulatory authorities or customers) that may impact the choice and the strictness of the control measures.

外部的要求（例如，来自法规部门或顾客），其可能影响到控制措施的选择和严格程度。

The variations resulting from expected seasonal changes or shift patterns shall be included as appropriate.

适当时，应考虑可预料的季节变换或调班导致的变化。

The descriptions shall be updated as appropriate.

适当时，应更新描述。

8.5.6.1 General

The food safety team shall conduct a hazard analysis, based on the preliminary information (see 8.5.2-8.5.5), to determine which hazards need to be controlled. The degree of control shall ensure food safety. Where appropriate a combination of control measures shall be used.

食品安全小组应基于预备信息（see 8.5.2-8.5.5）进行危害分析，确定那些危害需控制，以及为确保食品安全的控制程度。应使用的适宜的控制措施组合。

8.5.6.2 Hazard identification and determination of acceptable levels 危害识别和确定可接受水平

8.5.6.2.1 The organization shall identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities.

组织应识别并记录与产品类别、过程类别和实际生产设施相关的所有合理预期发生的食品安全危害。

The identification shall be based on: 这种识别应基于以下方面：

a) the preliminary information and data collected according to 8.5.2 to 8.5.5;

根据 to 8.5.2 到 8.5.5.3 收集的预备信息和数据；

b) experience; 经验

c) external information including, to the extent possible, epidemiological and other historical data;

外部信息，尽可能包括流行病学和其他历史数据；

d) information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products and the food at consumption; and

来自食品链中，可能与终产品、中间产品和消费食品的安全相关的食品安全危害信息

e) statutory/regulatory or customer requirements.

法律法规和客户要求。

NOTE 1 Experience can include staff and external experts who are familiar with the product and/or processes in other facilities.

经验能包括员工在其它工厂对产品和或工艺的了解。

NOTE 2 Statutory/regulatory requirements can include food safety objectives (FSOs). The Codex Alimentarius Commission defines FSOs as "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

8.5.6.2.2 The organization shall identify the step(s) (from raw materials, processing and distribution) at which each food safety hazard can be present, introduced, increase or persist.

流程图应为评价食品安全危害可能的出现、引入或增加提供基础。

When identifying hazards, the organization shall consider:

在识别危害时，组织应考虑：

- a) the steps preceding and following in the process; 加工的前后步骤；
- b) the process equipment, utilities/services, process environment and personnel;

加工设备、设施/服务、加工环境和人员；

- c) the stages preceding and following in the food chain.

在食品链中的前后阶段。

8.5.6.2.3 The organization shall determine the acceptable level in the end product of each food safety hazard identified.

组织应确定终产品中食品安全危害的可接受水平。

When determining acceptable levels, the organization shall consider:

确定可接受水平时，组织应考虑：

- a) statutory/regulatory and customer requirements;

法律法规要求和顾客要求

- b) intended use of end products; 终产品的预期用途

- c) any other relevant information. 其他相关信息

The organization shall maintain documented information concerning the determination of acceptable levels and the justification for the acceptable levels.

组织应保留确定的可接受水平的文件化信息和可接受水平的依据。

8.5.6.3 Hazard assessment 危害评估

The organization shall conduct for each identified food safety hazard, a hazard assessment to determine, whether its prevention, elimination or reduction to acceptable levels is **essential**, and whether its control measure(s) is needed to achieve the defined acceptable levels.

组织应对每种已识别的食品安全危害进行危害评估，以确定消除危害或将危害降至可接受水平是否是生产安全食品所必需的；以及是否需要控制危害以达到规定的可接受水平。

The organization shall evaluate each food safety hazard with regard to the likelihood of its occurrence and the possible severity of its adverse health effects. The organization shall identify any significant food safety hazards (3.40).

组织应根据食品安全危害造成不良健康后果的**严重性**及其发生的**可能性**，对每种食品安全危害进行评价。组织应识别显著的食品安全危害(3.40)。

The methodology used shall be described, and the result of the food safety hazard assessment shall be maintained as documented information.

应描述所采用的方法，食品安全危害评价的结果作为文件化信息加以保留。

8.5.6.4 Selection and categorization of control measures 控制措施的选择和分类

8.5.6.4.1 Based on the hazard assessment, the organisation shall select an appropriate control measure or combination of control measures that will be capable of preventing, eliminating or reducing the identified significant food safety hazards to defined acceptable levels.

基于危害评估，组织应选择适宜的控制措施或控制措施组合，以预防、消除或减少食品安全危害至规定的可接受水平。

The organization shall categorize the selected identified control measures to be managed as OPRPs or CCPs.

组织应对所选择的控制措施进行**分类**，以决定其是否需要通过操作性前提方案或 HACCP 计划进行管理。

The categorization of the control measures shall be carried out using a systematic approach that includes assessment of the feasibility of all the following:

应使用系统方法对控制措施进行分类，其包括下面可行性的评估：

a) establishing measurable critical limits and/or measurable/observable action criteria;

建立可测量的关键限值和或可测量/观察的行动标准；

b) monitoring to detect any failure to meet critical limit and/or measurable/observable action criteria;

监视可发现不符合关键限值和或可测量/观察的行动标准的任何失效；

c) applying timely corrections in case of such failure.

一旦不符合及时采取纠正。

8.5.6.4.2 In addition, for each control measure, the systematic approach shall include an assessment of the following:

另外，对于每个控制措施，系统方法应包括以下的评估：

a) its effect on identified significant food safety hazards;

对于识别的显著食品安全危害的效果；

b) its place in relation to other control measures;

相对于其他控制措施，该控制措施的位置；

c) the likelihood of failure of its functioning or significant processing variability;

控制措施功能失效或工艺发生显著变化的可能性

d) the severity of the consequence in the case of failure of its functioning;

控制措施功能失效后果的严重性；

e) whether it is specifically established and applied to eliminate or significantly reduce the level of hazards;

控制措施是否有针对性建立，并用于消除或显著降低危害水平；

f) whether it is a single measure or is part of combination of control measures, i.e. if there is interaction in this combination that creates synergistic effects being higher than the sum of their individual effects.

控制措施是否单项措施或控制措施组合的一部分（例如，组合的控制措施是否相互作用，产生协同效应）。

The decision making process and results of the categorization shall be maintained as documented information.

做决定的过程和分类的结果应保持文件化的信息。

External requirements (e.g. statutory/regulatory and customer requirements) that may impact the choice and the strictness of the control measures shall also be maintained as documented information.

对选择控制措施及其严格程度有影响的外部要求（例如，法律法规和顾客要求）也应作为文件化信息加以保留。

NOTE The wording ‘critical limit’ here does not in itself direct the assessment to be determined as a CCP.

备注：词语“关键限值”这里不能自己直接表明评估后作为 CCP.

When monitoring procedures are based on subjective data, e.g. visual inspection of products and/or processes, they shall be supported by instructions or specifications and/or education and training for persons with responsibility for the monitoring activities.

当监控程序基于主观信息，例如，对产品和或过程的感官检验，其应有负责监控活动人员的指导书、规范和（或）教育及培训的支持。

8.5.7 Validation of control measure(s) and combinations of control measures 控制措施和控制措施组合的确认

Prior to implementation of control measures to be included in the hazard control plan and after any change therein (see 7.4.2, 10.2, 10.3), the organization shall validate that:

在实施包括在危害控制计划里的控制措施之前和任何的变更后(see 7.4.2, 10.2, 10.3), 组织应确认：

a) the selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated, and

所选择的控制措施能使其针对的食品安全危害实现预期控制，和

b) the control measures are effective and capable of, in combination, ensuring control of the identified food safety hazard(s) to obtain end products that meet the defined acceptable levels.

控制措施和（或）其组合时有效，能确保控制已确定的食品安全危害，并获得满足规定可接受水平的终产品。

When the result of the validation shows that the above cannot be confirmed, the organization shall modify and re-assess the control measure and/or combinations of control measure.

当确认结果表明不能满足上述要素时，应对控制措施和（或）其组合进行修改和重新评价。

The organization shall retain the validation methodology and evidence of capability of the control measures to achieve the intended results as documented information.

组织应保留确认的方法和控制措施能够达到预期结果的文件化信息。

NOTE Examples of modifications can include:

修改的例子包括：

- change(s) in the control measure(s) (i.e. process parameters, strictness and/or their combination); and/or

控制措施变更（例如，生产参数、严格度和（或）其组合），和（或）：

- change(s) in the raw materials, technologies, end product characteristics, methods of distribution and/or intended use of the end product.

原料、生产技术、终产品特性、分销方式、终产品预期用途的变更。

8.5.8.1 General

The organization shall establish, implement and maintain a hazard control plan where control measures is identified as OPRPs or as CCPs (see 8.5.6.4).

组织应建立、实施和维护作为 OPRP 或 CCP 的危害控制计划(see 8.5.6.4)。

The hazard control plan shall be maintained as documented information and shall include the following information for each identified CCP or OPRP:

危害控制计划应作为文件化信息加以保留，并且每个 CCP 和 OPRP 应包括以下信息：

a) food safety hazard(s) to be controlled at the CCP or by the OPRP;

CCP 或 OPRP 控制的食品安全危害；

b) control measure(s); 控制措施；

c) critical limit(s) for CCP or action criteria for OPRP;

CCPR 的关键限值或 OPRP 的行动标准；

d) monitoring procedure(s);

监控程序；

e) corrections and corrective action(s) to be taken if limits or criteria are not met;

如果限值和标准不满足时的纠正和纠正措施；

f) responsibilities and authorities;

职责和权限；

g) records of monitoring.

监控记录。

8.5.8.2 Determination of critical limits and action criteria 关键限值和行动限值的确定

In order to allow monitoring, critical limits for CCPs and action criteria for OPRPs shall be specified. The rationale for their determination shall be maintained as documented information.

为了可以监控，应规定 CCP 的关键限值和 OPRP 的行动标准。其确定的理由应作为文件化的信息加以保留。

Critical limits at CCPs shall be measurable.

CCP 的关键限值应可以测量的。

Action criteria at OPRPs shall be measurable or observable.

OPRP 的行动标准应可以测量的或观察的。

Conformance with critical limits shall assure that the acceptable level of the food safety hazard is not exceeded.

符合关键限值应确保食品安全危害的可接受水平是不会超出。

Conformance with action criteria shall contribute to the assurance that the acceptable level of the food safety hazards is not exceeded.

符合行动标准应能够保证食品安全危害的可接受水平不会超出。

8.5.8.3 Monitoring systems for CCPs and OPRPs

CCP 和 OPR 监控系统

For a CCP, a monitoring system shall be established for each control measure (s) to detect any failure to meet critical limits. The system shall include all scheduled measurements relative to the critical limit(s).

对于 CCP，应建立每个控制措施的监控系统，以发现任何的不能满足关键限值。系统应包括与关键限值有关的所有计划的措施。

For each OPRP, a monitoring system shall be established for each control measure or combination of control measure(s) to demonstrate that action criteria are met.

对于 OPRP，应建立每个控制措施或控制措施组合的监控系统，以证明是符合行动标准的。

The monitoring system, for each CCP and OPRP, shall consist of documented information including procedures, instructions and records and shall include but is not limited to:

每个 CCP 和 OPRP 的监控体系，应由包括文件化信息的程序、指导书和记录，并应包括但不限于：

a) measurements or observations that provide results within an adequate time frame;

在适宜的时间框架内提供结果的测量或观察；

b) monitoring methods or devices used;

使用的监控方法和设备；

c) applicable calibration methods or, for OPRPs, equivalent methods for verification of reliable measurements or observations;

) 适用的校准方法，对于 OPRP，可靠的测量或观测的验证的等效方法；

d) monitoring frequency; 监控频率；

e) monitoring results; 监控结果；

f) responsibility and authority related to monitoring and evaluation of monitoring results. 与监视和评价监视结果有关的职责和权限

For CCPs, the monitoring method and frequency shall be capable of timely detection of any failure to meet critical limits, to prevent product use or consumption.

对于 CCP，监控方法和频次应能及时地发现不满足关键限值，以防止产品的使用和消费。

For OPRPs, the monitoring method and frequency shall be proportionate to the likelihood of failure and the severity of consequences.

对于 OPRP，监控方法和频次应与失效和后果的严重性的可能性相匹配。

When monitoring of OPRPs is based on subjective data from observations, it shall be supported by instructions or specifications and/or education and training for person with responsibility for the monitoring activities.

当 OPRP 的监控是基于观察的主观信息时，应有指导书和规范和（或）负责监控活动人员的教育和培训的支持。

8.5.8.4 Actions when critical limits or action criteria are not met 关键限值和行动限值不符合时的纠正

The organization shall specify in the hazard control plan the corrections and corrective actions to be taken when critical limits or action criteria are not met. The actions shall ensure that:

组织应危害控制计划中规定关键限值和行动标准不满足时所采取的策划的**纠正和纠正措施**。 这些行动应确保：

a) the cause of nonconformity is identified;

查明不符合的原因；

b) the parameter(s) controlled at the CCP or OPRP is brought back within the critical limits or action criteria; and,

CCP 或 OPRP 控制的参数重新回到关键限值或行动标准内，和；

c) recurrence is prevented.

防止再次发生。

The organization shall take corrections in accordance with 8.9.1.

组织应按照 8.9.1 采取纠正措施。

Documented information shall be established and maintained for corrections and corrective actions.

纠正和纠正措施的的文件化信息应建立和保留。

8.5.8.5 Implementation of the hazard control plan 危害控制计划的实施

The hazard control plan shall be implemented, maintained and updated and relevant evidence retained as documented information.

危害控制计划应实施、保留和更新，相关的证据应作为文件化信息加以保留。

7.6.5 Actions when monitoring results exceed

critical limits 监视结果超出关键限值时采取的措施

应在 HACCP 计划中规定关键限值超出时所采取的策划的**纠正和纠正措施**。这些措施应确保查明不符合的原因，使关键控制点控制的参数恢复受控，并防止再次发生（7.10.2）

Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified in the HACCP plan. The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented (see 7.10.2).

应建立和保持形成文件的程序，以适当处置潜在不安全产品，确保评价后再放行（见 7.10.3）。

Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated (see 7.10.3).

8.6 Updating of preliminary information and documents specifying the PRP and hazard control plan

Following the establishment and hazard control plan, the organization shall update the following information, if necessary:

制定 OPRP 计划和 (或) HACCP 计划后 , 必要时 , 组织应更新如下信息 :

a) characteristics of raw materials, ingredients and product-contact materials;

原料、辅料和与产品接触材料的特性 ;

b) characteristics of end products;终产品特性 ;

c) intended use; 预期用途

d) flow diagrams and descriptions of processes and process environment.

流程图、过程和过程环境描述 ;

When required, the hazard control and/or the PRP(s) shall be updated.

需要时 , 应对危害控制计划和或 PRP 更新。

8.7 Control of monitoring and measuring

The organization shall provide evidence that the specified monitoring and measuring methods and equipment in use is adequate for the monitoring and measuring activities related to the PRP(s) and the hazard control plan.

组织应提供证据表明采用的监视和测量方法以及设备 , 对于 PRP 和危害控制计划的监视和测量活动是适宜的。

The measuring equipment and methods used shall be:

所使用的测量设备和方法应 :

a) calibrated or verified at specified intervals prior to use,

使用前以规定的时间间隔校准或验证

b) adjusted or re-adjusted as necessary;进行调整或必要时再调整 ;

c) identified to enable the calibration status to be determined;

得到识别 , 以确定其校准状态 ;

d) safeguarded from adjustments that would invalidate the measurement results; and

防止可能使测量结果失效的调整 , 和

e) protected from damage and deterioration

防止损坏和失效。

The results of calibration and verification shall be retained as documented information. All equipment shall be calibrated using standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.

校准和验证结果应作为形成文件化的信息加以保留。所有设备应使用可追溯到国际或国家测量标准进行校准。当不存在上述标准时，标准或验证的依据应加以保留。

The organization shall assess and record the validity of the previous measurement results when the equipment or process is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

当发现设备或过程不符合要求时，组织应评估和记录以往测量结果的有效性。组织应对该设备以及任何受影响的产品采取适当的措施。

Software used in the monitoring and measurement within the food safety management system shall be validated by the organization, software supplier, or third party prior to use. Documented information on validation activities shall be maintained by the organization and the software shall be updated in a timely manner.

当计算机软件用于规定要求的监视和测量时，应确认其满足预期用途的能力，且确认应在初次使用前进行，必要时再确认

Whenever there are any changes, including software configuration/modifications to commercial off-the-shelf software they shall be authorized, documented and validated before implementation.

NOTE Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

8.8 Verification related to PRPs, OPRP plan and HACCP plan

8.8.1 Verification planning

The organization shall establish, implement and maintain a verification planning that defines the purpose, methods, frequencies and responsibilities for the verification activities.

组织应建立、实施和保持验证的策划，其规定了验证活动的目的、方法、频次和职责。

The verification activities shall confirm that:验证活动应证实：

a) the PRP(s) are implemented and effective; PRP 已实施且有效；

b) input to the hazard analysis is continually updated;

危害分析的输入持续更新；

c) the hazard control plan implemented is and effective;

危害控制计划已实施且有效；

d) hazard levels are within identified acceptable levels; and

危害水平在确定的可接受水平之内；

8.8.1 Verification planning

e) other actions determined by the organization are implemented and effective.

组织确定的其它措施得以实施且有效。

Verification results shall be retained as documented information and shall be communicated to the food safety team.

验证结果应作为形成文件化的信息加以保留，且应与食品安全小组沟通。

Where verification is based on testing of end product samples, and where such test samples show nonconformity with the acceptable level of the food safety hazard, the affected lots/batches of product shall be handled as potentially unsafe.

当验证是基于终产品的抽样，且测试样品的结果不满足食品安全危害的可接受水平时，受影响批次/批号的产品作为潜在不安全产品进行处置。

8.8.2 Analysis of results of verification activities

The food safety team shall systematically evaluate the individual results of verification plan including internal and external audits. Where verification does not demonstrate conformity with the planned arrangements, the organization shall take action to achieve the required conformity.

食品安全小组应系统地评价所策划验证的每个结果。当验证不能证实符合策划的安排时，组织应采取措施达到规定的符合性。

The analysis of the results of verification shall be an input of the verification of the food safety management system (see 9).

验证结果的分析应作为食品安全管理体系验证的输入(see 9)。

8.9.1 Corrections

The organization shall ensure that when critical limits for CCP(s) and/or action criteria for OPRPs are not met the products affected are identified and controlled with regard to their use and release.

组织应确保当 CCP 的关键限值或 OPRP 的行动限值未满足时，根据产品的用途和旅行要求，受影响的产品得到识别和控制。

The organization shall establish, maintain and update documented information that includes:

组织应建立、保持和更新文件化的信息，包括：

a) method of identification, assessment, correction and corrective action for affected end products to ensure their proper handling; and

受影响终产品的识别、评估、纠正和纠正措施，以确保对其正确的处置；

b) arrangements for review of the corrections carried out.

所实施的纠正评审的安排。

Products manufactured under conditions where critical limits are not met shall be identified and handled as potentially unsafe products.

在关键限值超出条件下生产的产品应得到识别并作为潜在不安全产品进行处置。

8.9.1.1 Where an action criteria for an OPRP is not met, the following shall be carried out:

当 OPRP 的行动限值未满足时，以下活动应执行：

a) determination of the cause(s) of failure;

确定失效原因；

b) determination of consequences of that failure with respect to food safety;

确定与食品安全有关的失效后果；

c) evaluation of potentially unsafe products.

评估潜在不安全产品；

The results of the evaluation shall be retained as documented information.

评估结果应作为文件化信息予以保留。

8.9.1.2 Documented information shall be retained to describe corrections taken on nonconforming products including:

文件化信息应保留，描述对不安全产品采取的措施，包括：

a) the nature of the nonconformity;

不符合的性质；

b) the cause(s) of the nonconformity;

不符合的原因；

c) the consequences as a result of the nonconformity; and

不符合的后果；

d) the traceability information related to the lots/batches of nonconforming products.

与不符合产品批号和批次有关的追溯信息。

8.9.2 Corrective actions

The organization shall make sure that data derived from the monitoring of OPRPs and CCPs are evaluated by designated personnel with sufficient competencies and the authority to initiate corrective actions.

通过监视 OPRP 和 CCP 获得的数据，应由具有能力的指定人员进行评估，该人员具备足够的知识和权限，以启动纠正措施。

The need for corrective actions shall be evaluated when critical limits for CCP(s) and/or action criteria for OPRPs are not met.

当 CCP 的关键限值 超出或 OPRP 的行动限值不满足时时，应评估是否需要采取纠正措施。

The organization shall establish and maintain documented information that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to bring the process back into control after a nonconformity is identified.

组织应建立和保留文件化的信息，以规定适宜的措施以识别和消除已发现的不符合的原因，防止其再次发生，并在不符合发生后，使相应的过程恢复控制。

These actions shall include:这些措施包括：

a) reviewing nonconformities (including customer complaints /regulatory inspection report)

评审不符合（包括顾客投诉和执行检查报告）；

b) reviewing trends in monitoring results that may indicate development towards loss of control;

评审监视结果可能和失控发展的趋势；

c) determining the cause(s) of nonconformities;确定不符合的原因；

d) evaluating the need for action to ensure that nonconformities do not recur;

评价采取措施的需求，以确保不符合不再发生；

e) determining and implementing the actions needed;

确定和实施所需的措施；

f) recording the results of corrective actions taken; and

记录所采取纠正措施的结果；

g) reviewing corrective actions taken to ensure that they are effective;

评审采取的纠正措施，以确定其有效；

Records of all corrective actions shall be retained as documented information.

全部纠正措施记录应作为文件化信息予以保留。

8.9.3 Handling of potentially unsafe products

潜在不安全产品的处置

8.9.3.1 General 总则

The organization shall take action(s) to prevent the nonconforming products from entering the food chain unless it is possible to ensure that:

组织应采取措施防止不符合产品进入食品链，除非有可能确保：

a) the food safety hazard(s) of concern are reduced to the defined acceptable levels;

相关的食品安全危害降至规定的可接受水平；

b) the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering into the food chain; or

相关的食品安全危害在进入食品链前将降至确定的可接受水平；

c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

尽管不符合，但产品仍能满足规定的相关食品安全危害的可接受水平。

8.9.3.1 General

Products that have been classified as potentially unsafe shall be held under control of the organization until they have been evaluated.

作为潜在不安全的产品应在评估之前处于受控状态。

If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal/recall.

当产品已离开组织的控制，并继而确定为不安全时，组织应通知相关方，并启动撤回。

The controls and related responses from relevant interested parties and authorization for dealing with potentially unsafe products shall be retained as documented information.

来自相关方的控制和呼应，以及处置潜在不安全产品的授权应作为形成文件化的信息加以保留。

8.9.3.2 Evaluation for release 放行的评价

Following evaluation, products affected by failure to meet critical limits for CCPs shall not be released but be dispositioned (see 8.9.3.3).

根据评价，不符合 CCP 关键限值的产品应不能放行，但应进行处理。

Following evaluation, products affected by failure to meet action criteria for OPRPs shall only be released as safe when any of the following conditions apply:

根据评价，不符合 OPRP 行动限值的产品 只有应用以下情况时才能放行：

a) evidence other than the monitoring system demonstrates that the control measures have been effective;

除监视系统外的其他证据证实控制措施仍有效：

b) evidence shows that the combined effect of the control measures for that particular product complies with the performance intended (i.e. identified acceptable levels);

8.9.3.2 Evaluation for release 放行的评价

证据表明，针对特定产品的控制措施的组合作用符合预期绩效（例如，确定的可接受水平）

c) the results of sampling, analysis and/or other verification activities demonstrate that the affected lot/batch of products complies with the identified acceptable levels for the food safety hazard(s) concerned.

抽样、分析和（或）其它验证活动的结果证实受影响批次/批号的产品符合确定的相关食品安全危害的可接受水平。

Records of results of evaluation for release of products shall be retained as documented information.
放行产品评估结果的记录应作为文件化信息加以保留。

8.9.3.3 Disposition of nonconforming products 不合格品的处理

Products that are not acceptable for release shall either be:

不能放行的产品应按如下之一进行处理：

a) reprocessed or further processed within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels;

在组织内部或组织外重新加工或进一步加工，以确保食品安全危害得到消除或降至可接受水平；

b) redirected for other use as far as food safety in the food chain is not affected;

只要食品链中的食品安全不受影响，可改做其它用途；

c) destroyed and/or disposed as waste. 销毁和（或）按废物处理。

Records of disposition of nonconforming product including designated approving authority shall be retained as documented information.

不符合产品的处理记录，包括指定的批准权限，应作为形成文件化的信息加以保留。

8.9.4 Withdrawal 撤回

The organization shall be able to ensure the complete and timely withdrawal of lots/batches of end products that have been identified as potentially unsafe by.

组织应能够确保完整、及时地撤回已被识别为潜在不安全的批次/批号的终产品，通过：

a) appointing personnel(s) having the authority to initiate and carry out the withdrawal, and
授予人员启动撤回和执行撤回的权限；和

b) establishing and maintaining documented information for:

建立和保留形成文件化的信息，为了：

1) notifying to relevant interested parties (e.g. statutory/regulatory authorities, customers and/or consumers);

通过相关方（如：立法和执法部门、顾客和（或）消费者）

2) handling withdrawn products as well as affected lots/batches of the products still in stock; and

处置撤回产品及库存中受影响的批次/批号产品，和

3) carrying out the sequence of actions to be taken.

按照顺序实施采取的措施

Withdrawn/recalled products and end products still in stock shall be secured or held under control of the organization until they are managed in accordance with 8.9.3.3:

撤回/召回的产品和库存中的产品应在组织的控制之下进行监控和扣留，直到按照 8.9.3.3 的要求进行管理。

The cause, extent and result of a withdrawal shall be retained as documented information and reported to the top management as input for the management review.

撤回的原因、范围和结果应作为形成文件化的信息加以保留，作为管理评审的输入之一向最高管理者汇报。

The organization shall verify the implementation and effectiveness of withdrawals through the use of appropriate techniques (e.g. mock withdrawal or practice withdrawal) and retain documented information.

组织应通过应用适宜技术（如模拟撤回或实际撤）验证撤回的实施和有效性，并保留文件化的信息。

9.1 Monitoring, measurement, analysis and evaluation 监视、测量、分析和评价

9.1.1 General 总则

The organization shall determine:组织应确定

a) what needs to be monitored and measured;

监视和测量的对象

b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;

适用时，监视、测量、分析和评价方法，确保有效结果；

c) when the monitoring and measuring shall be performed;

实施监视和测量的时机：

d) when the results from monitoring and measurement shall be analysed and evaluated.

分析和评价监视和测量结果的时机。

e) who shall analyse and evaluate the results from monitoring and measurements.

谁负责分析和评价监视和测量结果。

The organization shall retain appropriate documented information as evidence of the results.

组织应保留适当的形成文件化的信息，作为结果的证据。

The organization shall evaluate the food safety performance and the effectiveness of the food safety management system.

组织应评估食品安全绩效和食品安全管理体系的有效性。

9.1.2 Analysis and evaluation of the food safety management system

食品安全管理体系的分析和评价

The organization shall analyse the results of performance evaluation including the results of verification activities related to PRPs and the hazard control plan (see 8.8), the internal audits (see 9.2) and external audits.

组织应分析绩效评价的结果，包括与 PRP、危害控制措施、内审和外审有关的验证活动的结果。

The analysis shall be carried out in order to 应进行分析以实现:

a) confirm that the overall performance of the system meets the planned arrangements and the food safety management system requirements established by the organization,

证实体系的整体运行满足策划的安排和本组织建立食品安全管理体系的要求；

b) identify the need for updating or improving the food safety management system,

识别食品安全管理体系改进或更新的需求；

c) identify trends which indicate a higher incidence of potentially unsafe products or process failures,

识别表示潜在潜在不安全产品或过程失效高风险的趋势；

d) establish information for planning of the internal audit programme related to the status and importance of areas to be audited, and

确定信息，用于策划与受审核区域状况和重要性有关的内部审核审核方案；

) to provide evidence that any corrections and corrective actions that have been taken are effective.

提供证据证明已采取纠正和纠正措施的有效性。

The results of the analysis and the resulting activities shall be retained as documented information and shall be reported to top management and used as input to the management review (see 9.3) and the updating of the food safety management system (see 4.4).

分析的结果和由此产生的活动应作为形成文件化的信息予以保留，并向最高管理者报告，作为管理评审和食品安全管理体系更新输入。

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the food safety management system:

组织应按照策划的时间间隔进行内部审核，以提供有关食品安全管理体系的信息，是否：

a) conforms to:符合：

1) the organization' s own requirements for its food safety management system;

组织自身的食品安全管理体系的要求；

2) the requirements of this document;

本标准的要求。

b) is effectively implemented and maintained.

得到有效地实施和保持。

9.2.2 The organization shall:

组织应：

a) plan, establish, implement and maintain an audit programme (s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes and food safety controls concerned, changes impacting the organization and food safety management system, and the results of previous audits;

依据过程的重要性和食品安全控制关注点，对组织和食品安全管理体系产生影响的变化和以往的审核结果，策划、制定、实施和保持一个审核方案，审核方案包括频次、方法、职责、策划要求和报告；

b) define the frequency of the audit program based on the status and importance of the area to be audited;

根据拟审核区域的状况和重要性，规定审核方案的频次；

c) define the audit criteria and scope for each audit;

规定每次审核的审核准则和范围；

d) select competent auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

选择有能力的审核员进行审核，并确保审核过程的客观性和公正性；

e) ensure that the results of the audits are reported to relevant management;

确保相关的管理部门获得审核结果报告；

f) retain documented information as evidence of the implementation of the audit programme and the audit results;

保留作为实施审核方案以及审核结果的证据的文件化信息；

g) take necessary correction and corrective action within agreed timelines;

在协商一致的时间内采取必要的纠正和纠正措施；

h) shall ensure that the food safety management system is audited at a defined interval.

确保食品安全管理体系在规定的時間间隔进行了审核；

i) determine if the food safety management system meets the intent of the food safety policy (see 5.2), and food safety objectives (see 6.2).

确定是否食品安全管理体系满足食品安全方针的意图和食品安全目标。

NOTE 1 It is not necessary that the entire FSMS be audited at one time. The organization can choose to audit part of the food safety management system at predetermine times.

整个 FSMS 不必一次全部审核到，组织可在预定时间选择审核 FSMS 的一部分。

NOTE 2 ISO 19011 provides guidance for management system audits.

管理体系审核指南参见 GB/T19001

NOTE 3 The internal audit shall assess opportunities for improvement, and identify needs to change the food safety management system.

内部审核应评估改进机会，识别食品安全管理体系变更的需求。

Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.

跟踪活动应包括对所采取措施的验证和验证结果的报告。

9.3 Management review

9.3.1 General

Top management shall review the organization's food safety management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

最高管理者应按照策划的时间间隔对组织的食品安全管理体系进行评审，以确保其持续的适宜性、充分性和有效性。

9.3.2 Management review input 管理评审输入

The management review shall include consideration of:

管理评审应考虑下列内容：

a) the status of actions from previous management reviews;

以往管理评审采取措施的实施情况；

b) changes in external and internal issues that are relevant to the food safety management system including changes in the organization and its context (see 4.1);

有关食品安全管理体系的内外部因素，包括组织和其环境的变更；

c) information on the food safety performance and the effectiveness of the food safety management system, including trends in:

食品安全绩效和食品安全管理体系有效性的信息，包括以下趋势；

- result of system-updating activities (see 4.4 and 10.3);

体系更新活动的结果

- monitoring and measurement results; 监视和测量结果

- analysis of the results of verification activities related to PRPs and the hazard control plan; 与 PRP 和危害控制计划有关的验证活动结果的分析；

- nonconformities and corrective actions; 不符合和纠正措施

- audit results (internal and external) including inspection results; 审核结果（内部和外部）包括执法检查结果；

- performance of external providers; 外部供方绩效

- review of risks and opportunities and of the effectiveness of actions taken to address them, and
评审风险和机遇以及其应对措施的有效性；

- extent to which objectives of the food safety management system have been met; 食品安全管理体系目标的实现程度

d) the adequacy of resources; 资源的充分性；

e) any emergency situation, accident (see 8.4) or withdrawal/recall (see 8.9.4) that occurred;

任何发生的紧急情况、事故或撤回和召回

f) relevant information obtained through external and internal communication, including requests and complaints from interested parties;

通过内外部沟通得到的相关信息，包括相关方的要求和投诉；

g) opportunities for continual improvement.

持续改进的机会

The data shall be presented in a manner that enables top management to relate the information to stated objectives of the food safety management system.

数据应以能使最高管理者将信息与食品安全管理体系所声明的目标相联系的方式提交。

9.3.3 Management review output 管理评审输出

The outputs of the management review shall include:

管理评审的输出应包括：

a) decisions and actions related to continual improvement opportunities; and

与持续改进的机会有关的决定和措施；

b) any need for updates and changes to the food safety management system, including resource needs and revision of the food safety policy and objectives of the food safety management system.

食品安全管理体系更新和变更的需求，包括资源需求和食品安全方针和目标的修订

The organization shall retain documented information as evidence of the results of management review.

组织应保留作为管理评审结果证据的文件化的信息。

8.4.1 内部审核 Internal audit

8.4.1 内部审核 Internal audit

组织应按照策划的时间间隔进行内部审核,以确定食品安全管理体系是否：

The organization shall conduct internal audits at planned intervals to determine whether the food safety management system

a)符合策划的安排、组织所建立的食品安全管理体系的要求和本准则的要求；

conforms to the planned arrangements, to the food safety management system requirements established by the organization, and to the requirements of this International Standard, and

b)得到有效实施和更新。 is effectively implemented and updated.

策划**审核方案**要考虑拟审核过程和区域的状况和重要性，以及以往审核（见 8.5.2 和 5.8.2）产生的更新措施。应规定审核的准则、范围、频次和方法。审核员的选择和审核的实施应确保审核过程的客观性和公正性。审核员不应审核自己的工作。

10 Improvement

10.1 Nonconformity and corrective action

不符合和纠正措

10.1.1 When a nonconformity to the requirements of this document occurs, including those arising from complaints, the organization shall:

若出现与本标准要求的不符合，组织应：

a) react to the nonconformity and, as applicable:对不符合做出应对，适用时：

1) take action to control and correct it; 采取措施予以控制和纠正；

2) deal with the consequences;处置产生的后果

b) evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by:

通过以下活动，评价是否需要采取措施，以消除产生不符合的原因，避免其再次发生或者在其他场合发生；

1) reviewing the nonconformity;评审不符合

2) determining the causes of the nonconformity;确定不符合的原因 ;

3) determining if similar nonconformities exist, or could potentially occur;

确定是否存在或可能发生类似的不符合

c) implement any action needed;实施所需的措施 ;

d) review the effectiveness of any corrective action taken;评审所采取的纠正措施的有效性 ;

e) make changes to the food safety management system, if necessary.需要时 , 变更食品安全管理体系。

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

纠正措施有应与产生的不符合的影响相适应。

10.1.2 The organization shall retain documented information as evidence of:

组织应保留作为证据的文件化的信息 :

a) the nature of the nonconformities and any subsequent actions taken;

不合格的性质以及随后所采取的措施 ;

b) the results of any corrective action.

纠正措施的结果。

10.2 Continual Improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the food safety management system to enhance the operation of the organization.

组织应持续改进食品安全管理体系的适宜性、充分性和有效性 , 以加强组织的运营。

Top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication (see 7.4), management review (see 9.3), internal audit (see 9.2), analysis of results of verification activities (see 8.8.2), validation of control measure combinations (see 8.5.7), corrective actions (see 8.9.2) and food safety management system updating (see 10.3).

最高管理才应确保组织通过以下活动 , 持续改进食品安全管理体系的有效性 : 沟通(see 7.4)、管理评审(see 9.3)、内部审核(see 9.2)、验证活动结果的分析(see 8.8.2)、控制措施组织的确认(see 8.5.7)、纠正措施(see 8.9.2)和食品安全管理体系的更新(see 10.3)。

10.3 Updating the food safety management system

Top management shall ensure that the food safety management system is continually updated. To achieve this, the food safety team shall evaluate the food safety management system at planned intervals. The team shall then consider whether it is necessary to review the hazard analysis (see 8.5.6),

the established hazard control plan (see 8.5.8). The evaluation and updating activities shall be based on:

最高管理者应确保食品安全管理体系持续更新。为此,食品安全小组应按策划的时间间隔评价食品安全管理体系。小组应考虑评审危害分析(see 8.5.6)和已建立的危害控制计划(see 8.5.8)的必要性。评价和更新活动应基于:

a) input from communication, external as well as internal, (see 7.4);

内部和外部沟通的输入

b) input from other information concerning the suitability, adequacy and effectiveness of the food safety management system;

与食品安全管理体系适宜性、充分性和有效性有关的其他信息的输入

c) output from the analysis of results of verification activities (see 8.8.2), and

验证活动结果分析(see 8.8.2)的输入

d) output from management review (see 9.3).

管理评审的输出(see 9.3).

System updating activities shall be retained as documented information and reported as input to the management review (see 9.3).

体系更新活动应以文件化信息予以保留,并作为管理评审的输入(see 9.3).