



# **FAMI-QS CODE OF PRACTICE**

## **FAMI-QS**

## **操作规范**

**VERSION 6/ Rev. 4  
2018-10-02**

## TABLE OF CONTENTS 目录

|   |           |
|---|-----------|
| <b>1. Introduction 引言 .....</b>   | <b>5</b>  |
| <b>2. Scope 范围.....</b>   | <b>7</b>  |
| 2.1. FAMI-QS Scope FAMI-QS 范围.....  | 7         |
| 2.2. Exclusions to the Scope 不适用的范围.....  | 9         |
| <b>3. Terms and Definitions 术语和定义.....</b>  | <b>10</b> |
| <b>4. Context of the Operator 经营者环境.....</b>  | <b>17</b> |
| 4.1. Understanding the Operator and its context 理解经营者及其环境.....                                    | 17        |
| 4.2. Understanding the needs and expectations of interested parties 理解相关方的需求和期望 .....             | 17        |
| 4.3. Feed Safety and Quality Management System and its Processes 饲料安全和质量管理体系及其过程.....             | 18        |
| 4.4. Feed Safety and Quality Management System Documentation 饲料安全和质量管理体系文件 .....                  | 18        |
| 4.5. Determining the scope of the Feed Safety and Quality Management System 确定饲料安全和质量管理体系的范围..... | 20        |
| 4.6. Feed Safety and Quality Policy 饲料安全和质量方针 .....   | 20        |
| <b>5. Leadership 领导作用 .....</b>   | <b>22</b> |
| 5.1. Leadership commitment 领导作用和承诺 .....  | 22        |
| 5.2. Responsibilities 职责 .....  | 22        |
| <b>6. Planning 策划 .....</b>   | <b>24</b> |
| 6.1. Actions to address risks and opportunities 应对风险和机遇的措施 .....                                  | 24        |
| 6.2. Feed safety and Quality objectives and planning to achieve them 饲料安全和质量目标及其实现的策划 .....       | 24        |
| 6.3. Planning of Changes 变更的策划 .....  | 25        |
| <b>7. Good Manufacturing Practices 良好操作规范 .....</b>   | <b>26</b> |
| 7.1. Establishment 企业/工厂 .....  | 26        |
| 7.1.1. Local site environment 厂区环境 .....  | 27        |
| 7.1.2. Layout and workspace 布局及工作空间 .....   | 27        |
| 7.1.3. Internal structures and fittings 内部结构和设施 .....   | 27        |
| 7.2. Equipment 设备 .....   | 28        |
| 7.3. Storage 存储 .....   | 28        |
| 7.4. Utilities 公共设施 .....   | 30        |
| 7.4.1. Water supply 供水 .....  | 30        |
| 7.4.2. Ventilation 通风 .....   | 30        |
| 7.4.3. Compressed air and other gases 压缩空气和其他气体 .....   | 30        |
| 7.4.4. Lighting 照明 .....  | 30        |
| 7.5. Waste disposal 废弃物处置 .....   | 31        |
| 7.5.1. Waste control 废弃物控制 .....  | 31        |

|   |           |
|---|-----------|
| 7.5.2. Drains and drainage 排水系统 .....   | 31        |
| 7.6. Equipment suitability 设备适宜性 .....  | 32        |
| 7.6.1. Measuring devices 测量装置 .....   | 32        |
| 7.6.2. Maintenance 维护保养 .....   | 33        |
| 7.7. Measures for prevention of cross-contamination 防止交叉污染的措施 .....                                       | 33        |
| 7.8. Cleaning and sanitation 清洁和卫生 .....  | 34        |
| 7.8.1. Cleaning and sanitizing programmes 清洁和消毒计划 .....   | 34        |
| 7.8.2. Cleaning agents and tools 清洗剂和工具 .....   | 34        |
| 7.9. Pest control 虫害控制 .....  | 35        |
| 7.10. Personnel hygiene 个人卫生 .....  | 36        |
| 7.10.1. Personal behaviour and cleanliness 个人行为和清洁 .....  | 36        |
| 7.10.2. Clothing and protective equipment 工作服和防护装备 .....  | 37        |
| 7.10.3. Health status 健康状况 .....  | 37        |
| 7.11. Transport 运输 .....  | 37        |
| 7.11.1. Driver Responsibility 司机职责 .....  | 37        |
| 7.11.2. Transport of packed goods 包装产品的运输 .....   | 38        |
| 7.11.3. Transport of bulk products 散装产品运输 .....   | 38        |
| 7.12. Feed packaging information and customer communication 饲料包装信息及顾客沟通 .....                             | 39        |
| 7.13. Competence and training 能力和培训 .....   | 40        |
| 7.14. Awareness 意识 .....  | 40        |
| 7.15. Communication 沟通 .....  | 40        |
| 7.16. Complaint handling system 投诉处理系统 .....  | 40        |
| 7.16.1. Feed Safety Incident Communication (Crisis Management) 饲料安全事件沟通（危机管理） .....                       | 41        |
| 7.16.2. Recall procedures 召回程序 .....  | 42        |
| <b>8. Operation 运行 .....</b>  | <b>43</b> |
| 8.1. Operational planning and control 运行的策划和控制 .....  | 43        |
| 8.2. Determination of requirements for products 与产品有关要求的确定 .....  | 43        |
| 8.3. Design and development 设计和开发 .....   | 44        |
| 8.3.1. Design and development planning 设计和开发策划 .....  | 44        |
| 8.3.2. Design and development Inputs 设计和开发输入 .....  | 45        |
| 8.3.3. Design and development controls 设计和开发控制 .....  | 45        |
| 8.3.4. Design and development outputs 设计和开发输出 .....   | 45        |
| 8.4. Change control 变更控制 .....  | 46        |
| 8.5. Control of externally provided products and services 外部提供的产品和服务的控制 .....                             | 46        |
| 8.5.1. Type and extent of control of external provision – Contract Manufacturers 外部提供（合同制造商）控制类型和程度 ..... | 47        |
| 8.6. Purchased materials 原料采购 .....   | 48        |
| 8.6.1. Selection and management of suppliers 供应商的选择和管理 .....  | 48        |
| 8.6.2. Verification of incoming materials 购进原料的验证 .....   | 50        |

|  |           |
|--|-----------|
| 8.7. HACCP Programme HACCP 计划.....   | 51        |
| 8.7.1. Determination of critical limits for critical control points and monitoring 关键限值的确定和关键控制点监视 | 52        |
| 8.7.2. HACCP team leader HACCP 小组组长 .....  | 53        |
| 8.8. Control of Production 生产过程的控制.....  | 53        |
| 8.8.1. Identification and traceability 标识和可追溯性.....  | 53        |
| 8.8.2. Preservation of product 产品防护 .....  | 54        |
| 8.8.3. Post-delivery activities 交付后的活动 .....   | 54        |
| 8.8.4. Release of products 产品的放行.....  | 55        |
| 8.8.5. Control of nonconforming process outputs and products 不合格的输出和产品的控制.....                     | 55        |
| <b>9. Performance Evaluation 绩效评价.....</b>   | <b>57</b> |
| 9.1. Monitoring 监视 .....   | 57        |
| 9.2. Internal audit 内部审核.....  | 57        |
| 9.3. Management review 管理评审 .....  | 58        |
| <b>10. Improvement 改进.....</b>   | <b>60</b> |
| 10.1. Nonconformity and corrective action 不合格和纠正措施 .....   | 60        |
| 10.2. Continual improvement 持续改进 .....   | 60        |

## 1. Introduction 引言

The FAMI-QS Code of Practice provides requirements for implementing measures necessary to ensure feed safety and quality of products manufactured by processes, as defined by FAMI-QS. The text of the Code is designed to set out general requirements and to be used as a tool for Operators to develop their specific procedures.

FAMI-QS 操作规范提供了实施必要措施的要求，以确保由 FAMI-QS 定义的过程生产的饲料产品的质量和安全。规范文本的内容旨在制定一般性要求，并作为经营者制定具体程序的工具。

The Code covers requirements on Good Manufacturing Practices, on the HACCP programme and suggestions on continuous improvements to the design, management of operations and risks with a goal of maintaining feed safety and quality.

该操作规范涵盖了良好操作规范的要求，HACCP 计划和关于持续改进设计、操作和风险管理的建议，以保持饲料安全和质量为目标。

A set of Process Documents are provided as add-ons to the FAMI-QS Code. These are auditable documents, established in line with *Codex Alimentarius* (including HACCP programme) principles, for each process described in the Scope Chapter (see Chapter 2 of this document). The Process Documents are meant to check for specific risks per process and to provide information on how to deal with particular issues in a more detailed and practical way. These documents will be submitted to periodical review, in line with emerging relevant technological, scientific and legislative developments or statutory modification in the sector.

提供了一套过程文件，作为 FAMI-QS 操作规范的附件。这些文件是根据食品法典（包括 HACCP 计划）原则制定的可用于审核的文件，适用于范围章节（见本文件第 2 章）中描述的每个过程。过程文件的目的是检查每个过程的特定风险，并提供关于如何以更详细和实际的方式处理特定问题的信息。这些文件将定期提交评审，以符合与新兴的相关技术、科学和立法的发展或部门的法令修改。

The ultimate goal of this Code of Practice is to ensure feed safety by minimizing unsafe practices and the risk of hazardous ingredients entering the food chain. Feed is considered unsafe for its intended use if it is likely to pose a risk to (has adverse effect on) human or animal health, or if the food derived from food-producing animals is unsafe for human consumption.

该操作规范的最终目标是通过减少不安全操作和有害成分进入食品链的风险来确保饲料安全。如果饲料有可能对人类或动物健康构成威胁（产生不良影响），或源于食源性动物的食品对于人类食用是不安全的，则该饲料被认为是不安全的。

Compliance with FAMI-QS does not exonerate the Operator from meeting statutory or regulatory requirements including:

遵守 FAMI-QS 规范并不免除经营者满足法律法规要求的责任，包括：

- a) in the country where the Operator is based;  
经营者所在国；
- b) in the country where the final product coming from a FAMI-QS certified process is placed.  
经 FAMI-QS 认证的终产品的投放国。

In case there are no applicable feed regulatory requirements in the country of production and/ or destination, the Operator should follow the European regulatory guidelines.

如果在生产国和/或目的国没有适用的饲料法规要求，经营者应遵循欧洲法规准则。

The FAMI-QS Code of Practice is a public document and its contents can be followed freely by any Operator.  
Participation in the FAMI-QS auditable system is voluntary.

FAMI-QS 操作规范是一份公开文件，其内容可由任何经营者自由遵守。参与 FAMI-QS 体系审核是自愿的。

## 2. Scope 范围

This chapter helps Operators to identify their products, according to the definitions within the scope of this Code of Practice.

本章帮助经营者根据本操作规范范围内的定义确定其产品。

Operators wishing to get FAMI-QS certification or to extend the scope of already existing FAMI-QS certification, must follow the procedure described in the Rules for Operators.

希望获得 FAMI-QS 认证或扩大现有 FAMI-QS 认证范围的经营者必须遵守经营者规则中所述的程序。

### 2.1. FAMI-QS Scope FAMI-QS 范围

The Scope of FAMI-QS is Specialty Feed Ingredients. A specialty feed ingredient is defined as any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animals/ animal products and animal performance (*Codex Alimentarius and adapted*).

FAMI-QS 的范围是特殊饲料成分，特殊饲料成分是指任何有意添加的能够影响饲料或动物产品的特性和动物（生产）性能的成分，无论其是否具有营养价值，通常本身不作为饲料使用(*Codex Alimentarius and adapted*)。

Specialty feed ingredients can be obtained via the following production processes or their combination:  
特殊饲料成分可通过以下生产工艺或其组合获得：

- **Chemical** – The typical production process consists of a chemical reaction of organic and/or inorganic raw materials under defined conditions whereby organic and/or inorganic processing aids, steam, water, air and/or gas could be inserted into the process. After the synthesis the final product can be purified by for e.g. distillation/ crystallization/ filtration and dried.

**化学：**典型的生产过程是由有机和/或无机原料在规定条件下的化学反应组成，有机和/或无机加工助剂、蒸汽、水、空气和气体可加入到该过程中。经过合成，最终产品可以通过蒸馏/结晶/过滤和干燥等方式进行提纯。

- **Bioprocessing** – The process uses biological material or its components to obtain the desired product. Bioprocessing is mainly based on upstream processes to produce biological material (cell culture, fermentation) and downstream processes which include recovery, separation/purification of the desired material/ intermediate products, and possible preservations steps such as drying/ freeze drying and formulation.

**生物过程：**生物过程是利用生物材料或其成分获得所需的产品。生物过程主要是基于上游工序生产生物材料(细胞培养、发酵)和下游工序（包括回收、分离/提纯所需的材料/中间体产品），以及可能的保存步骤（如干燥/冷冻干燥和配制）。

- **Mining** – Mining is the extraction of valuable minerals or other geological materials from the earth. Mineral processing is mainly based on various mechanical means of crushing, grinding, washing, precipitating, etc. that enable the separation of valuable minerals from the source.

**采矿：**采矿是从地球上提取有价值的矿物质或其他地质材料。矿物加工主要是利用各种机械手段粉碎、研磨、洗涤、沉淀等，使有价值的矿物质从源头分离出来。

- **Extraction** – Extraction mainly is executed either by aqueous solution or by using organic solvents, or by a combination of both. The distinctive characteristics of such production methods are the combination of a

series of dissolution and precipitation steps, pH, temperature and moisture adjustments, in order to isolate the molecule from its organic matrix and further refine it to the desired properties.

The down-stream process(es) usual comprise of the removal of the solvent agent, distillation, temperature treatment to inactivate potentially harmful substances, drying, granulation, formulating, sieving and packaging.

**提取:** 提取主要是通过水溶液或使用有机溶液, 或两者的组合来进行。这种工艺的显著特点是将一系列的生产方法 (溶解和沉淀步骤、pH 值、温湿度调整) 相结合, 以便将分子从有机基质中分离出来, 并进一步将其提炼到所需的特性。下游工序通常包括去除溶剂、蒸馏、温度处理以灭活潜在有害物质、干燥、造粒、配制、筛选和包装。

- **Mixing** – Dry or liquid mixtures of one or more speciality feed ingredients with or without a carrier. These mixtures are not intended for direct feeding to animals or can be combined with the daily ration and must perform specific, technological, sensory, zootechnical or other functions related to the specialty feed ingredients.

**混合:** 一种或多种特殊饲料成分 (含或不含载体) 的固体或液体混合物。这些混合物不能直接用于饲喂动物, 或者可以配合日粮使用, 但必须体现特殊饲料成分相关的特定的, 技术性, 感官性, 动物养殖性或其他功能。

- **Formulations/ preparations** – The typical production process consists of mixing organic and/or inorganic raw materials in a solution until dissolved followed by drying the solution with a carrier before packaging of the final product. Processing aids such as steam, water, air, gas and solvents could be used in the process. Process is carried out under defined conditions.

**配方/制剂:** 有机和/或无机原料在溶液中混合直至溶解, 在成品包装前用载体干燥该溶液的典型的生产过程。蒸汽、水、空气、气体和溶剂等加工助剂均可用于该过程。该过程是在一定的条件下进行的。

Specialty feed ingredients must be defined and labelled with clear directions of use, according to the applicable animal feed legislation of the intended market. The regulatory status of the products will be under the responsibility of the Operator. The Operator must ensure that the product is in conformance with all necessary legal requirements including:

根据目标市场适用的动物饲料法规, 特殊饲料成分须明确并标明使用说明。产品的监管状态将由经营者负责, 经营者须确保产品符合所有必要的法律要求, 包括:

- being legally produced in the country of origin and  
在原产国合法生产, 且
- meeting the regulatory requirements of the country of destination.  
满足目的国的法规要求。

The Feed Chain Activities covered by FAMI-QS are the following:

FAMI-QS 覆盖的饲料链活动如下:

- **Production** – The processes and methods used to transform tangible inputs (raw materials, semi-finished goods) and intangible inputs (information, data) into goods. Resources are used in this process to create an output that is suitable for use or has exchange value.

**生产** – 用于将有形输入 (原材料, 半成品) 和无形输入 (信息, 数据) 转化为商品的过程和方法。在这个过程中, 资源用于创造适合使用或具有交换价值的输出。

- **Trade** – The action of buying, handling, storage, transporting and selling goods and services.  
**贸易** – 购买、处理、存储、运输和销售货物和服务的活动。

## 2.2. Exclusions to the Scope 不适用的范围

- 1) Complete feedingstuffs, e.g., mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration (*Article 2(c) of Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition*) are not covered within the scope.  
配合饲料，例如其成分足以作为日粮的混合物 (*Article 2(c) of Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition*)，不包含在范围内。
- 2) Any substance or combination of substances presented for treating or preventing disease in animals, which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals (e.g. Veterinary medicinal products as defined in Article 1 of Council Directive 2001/82/EC on the Community code relating to veterinary medicinal products), are not covered within the scope, with the exception of coccidiostats and histomonostats used as, for example, feed additives in the EU.  
用于治疗或预防动物疾病的任何物质或物质的组合，为了进行医学诊断或者恢复、矫正或改变动物的生理功能而可用于动物的物质 (e.g. Veterinary medicinal products as defined in Article 1 of Council Directive 2001/82/EC on the Community code relating to veterinary medicinal products) 不包括在该范围内，但在欧盟用作饲料添加剂的球虫抑制剂和组织抑制剂除外。

### 3. Terms and Definitions 术语和定义

The following terms and definitions are used in this Code and associated documents:

下列术语和定义适用于本规范及相关文件:

**Adequate:** The terminologies “adequate”, “where appropriate”, “where necessary”, or “sufficient” mean that it is up to the Operator in first instance to decide whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives of the Code. In determining whether a requirement is adequate, appropriate, necessary, or sufficient, account should be taken to the nature of the feed and of its intended use. (*adopted from EC Guidance Document 2005 on Regulation 852/2004/EC and modified*)

**足够:** 术语“足够”、“在适当情况下”、“必要时”或“充分”的含义是，首先由生产经营者决定一项要求对达到本规范的目标是否是必要、适当、足够或充分的。在确定一项要求是否足够、适当、必要或充分时，应考虑饲料的性质以及其预期用途。 (*adopted from EC Guidance Document 2005 on Regulation 852/2004/EC and modified*)

**Authorised personnel:** Persons who have skills, permission and purpose as specified by job descriptions, process descriptions or management.

**被授权人员:** 由职位描述、过程描述或管理规定的具有技能、许可和用途的人员。

**Batch:** Unit of production from a single site using uniform production parameters or a number of such units, when produced in continuous order and stored together. It consists of an identifiable quantity of feed which is determined to have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling. (*COM(2008)124 final and Regulation 767/2009/EC*)

**批次:** 当按连续订单生产且存储在一起时，来自单一工厂采用统一生产参数的生产单位或许多这样的单位。它由可定量的饲料组成，并且由共同的特性所决定，这些特性如原产地，品种，包装类型，包装者，发货人或标签。 (*COM(2008) 124 final and Regulation 767/2009/EC*)

**Calibration:** The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.

**校准:** 在适当的测量范围内，一台特定的仪器或装置产生的结果与可参照或可追溯的标准进行对比，对比的结果在规定的范围内的证明。

**Carrier:** Substance used to dissolve, dilute, disperse or otherwise physically modify a specialty feed ingredient in order to facilitate its handling, application or use without altering its technological function and without exerting any technological effect themselves. (*COM(2008)124 final & Regulation 767/2009/EC and adapted*)

**载体:** 用于溶解、稀释、分散或以其他物理方式改变特殊饲料成分，使其便于处理、应用和使用而不改变其技术功能，且本身并不发挥任何技术作用的物质。 (*COM(2008)124 final & Regulation (EC) 767/2009*)

**Carry-over:** Contamination of a material or product with another material or product that originates from previous use of equipment and would alter the quality and safety beyond the established specifications.

**残留:** 源自于以前使用设备的原料或产品对另一种原料或产品的污染，它将改变被污染原料或产品的质量和安全并超出既定的规范。

**Check/control:** Monitor and measure processes against policies, objectives and requirements for the product and report results. The state wherein correct procedures are being followed and criteria are being met. (*Codex Alimentarius*)

**检查/控制:** 根据方针、目标和产品要求对过程进行监视和测量，并报告结果。执行正确的程序满足标准要求。 (*Codex Alimentarius*)

**Compound feed:** Mixture of feed materials, whether or not containing feed additives, for oral animal feeding in the form of complete or complementary feed. (COM(2008)124 final & Regulation 767/2009/EC)

**配合饲料:** 饲料原料的混合物，不论是否含有饲料添加剂，以全价或补充饲料的形式用于饲喂动物。  
(COM(2008)124 final & Regulation (EC) 767/2009)

**Contaminant:** Any biological or chemical agent, foreign matter, or other substances not intentionally added to food or feed which may compromise food and/or feed safety or suitability. (*Codex Alimentarius and adapted*)

**污染物:** 并非有意添加但可能危及食品和/或饲料安全性或适用性的任何生物或化学物质，异物或其他物质。  
(*Codex Alimentarius and adapted*)

**Contamination:** The undesired introduction of impurities/contaminant (chemical or microbiological nature or of foreign matter), into or onto a raw material, intermediate, and products covered by FAMI-QS scope during production, sampling, packaging or repackaging, storage or transport. (*Codex Alimentarius and adapted*)

**污染:** 在生产、取样、包装或二次包装、存储或运输过程中，由杂质/污染物（化学或微生物性质的物质或外来物质）进入或附着于原料、中间产品、FAMI-QS 范围所覆盖产品而造成的非预期的引入。 (*Codex Alimentarius and adapted*)

**Contract Manufacturer:** A contract manufacturer is an external service provider performing (parts of) production processes leading to feed products or their mixtures on behalf of the Operator.

**合同制造商:** 负责执行（部分）生产过程，代表经营者提供饲料产品或其混合物的外部服务提供商。

**Control Measure:** any action and activity that can be used to prevent or eliminate a feed / food safety hazard or reduce it to an acceptable level. (*Codex Alimentarius and adapted*)

**控制措施:** 能够用于防止或消除饲料/食品安全危害或将其降低到可接受水平的行动或活动。 (*Codex Alimentarius and adapted*)

**Corrective Action:** Action to eliminate the cause of a detected nonconformity or other undesirable situation. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. (ISO 22000:2005)

**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。采取纠正措施是为了防止再发生而采取预防措施是为了防止发生。 (ISO 22000:2005)

**Crisis:** An event that represents an immediate and significant threat to animal and/or human health resulting from the production or supply of unsafe or illegal product; where the product has left the immediate control of the Operator. (*Synopses from articles 15 & 19, Regulation 178/2002/EC*)

**危机:** 由于不安全或非法产品的生产或提供导致对动物和/或人类健康产生直接和显著威胁的事件，同时该产品已脱离经营者的直接控制。 (摘自 *articles 15 & 19, Regulation 178/2002/EC*).

**Critical Control Point (CCP):** A step at which control can be applied and that is essential to prevent or eliminate a feed/ food safety hazard or to reduce it to an acceptable level. (*Codex Alimentarius and adapted*)

**关键控制点 (CCP) :** 能够进行控制，并且该控制是防止或消除某一饲料/食品安全危害或将其降低到可接受水平所必需的某一步骤。 (*Codex Alimentarius and adapted*)

**Critical Limit:** Minimum or maximum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of the Feed Safety Hazard. (FDA)

**关键限值 (CL) :** 在 CCP 中必须控制的生物的、化学的或物理的参数的最小值或最大值，以防止、消除饲料安全危害或将其降低到可接受水平。 (FDA)

**Cross-Contamination:** Contamination of a material or product with another material or product.

**交叉污染:** 一种原料或产品对另一种原料或产品的污染。

**Defect:** Nonconformity related to an intended or specified use. (ISO 9001:2015)

**缺陷:** 与预期或规定用途有关的不合格。 (ISO 9001:2015)

**Documented information:** Information required to be controlled and maintained by an Operator and the medium on which it is contained. (ISO 9000:2015 and adapted)

**成文信息:** 经营者需要控制和保持的信息及其载体。 (ISO 9000:2015 and adapted)

**Establishment:** Any unit of a feed business that carries out the manufacture/production and/or the placing on the market of products covered by FAMI-QS scope. (Regulation 183/2005/EC and adapted)

**企业:** 从事 FAMI-QS 范围所覆盖产品的制造/生产和/或将其投放市场的饲料经营的任何单位。 (Regulation 183/2005/EC and adapted)

**External provider:** An external provider can be a service provider, a contract manufacturer or a supplier of raw materials etc.

**外部供方:** 外部供方可以是服务提供商，合同制造商或原材料供应商等。

**Feed:** Any substance or product, including specialty feed ingredients, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals. (Regulation 178/2002/EC and adapted)

**饲料:** 用于饲喂动物的任何物质或产品，包括特殊饲料成分，不管是经过加工、部分加工或未经加工的产品。 (Regulation 178/2002/EC and adapted).

**Feed Fraud:** The intentional and economically motivated adulteration of feed. (USP Guidance on Food Fraud Mitigation Guidance and adapted)

**饲料诈骗:** 为了经济利益而故意进行的饲料掺假。 (USP Guidance on Food Fraud Mitigation Guidance and adapted)

**Feed Safety:** Concept that feed will not cause harm to animals and/or lead to contamination. (Codex Alimentarius and adapted)

**饲料安全:** 饲料不会对动物造成伤害和/或导致污染的概念。 (Codex Alimentarius and adapted)

**Feed Safety Hazard:** Biological, chemical or physical agent in feed, with the potential to cause an adverse health effect in animals and/or humans. (Codex Alimentarius and adapted)

**饲料安全危害:** 饲料中所含有的对动物和/或人类健康有潜在不良影响的生物、化学或物理的因素。 (Codex Alimentarius and adapted)

**Good Manufacturing Practice (GMP):** Processes and actions taken to maintain hygienic conditions throughout the food chain that provide the foundation for the HACCP Programme. Equivalent term: PRP (Pre-requisite Programme) (ISO 22000:2005)

**良好操作规范 (GMP) :** 在整个食品链中为保持卫生环境所必需的基本条件和活动，为 HACCP 计划提供基础。

等同术语: PRP (前提方案) (ISO 22000:2005)

**HACCP (Hazard Analysis and Critical Control Point) Programme:** A system which identifies, evaluates, and controls hazards which are significant for feed safety.

**HACCP (危害分析和关键控制点) 计划:** 一种识别、评价和控制对饲料安全有重大影响的危害的系统。

**Hazard analysis:** The process of collecting and evaluating information on hazards, and conditions leading to their presence, to decide which are significant for feed safety and therefore must be addressed in the HACCP Programme. (Codex Alimentarius)

**危害分析:** 收集和评价危害信息和导致其存在的条件, 确定哪些对饲料安全有重大影响, 然后在 HACCP 计划中予以解决的过程。 (*Codex Alimentarius*)

**Incoming material:** A general term used to denote raw materials delivered at the beginning of the production chain.  
**来料:** 用于表示在生产链开始时交付的原材料的通用术语。

**Intermediate (product):** Any material processed by the Operator before the final product is obtained. Substance that is manufactured for, and consumed in, or used for chemical processing, in order to be transformed into another substance. (*REACH Article 3(15)*).

**中间产品:** 在获得最终产品之前由经营者加工过的任何原料。用于制造、消费或用于化学加工以转化为另一种物质的物质。 (*REACH Article 3(15)*).

**Labelling:** Means the attribution of any words, particulars, trademarks, brand name, pictorial matter or symbol to a feed by placing this information on any medium referring to or accompanying such feed, such as packaging, container, notice, label, document, ring, collar or the Internet, including for advertising purposes. (*Regulation 767/2009/EC*)

**贴标签:** 将任何关于饲料属性的文字、条目、商标、品牌、插图或符号的信息, 包括用于广告目的, 通过任何媒介提及或附加在该饲料上, 如包装、容器、通知、标签、文件、环形物、封口处或网络。 (*Regulation 767/2009/EC*).

**Management System:** Set of interrelated or interacting elements of an organisation to establish policies and objectives and processes to achieve those objectives. (*ISO 9001:2015*)

**管理体系:** 组织建立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。 (*ISO 9001:2015*)

**Manual:** One document or a series of documents. (*ISO 9001:2015 and adapted*)

**手册:** 一个或一组文件。 (*ISO 9001:2015 and adapted*)

**Manufacture/production:** All operations encompassing receipt of materials, processing, packaging, repackaging, labelling, relabelling, quality control, release, storage, and distribution of products covered by FAMI-QS scope and related controls.

**制造/生产:** 所有涉及 FAMI-QS 范围所覆盖产品的原料接收、加工、包装、重新包装、贴标签、重新贴标签、质量控制、发放、存储和分销以及相关控制的所有操作。

**Must:** Compliance with a requirement which is mandatory for compliance with this standard (obligation to follow the exact requirement as stated by this Code).

**必须:** 遵守本标准的强制性要求。(有义务按照本文件规定的要求执行)。

**Non-compliance:** failure to adhere to an Act or its Regulations.

**不合规:** 未遵守某一法案或其条例。

**Nonconformity:** Non-fulfilment of a requirement. (*ISO 9000:2015*)

**不合格:** 未满足要求。 (*ISO 9000:2015*)

**Operator:** The natural or legal persons responsible for ensuring that the requirements of food/feed law are met within the feed business under their control. (*Regulation 178/2002/EC and adapted*).

**经营者:** 负责确保在其控制下的饲料业务满足食品/饲料法规要求的自然人或法人。 (*Regulation 178/2002/EC and adapted*)

**Organisation:** Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives. (ISO 9000:2015)

组织：为实现其目标，由职责、权限和相互关系构成自身功能的一个人或一组人。 (ISO 9000:2015)

**Plan:** To establish the objectives and processes necessary to deliver results in accordance with the Operator's policies regarding quality and safety.

策划：根据经营者的质量和安全方针建立实现结果所需的目标和过程。

**Policy:** Intentions and direction of an organisation, as formally expressed by its top management.(ISO 9001:2015)

方针：由最高管理者正式发布的组织的宗旨和方向。 (ISO 9001:2015)

**Pre-requisite Programme (PRP):** See 'Good Manufacturing Practice (GMP)'

前提方案 (PRP)：见“良好操作规范” (GMP)

**Preventive Action:** Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. (ISO 9000:2005)

预防措施：为消除潜在不合格或其他潜在不期望情况的原因所采取的措施。采取预防措施是为了防止发生，而采取纠正措施是为了防止再发生。 (ISO 9000:2005)

**Procedure:** Operations to be performed, precautions to be taken and measures to be applied directly or indirectly related to the manufacturing of a material or products covered by FAMI-QS scope. (Modified from ICH Q7A). A specified way to carry out an activity or a process. (ISO 9000:2005)

程序：与原料、或 FAMI-QS 范围所覆盖产品的生产相关的直接或间接执行的操作、采取的预防措施和使用的方法。 (Modified from ICH Q7A) 为进行某项活动或过程所规定的途径。 (ISO 9000:2005)

**Quality:** Degree to which a set of inherent characteristics fulfils requirements. (ISO 9000:2005)

质量：一组固有特性满足要求的程度。 (ISO 9000:2005)

**Raw material:** Any material which enters the manufacturing process of the products covered by the FAMI-QS scope. See 'Incoming Material'.

原材料：进入 FAMI-QS 范围所覆盖产品生产过程的任何原料。见“来料”

**Recall:** Any measure aimed at achieving the return of an unsafe feed that has already placed on the market by an Operator. Feed is considered unsafe if it has an adverse effect on human or animal health and/or will make the food derived from food-producing animals unsafe for human consumption.(adaptation of the definitions in Directive 2001/95/EC and Regulation 178/2002/EC)

召回：旨在将饲料经营者已投放市场的不安全饲料收回的任何措施。如果饲料对人类或动物健康有不利的影响，和/或源自食源性动物的食品对于人类消费是不安全的，则饲料被认为是不安全的。 (adaptation of the definitions in Directive 2001/95/EC and Regulation 178/2002/EC)

**Record:** Written documents containing actual data. Document stating results achieved or providing evidence of activities performed. (ISO 9000:2005)

记录：包含实际数据的书面文件，阐明所取得的结果或提供所完成活动的证据的文件。 (ISO 9000:2005)

**Regulatory requirement:** Obligatory requirement specified by an authority mandated by a legislative body.(ISO 9000:2015)

法规要求：立法机构授权的部门规定的强制性要求。 (ISO 9000:2015)

**Requirement:** Need or expectation that is stated, generally implied or obligatory. (*ISO 9000:2015*)

**要求:** 明示的、通常隐含的或必须履行的需求和期望。(*ISO 9000:2015*)

**Reworking / rework:** Action on a nonconforming product to make it conform to the requirements. (*ISO 9000:2005*)

**返工:** 为使不合格产品符合要求而对其采取的措施。(*ISO 9000:2005*)

**Risk:** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard. (*Regulation 178/2002/EC*)

**风险:** 对健康有不利影响发生的概率和该影响导致一种危害的严重程度的函数。(*Regulation 178/2002/EC*)

**Risk assessment:** Means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk Characterisation. (*Regulation 178/2002/EC*)

**风险评估:** 一个以科学为基础的过程，该过程包括四个步骤：危害识别、危害描述、暴露评估和风险描述。(*Regulation 178/2002/EC*)

**Safety:** See 'feed safety'.

**安全:** 见“饲料安全”

**Shelf life:** A defined time period for which a product fully complies with its specification if stored appropriately.

**保质期:** 如果储存得当，产品完全符合其规格要求的时间段。

**Should:** Means "must" and the activities, descriptions or specifications accompanied by the word "should" are intended to be mandatory, unless the manufacturer is able to demonstrate that the activity, description or specification is inapplicable or can be replaced by an alternative which must be demonstrated to provide at least an equivalent level of quality and safety assurance. (Operators are obligated to achieve the goal of the Code by appropriate means).

**应:** 意思是“必须”，用到“应当”这个词的活动、说明或规范都意指是强制性的，除非制造商能够证明这种活动、说明或规范是不适用的，或可以用其他可选方案来代替，但必须证明该选择方案至少能够提供相等水平的质量和安全保证（经营者有义务通过适当的手段达到规范的要求）。

**Site:** Area in which animal feed is handled, together with any immediate surrounding area. (*adapted from PAS 222*)

**现场:** 动物饲料处理区连同任何直接的周边地区。 (*adapted from PAS 222*)

**Sign / signature:** Confirmation of an authorised person in writing or by electronic means with controlled access.

**签署/ 签名:** 被授权人以书面或电子方式对所控制范围的批准/确认。

**Specialty Feed Ingredients:** Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animal products and animal performance (*Codex Alimentarius and adapted*).

**特殊饲料成分:** 任何有意添加的能够影响饲料或动物产品的特性和动物（生产）性能的成分，无论其是否具有营养价值，通常本身不作为饲料使用。(*Codex Alimentarius and adapted*)

**Specification:** A list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the test described. It establishes the set of criteria to which a material must conform to be considered acceptable for its intended use. 'Compliance to specification' means that the material, when tested according to the listed analytical procedures, meets the listed acceptance criteria. Document stating requirement. (*ISO 9000:2005*)

**规格:** 一系列参照分析程序进行的试验, 以及由数字限定、范围或描述试验的其他标准组成的适当的接受标准。它建立了一套标准, 一种原料只有符合这个标准才能被认为可接受用于其目的用途。“符合规格”意思是在根据所列的分析步骤进行试验时, 原料符合所列的接收标准。阐明要求的文件。(ISO 9000:2005)

**Stages of production, processing and distribution:** Any stage, including import, from and including the primary production of a feed, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the import, production, manufacture, storage, transport, distribution, sale and supply of feed.(Regulation 178/2002/EC)

**生产、加工和分销阶段:** 任何阶段, 包括进口, 从一种饲料的初级生产, 直到它的存储、运输、向最终消费者销售或供应, 以及与之相关的, 饲料的进口、生产、制造、存储、运输、分配、销售和供应。(Regulation 178/2002/EC)

**Statutory requirement:** Obligatory requirement specified by a legislative body. (ISO 9000:2015)

**法律要求:** 立法机构规定的强制性要求。(ISO 9000:2015)

**Sufficient:** See “Adequate”.

**充分:** 见“足够”

**Top management:** Person or group of people who directs and controls an organisation at the highest level. (ISO 9000:2015)

**最高管理者:** 在最高层指挥和控制组织的一个人或一组人。(ISO 9000:2015)

**Traceability:** The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed through all stages of production, processing and distribution. (Regulation 178/2002/EC)

**可追溯性:** 追溯和跟踪一种食品、饲料、食源性动物、以及预期通过生产、加工和销售的所有阶段引入食品或饲料中的物质的能力。(Regulation 178/2002/EC)

**Undesirable substances:** Any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for the animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production. (Directive 2002/32/EC)

**不良物质:** 存在于用于动物饲料的产品中和/或产品上, 对动物或人类健康或环境具有潜在危害, 或可能严重影响畜牧生产的, 除病原体之外的任何物质或产品。(Directive 2002/32/EC)

**Validation:** Obtaining evidence that the control measures will be effective. (ISO 22000:2005)

**确认:** 获取证据以证实控制措施有效。(ISO 22000:2005)

**Verification:** The application of methods, procedures, tests and other evaluations to confirm – through the provision of objective evidence – that specified requirements have been fulfilled. (Codex Alimentarius and adapted)

**验证:** 应用方法、程序、测试和其他评估方式 – 通过提供客观证据对规定要求已得到满足的认定。(Codex Alimentarius and adapted)

**Where appropriate:** See “Adequate”.

**适当时:** 见“足够”

**Where necessary:** See “Adequate”.

**必要时:** 见“足够”

## 4. Context of the Operator 经营者环境

### 4.1. Understanding the Operator and its context 理解经营者及其环境

The Operator must determine the external and internal risks that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its Feed Safety and Quality Management System.

经营者须确定与其宗旨和战略方向相关并影响其实现饲料安全和质量管理体系预期结果的能力的各种外部和内部风险。

The Operator must monitor, review and record the information about these external and internal risks.  
经营者须对这些外部和内部风险的相关信息进行监视、评审和记录。

Note1: Understanding the external context can be facilitated by considering risks arising from legal, regulatory, technological, market, cultural, and economic environments, whether international, national, regional or local.

注 1: 考虑来自于国际、国内、地区和当地的各种法律、法规、技术、市场、文化和经济环境风险，有助于理解外部环境。

Note2: Understanding the internal context can be facilitated by considering risks related to values, culture, knowledge and performance of the Operator.

注 2: 考虑与经营者的价值观、文化、知识和绩效等相关的风险，有助于理解内部环境

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

FAMI-QS Certified Operator is part of the global feed and food chain. Due to the impact or potential impact of interested parties on the Operator's ability to consistently provide speciality feed ingredients that meet customer and applicable statutory and regulatory requirements, the Operator must determine the following:

FAMI-QS 认证的经营者是全球饲料和食品链的一部分。由于相关方对经营者稳定提供符合顾客要求及适用法律法规要求的特殊饲料成分的能力具有影响或潜在影响，因此，经营者须确定以下内容：

- a) interested parties that are relevant to the Feed Safety and Quality Management System;  
与饲料安全和质量管理体系有关的相关方；
- b) requirements of those interested parties that are relevant to the Feed Safety and Quality Management System. The Operator must monitor and review the information about these interested parties and their relevant requirements;  
与饲料安全和质量管理体系有关的相关方的要求。经营者须监视和评审这些相关方的信息及其相关要求；
- c) regulatory requirements and ensure they are met;  
法规要求并确保满足；
- d) risks and opportunities that can affect conformity of products and the ability to enhance customer satisfaction and ensure all these are addressed;  
影响产品符合性和增强顾客满意能力的风险和机遇并确保这些问题得到解决；
- e) and focus on consistently providing products that meet customer and applicable regulatory requirements and ensure they are maintained.  
致力于持续提供满足顾客要求和适用法规要求的产品并确保保持。

#### 4.3. Feed Safety and Quality Management System and its Processes 饲料安全和质量管理体系及其过程

The Operator must establish, implement, maintain and continually improve a Feed Safety and Quality Management System, including the processes needed and their interactions, in accordance with the requirements of the FAMI-QS Code.

经营者须按照FAMI-QS规范的要求，建立、实施、保持和持续改进饲料安全和质量管理体系，包括所需过程及其相互作用。

The Operator must determine:

经营者须确定：

- a) the processes needed for the Feed Safety and Quality Management System and their application;  
饲料安全和质量管理体系所需的过程及其应用；
- b) the inputs required and the outputs expected from these processes;  
这些过程所需的输入和期望的输出；
- c) the sequence and interaction of these processes;  
这些过程的顺序和相互作用；
- d) the criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of these processes;  
所需的准则和方法（包括测量和相关绩效指标）以确保这些过程的有效运行和控制；
- e) the resources needed and how they are ensured;  
如何确保所需的资源；
- f) the risks and opportunities in accordance with the requirements, and plan and implement the appropriate actions to address them;  
与要求相关的风险和机遇，并策划和实施适当的应对措施；
- g) the methods for monitoring, measuring, as appropriate, evaluating processes and, if needed, changes to processes to ensure that they achieve intended results;  
监视、测量、评价过程的适当方法，如有需要，变更过程，以确保实现预期结果；
- h) the opportunities for improvement of the processes and the Feed Safety and Quality Management System;  
改进过程和饲料安全和质量管理体系的机会；
- i) and assign responsibilities and authorities for the processes.  
分配这些过程的职责和权限。

The Feed Safety and Quality Management System must ensure that all activities carried out by the Operator that could impact the feed safety and quality of the product are consistently defined, implemented and maintained at all levels.

饲料安全和质量管理体系须确保经营者执行的所有可能影响饲料安全和产品质量的活动，在各个层次上得到一致的确定、实施和保持。

The Feed Safety and Quality Management System must include documented information that the product consistently conforms to the regulatory requirements of the country of production (where statutorily required) and destination.

饲料安全和质量管理体系必须包括产品始终符合生产国和目的国法律法规要求（如有法律要求）的成文信息。

#### 4.4. Feed Safety and Quality Management System Documentation 饲料安全和质量管理体系文件

The Operator must have a documented management system which reflects all the aspects of this Code. Records must contain all relevant data to permit investigation of any nonconformity or deviation(s) from planned procedure(s).

经营者必须建立一个反映本规范所有方面的文件化管理体系。记录须包括可对任何不符合或与所策划程序的偏离进行调查的所有相关资料。

All quality and safety related activities must be recorded without delay after they have been performed. The design and nature of use of records is at the discretion of the Operator.

所有质量和安全相关活动须在执行后立即进行记录。记录的设计和使用的类型由经营者自行确定。

The Operator's Feed Safety and Quality Management System must include:

经营者饲料安全和质量管理体系须包括:

- a) Feed Safety and Quality Manual compliant with the FAMI-QS Code Requirements, including references to quality and feed safety procedures in support of the HACCP programme.  
符合 FAMI-QS 规范要求的饲料安全和质量手册，包括支持 HACCP 计划的质量和饲料安全程序；
- b) documented information determined by the Operator as being necessary for the effectiveness of the Feed Safety and Quality Management System;  
由经营者确定的饲料安全和质量管理体系有效性所必须的成文信息；
- c) a written Feed Safety and Quality Policy;  
书面的饲料安全和质量方针；
- d) documented information, records and information needed by the Operator to ensure the effective planning, operation and control of its processes and information, including HACCP plans and reviews and product crisis management procedure;  
经营者为确保有效的策划、运行和控制其过程和信息（包括 HACCP 计划和评审以及产品危机管理程序），所需的成文文件、记录和信息；
- e) reference(s) to the risk assessments where applicable according to the FAMI-QS requirements addressed in this code.  
适用时，本规范提及的根据 FAMI-QS 要求进行风险评估的引用。

The documented information must:

成文信息必须:

- f) have unambiguous contents: the title, nature and purpose must be clearly stated;  
内容明确：标题、性质及目的须明确说明；
- g) be approved, signed (written or electronically) and dated by appropriate authorised persons. No document must be changed without authorisation and all changes must be recorded;  
经适当的授权人批准，签署（书面或电子）并标注日期。未经授权不得对任何文件进行修改，如有更改，必须记录所有的更改；
- h) be legible, controlled and kept up to date;  
清晰、受控并保持最新；
- i) be available and suitable for use, where and when it is needed;  
在需要的场合和时机，均可获得并适用；
- j) be adequately protected (e.g. confidentiality status, improper use, or loss of integrity);  
予以妥善保护（如防止泄密、不当使用或缺失）；
- k) be kept, at least, for the shelf life of the product.  
至少要保存到产品的保质期。

Documented information of external origin, determined by the Operator to be necessary for the planning and operation of the Feed Safety and Quality Management System, must be identified, as appropriate, maintained with suitable access rights and controlled. 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.  
对于经营者确定的策划和运行饲料安全和质量管理体系所必需的来自外部的成文信息，经营者须进行识别，适当时，保持适当的访问权限并予以控制。对成文信息的“访问”可能意味着仅允许查阅，或者意味着允许查阅并授权修改。

#### **4.5. Determining the scope of the Feed Safety and Quality Management System** **确定饲料安全和质量管理体系的范围**

The Operator must determine the boundaries and applicability of the Feed Safety and Quality Management System to establish the concerned scope. The scope must specify the process, the products or product categories and production sites that are covered and addressed by the Feed Safety and Quality Management System.

经营者须确定饲料安全和质量管理体系的边界和适用性，以确定有关的范围。范围须明确饲料安全和质量管理体系所覆盖和涉及的过程、产品或产品类别以及生产场所。

The scope must include all activities, processes or products that are essential and can have an influence on the feed safety and quality of end product. When exclusions are made, the scope of the Feed Safety and Quality Management System must justify them.

范围须包括可能影响最终产品的饲料安全性和质量的所有必要的活动，过程或产品。当不适用时，饲料安全和质量管理体系的范围须说明理由。

The scope must be available and be maintained as an integral part of the Feed Safety and Quality Manual.  
作为饲料安全和质量手册的一部分，范围须可获得并得到保持。

#### **4.6. Feed Safety and Quality Policy 饲料安全和质量方针**

Top management must ensure that a Feed Safety and Quality Policy is established, implemented and maintained. This Feed Safety and Quality Policy must:

最高管理者须确保制定、实施和保持饲料安全和质量方针，饲料安全和质量方针须：

- a) be suitable for the purpose of the operation and the scope;  
与经营宗旨和范围相适应；
- b) include a commitment to provide safe specialty feed ingredients;  
包括提供安全的特殊饲料成分的承诺；
- c) include a commitment to satisfy applicable regulatory requirements;  
包括满足适用的法规要求的承诺；
- d) include a commitment towards continuous improvement of the Feed Safety and Quality Management System;  
包括持续改进饲料安全和质量管理体系的承诺；
- e) include a commitment to take the necessary actions for preventing fraud/adulteration;  
包括采取必要措施防止欺诈/掺假的承诺；
- f) provide a framework for setting and reviewing feed safety and quality objectives.  
为建立和评审饲料安全和质量目标提供框架。

The Feed Safety and Quality Policy must be:

饲料安全和质量方针须:

- g) available as documented information;  
可获得成文信息;
- h) communicated within by the Operator in appropriate language;  
以适当的语言在经营者内部得到沟通;
- i) available to interested parties, as appropriate;  
适宜时, 可为有关相关方所获取;
- j) communicated, implemented and maintained at all levels within the organisation;  
在组织内得到沟通、实施和保持;
- k) reviewed at planned intervals (at least yearly), to ensure its continuing suitability, adequacy and effectiveness. Records of this review must be maintained.  
按照策划的时间间隔 (至少每年一次) 进行评审, 以确保其持续的适宜性、充分性和有效性。须保持评审的记录。

## 5. Leadership 领导作用

### 5.1. Leadership commitment 领导作用和承诺

Top management must demonstrate leadership and commitment with respect to Feed Safety and Quality Management System by ensuring that:

最高管理者必须通过以下方面，证实其对饲料安全和质量管理体系的领导作用和承诺：

- a) the Feed Safety and Quality Policy and Objectives are established for the Feed Safety and Quality Management System and are compatible with the strategic direction and the context of the Operator;  
确保制定饲料安全和质量方针及目标，并与经营者环境相适应，与战略方向相一致；
- b) the resources needed for the Feed Safety and Quality Management System are available;  
确保饲料安全和质量管理体系所需的资源是可获得的；
- c) the Feed Safety and Quality Management System achieves its intended result(s);  
确保饲料安全和质量管理体系实现其预期结果；
- d) the Feed Safety and Quality Policy and Objectives direct and support persons to contribute to the effectiveness of the Feed Safety and Quality Management System;  
确保饲料安全和质量管理体系方针和目标指导和支持人员为体系的有效性作出贡献；
- e) the Feed Safety and Quality Policy and Objectives promote continual improvement;  
确保饲料安全和质量管理体系方针和目标推动持续改进；
- f) the Feed Safety and Quality Policy and Objectives support other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility;  
确保饲料安全和质量管理体系方针和目标支持其他相关管理者在其职责范围内发挥领导作用；
- g) the Feed Safety and Quality Policy is communicated, understood and applied by all internal and external parties concerned with the operation(s).  
确保饲料安全和质量管理体系方针和目标在经营者内部及外部相关方得到沟通，理解和应用。

### 5.2. Responsibilities 职责

Top Management must ensure that the responsibilities and authorisations for relevant roles within the Feed Safety and Quality Management System are assigned, communicated and understood within the organisation.

最高管理者必须确保饲料安全和质量管理体系内相关岗位的职责和权限在组织内部得到分配、沟通和理解。

The Operator must ensure that:

经营者必须确保：

- h) an organisational chart of the organisation is maintained and made available to the Operator's staff and relevant external bodies;  
保持组织机构图，并可为经营者的员工和外部相关方所获取；
- i) the job descriptions are available to clearly define the responsibilities of all staff involved in the production, handling, storage and distribution of products covered by the Feed Safety and Quality Management System scope;  
职位描述可被获取，并明确规定饲料安全和质量管理体系范围内参与生产、处理、存储和分发产品的所有员工的职责；
- j) responsibility and authority is assigned to ensure compliance with regulatory requirements;  
职责和权限被指定，以符合法规要求；
- k) responsibility is assigned in case of a feed safety incident;

职责被分配，以处理饲料安全事件；

- l) adequate resources are provided for the implementation, management and control of the HACCP programme;  
提供充分的资源确保HACCP计划的实施、管理和受控；
- m) a HACCP team leader is appointed;  
任命HACCP小组组长；
- n) the problems with regard to the Feed Safety and Quality Management System are identified and corrective actions undertaken;  
有关饲料安全和质量管理体系的问题被识别，并实施了纠正措施；
- o) actions are initiated to prevent the (re-)occurrence of nonconformities related to product's quality and safety.  
采取措施，以防止有关产品质量和安全的不符合（再）发生。

## 6. Planning 策划

### 6.1. Actions to address risks and opportunities 应对风险和机遇的措施

The Operator must monitor and review the information about the external and internal risks related to Feed Safety and Quality. The Operator must determine the risks and opportunities that need to be addressed, and must plan actions to address these risks and opportunities.

经营者必须监视和评审与饲料安全和质量有关的外部和内部的风险信息。经营者必须确定需要应对的风险和机遇，并策划应对这些风险和机遇的措施。

The actions must be proportionate to the context of the Operator and the requirements of interested parties. The actions must include the development and implementation of:

这些措施必须与经营者所处的环境及相关方的需求相适应。这些措施须包括下列内容的制定和实施：

- a) good Manufacturing Practices;  
良好操作规范;
- b) HACCP plan and reviews;  
HACCP计划和评审;
- c) emergency preparedness and response plan.  
应急准备和响应计划。

### 6.2. Feed safety and Quality objectives and planning to achieve them 饲料安全和质量目标及其实现的策划

The Operator must establish Feed Safety and Quality objectives at relevant functions and for relevant processes, throughout the organisation.

经营者必须针对组织中的相关职能和相关过程，建立饲料安全和质量目标。

The Feed Safety and Quality objectives must:

饲料安全和质量目标必须：

- a) be consistent with the Feed Safety and Quality Policy;  
与饲料安全和质量方针保持一致;
- b) be measurable, if practicable;  
可行时，可测量;
- c) take into account applicable regulatory or contractual requirements;  
考虑了适用的法规或合同要求;
- d) be monitored in a timely manner;  
适时予以监视;
- e) be communicated;  
予以沟通;
- f) be updated and revised as appropriate;  
适时更新和修订;
- g) promote continual improvement.  
促进持续改进。

Documented information related to the monitoring efforts must be retained.  
必须保留有关监视工作的成文信息。

### 6.3. Planning of Changes 变更的策划

Where the Operator determines the need for change in the Feed Safety and Quality Management System, the change must be carried out in a planned and systematic manner, according to written procedures. Changes must be approved by authorised personnel.

当经营者确定需要对饲料安全和质量管理体系进行变更时，变更须依据书面程序，按所策划的和系统的方式实施。变更须被授权人员批准。

The Operator must consider:

经营者必须考虑：

- a) the purpose of the change and any of its potential consequences;  
变更目的及其潜在后果；
- b) the integrity of the Feed Safety and Quality Management System;  
饲料安全和质量管理体系的完整性；
- c) the availability of resources;  
资源的可获得性；
- d) the allocation or reallocation of responsibilities, accesses and authorisations.  
职责或权限的分配或再分配。

## 7. Good Manufacturing Practices 良好操作规范

Where applicable, Good Manufacturing Practices (GMP) must be designed and established before proceeding to the hazard analysis. The Operator must maintain Good Manufacturing Practices to control:

适用时，在实施危害分析前须设计和制定良好操作规范。经营者必须保持良好操作规范，以利于控制：

- a) the likelihood of introducing contaminants to the product through the work environment;  
通过工作环境引起产品污染的可能性；
- b) the biological, chemical and physical contamination of products, including cross contamination between them;  
产品的生物性、化学性和物理性污染，包括产品之间的交叉污染；
- c) the levels of contaminants in the final products and processing environment.  
终产品和加工环境中的污染物水平。

The Good Manufacturing Practices must be:

良好操作规范必须：

- d) appropriate to the organisation and its context with regard to feed safety;  
与组织及其环境有关的饲料安全相适宜；
- e) appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled;  
与组织运行的规模和类型、制造和/或处置的产品性质相适宜；
- f) implemented across the entire production system, either as general programmes or as specific programmes for a particular product or operational line.  
在整个生产系统中实施，无论是普遍适用还是适用于特定产品或生产线。

### 7.1. Establishment 企业/工厂

Establishments must be designed, constructed and maintained in a manner that:

工厂须被设计、建造和维护以便于：

- a) facilitates satisfactory performance of all operations;  
设施满足所有操作的需要；
- b) eliminates or minimizes to acceptable levels the feed safety hazards associated with those operations;  
将操作中涉及的饲料安全危害消除或减小到可接受的水平；
- c) prevents contamination from the surroundings.  
防止环境造成的污染。

Establishments must be maintained in good order. Establishments must be designed, constructed and maintained to allow adequate drainage and cleaning.

工厂必须保持良好秩序。工厂必须设计、建造和维护，排水顺畅，便于清洁。

The establishment boundaries must be defined and documented. Access to the establishment must be managed to address feed safety hazards. Access by non-employees must be controlled in a manner depending on the risk to feed safety. Where it is not feasible to control access to the establishment, measures to prevent contamination must be taken.

工厂的边界须明确并形成文件。为应对饲料安全危害，须对进入工厂实施管理。基于饲料安全的风险，非员工的进入必须受控。对进入工厂的控制不可行时，必须采取预防污染的措施。

Access points to bulk material receiving lines must be identified and secured from unintended use, intrusion and contamination.

必须对散装原料接收线路的进入点进行识别并防止被非预期的使用、侵害和污染。

The Operator must provide appropriate work environment, in line with local regulations, including to achieve product conformity.

经营者必须提供适宜的工作环境，符合当地法规，包括实现产品的符合性。

The Operator must assess if feed safety hazards may be expected to occur by potential acts of sabotage, vandalism or terrorism and must put in place adequate protective measures.

经营者必须评估潜在阴谋破坏、肆意破坏或恐怖行为引起的饲料安全危害，并建立充分的防护措施。

### 7.1.1. Local site environment 厂区环境

Potential sources of contamination from the local site environment (such as air pollution, contaminated water, soil pollution, dust exposure) must be identified and assessed. Measures taken to protect against potential sources of contamination must be documented and reviewed for effectiveness.

对潜在的源自厂区环境的污染（如空气污染、水污染、土壤污染、暴露灰尘）须进行识别和评估。对潜在污染所采取的措施须形成文件，并评审其有效性。

Vegetation must be tended, removed or otherwise managed to address feed safety hazards where relevant.  
植被须被照料、移除或管理以应对相关的饲料安全危害。

### 7.1.2. Layout and workspace 布局及工作空间

Production process areas and workspaces must be designed, constructed and maintained to prevent and control feed safety hazards.

生产加工区域和工作空间须设计、建造和维护，以预防和控制饲料安全危害。

The establishment must be designed in such a way that the movement of materials, end products, and people don't contribute to any contamination.

工厂的设计须利于原料、产品的流转，人员不造成任何污染。

Testing areas and laboratories must be designed, located and operated so as to prevent contamination.  
检测区域和实验室的设计、位置和操作不得造成污染。

The lay-out, design, construction of the facilities and equipment must permit adequate cleaning and/or disinfection and be in such way to minimise the risk of error and to avoid contamination, cross-contamination and any generally adverse effects on the safety and quality of the feed.

设备和设施的布局、设计、结构须方便清洁和/或消毒，并减小因错误导致的风险，避免造成饲料安全和质量方面的污染、交叉污染和任何不利的影响。

### 7.1.3. Internal structures and fittings 内部结构和设施

Where applicable, process area walls, floors and floor-wall junctions must be cleanable. Structural materials must be resistant to the cleaning system applied. Standing water must be prevented and/or removed.

适用时，车间墙壁、地面及两者连接处须便于清洁。建筑材料须耐用且便于清洁。积水须防止产生和/或被清除。

Openings must be managed to prevent entry of foreign matter, precipitation and pests coming from the outside. This includes external openings for the transfer of materials within the establishment. Roofs in manufacturing and storage locations must be adequately drained and must not leak.

开放区域须被管理，防止异物、灰尘、害虫从外部进入，包括为传递物料进入场所的外部开口。生产和存储区域的房顶须排水良好，不渗漏。

Ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation. Growth of undesirable microorganisms and the shedding of particles that can affect the safety and quality of feed must be kept under control.

天花板和固定装置须设计、建造完善，以防止灰尘的积累和减少凝结。对影响饲料安全和质量的不良微生物的生长及碎物的脱落，须进行控制。

Ventilation systems and devices must be sufficient in number and capacity to prevent dirt or condensation from collecting on walls and ceiling. If necessary to keep rooms free of excessive steam and condensation, mechanical ventilation of sufficient capacity must be provided. If necessary, heating, cooling or air-conditioning systems must be designed and installed so that air-intake or exhaust vents do not cause contamination of products, equipment or utensils.

通风系统和设备在数量和能力上须充足，以防止灰尘或凝结物聚集在墙壁和天花板上。如果有必要控制房间过多的蒸汽和冷凝水，须提供有足够能力的机械通风。必要时，须设计和安装加热、冷却或空调系统，以便进风口、排风口不会造成产品、设备或器具的污染。

## 7.2. Equipment 设备

Equipment must be designed and located to permit access for operation, cleaning and maintenance.  
设备须设计和放置，以便于操作、清洁和维护。

Manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of the products concerned.

生产设备必须放置、设计、建造和维护，以适应有关产品的生产。

Where applicable, the equipment must be designed to facilitate manual or *Cleaning In Place* (CIP) and/or disinfection by having surfaces that are smooth, free of sharp angles, corners, crevices and with smooth welds.

适用时，设备必须被设计成便于手工操作或在线清洗 (CIP) 和/或消毒，表面平滑、无锐角、无死角、无裂缝、焊缝平滑。

Where applicable, equipment must be placed away from walls to allow easy access for cleaning and to prevent pest infestation.

适用时，设备放置必须远离墙壁，以方便清洁并防止虫害侵袭。

Mobile structures and equipment, including those which are used temporarily, must be managed to prevent contamination.

移动的结构和设备，包括临时使用的，必须被管理以防止污染。

## 7.3. Storage 存储

All storage activities, including owned and contracted storage services, must be controlled. Control measures for the storage must be adequate and documented.

所有存储活动必须受控，包括自有或外包存储服务。控制措施须充分并形成文件。

A storage management system must be in place. Deliveries into and loads out of each storage area/bin must be recorded. Where possible, stock rotation systems must be applied (e.g. First In - First Out (FIFO) or First Expired - First Out (FEFO)).

必须建立仓库管理系统。必须记录每个存储区域/容器的交货和装载情况。适用时，须建立库存周转系统（如先进先出或先到期先出）。

Storage conditions must be appropriate for the intended use of the material. Temperature and humidity and other environmental conditions must be controlled, where necessary.

存储条件必须适合物料的预期用途。必要时，温度、湿度和其他环境条件必须受控。

Storage must provide protection from dust, condensation, waste, pests and other sources of contamination.

存储须提供防护防止受到尘土、冷凝水、废弃物、虫害及其他来源的污染。

Dedicated storage areas for materials that have to be kept dry and appropriately ventilated must be provided. Storing materials directly on the floor must be avoided, if potential contamination is relevant.

专用的物料存储区域必须保持干燥，通风得当。存储物料不得直接落地存放以避免潜在的污染。

Sufficient space (risk based) must be maintained between packaged materials and walls to allow cleaning, inspection and pest control activities to be carried out. Packaging must be fit for purpose.

包装的物料与墙之间必须保持充分空间（基于风险），可实施清洁、检查、防虫害等活动。包装必须适合其目的。

For bulk – not free-flowing stores capable of storing more than one type of feed – bays must be identified and there must be a floor plan of the storage areas.

针对可能存储一种以上且流动性不佳的散装物料的存储设施，须识别其围堰，并建立存储区域的平面图。

Materials (i.e. feed, waste materials and hazardous chemicals, pharmaceutical products) with the potential to introduce a hazard must be separated during storage and secured based on suitable risk assessment and management procedure. Nonconforming materials must be identified and separated in a manner to prevent unintended use.

可能导致危害的物料（如饲料、废弃物、危险化学品、药物）在存储时必须隔离，并基于适当的风险评估和管理程序的要求进行保管。不合格的物料必须被识别及隔离，防止非预期使用。

Area for defective or customer returned products must be identified and separated.

用于存储有缺陷或顾客退回产品的区域必须被识别和隔离。

Storage areas/bins must be cleaned at planned intervals.

存储区域/容器须按计划定期清洁。

Dispatch area must be secured from material theft, uncontrolled access and contamination.

出货区域不得有无关人员进入，防止物料被盗和污染。

Note: Separation can be managed physically and/or electronically, as appropriate.

备注：适当，隔离可以物理方式和/或电子方式进行管理。

## 7.4. Utilities 公共设施

The provision and distribution routes for utilities, to and around processing and storage areas, must be designed to prevent contamination.

加工和存储区域公共设施的提供和分布，必须设计合理，防止污染。

### 7.4.1. Water supply 供水

All forms of water, used as a product ingredient or that comes into direct contact with feed or product contact surfaces, must be assessed on potential feed safety hazards.

用作产品配料或直接与饲料或产品表面接触的各种形态的水，必须评估其潜在的饲料安全危害。

Facilities for storage and distribution of water must be designed to meet specified water quality requirements.  
储存和传输水的设施必须设计成满足特定的水质要求。

Use of recycled water, including the supply system must be justified by a risk assessment.  
循环水的使用，包括供水系统，必须通过风险评估来证实其符合要求。

### 7.4.2. Ventilation 通风

Production and storage areas must be appropriately ventilated to prevent contamination. Measures must be taken to remove excess humidity and to facilitate drying after wet cleaning. Ventilation systems, including intake ports and filters, must be inspected and maintained.

生产和存储区域须适当通风，以防止污染。须采取措施去除过多的湿气，除湿后便于干燥。包括入口和滤网在内的通风系统，必须进行检查和维护。

### 7.4.3. Compressed air and other gases 压缩空气和其他气体

Air and gases that come into direct contact with feed, including those used for transferring, blowing or drying, must be suitable, for example, to prevent contamination.

与饲料直接接触的包括转移、鼓风或干燥用途的空气和气体，必须适宜，如防止污染。

Gases from combustion intended for direct contact with feed must not be a source of contamination. The fuel used as the combustion source must be fit for purpose.

燃烧产生的气体如直接与饲料接触，不应是污染的来源。用于燃烧的燃料必须适宜，符合其目的。

Oils used in compressors must not compromise product integrity (for example, should be of appropriate technical grade, e.g. food, if possibility of contact with product could occur).

压缩机用油不得对产品造成影响（例如，应有适当的技术级别，如食品级，在可能与产品发生接触的情况下）。

### 7.4.4. Lighting 照明

Lighting must be of sufficient intensity to ensure that sanitary conditions can be maintained throughout the production and storage areas, as well as where equipment and utensils are cleaned including hand-washing areas and toilets.

生产和存储区域的照明强度必须充足，以确保能保持良好卫生条件，包括洗手区域和厕所的设备和用具的清洁。

Light fixtures must be designed in such a way to prevent contamination in the case of breakages. Lights must be shatterproof and provisions for glass/brittle registry must be in place.

灯具必须固定并防止破碎造成污染。灯具必须是防碎的，玻璃/易碎品须进行登记。

## 7.5. Waste disposal 废弃物处置

### 7.5.1. Waste control 废弃物控制

Containers for waste must be closed and:

废弃物容器必须密闭且：

- a) clearly identified for their intended use, marked and designated for that purpose only;  
能清晰地识别出它们的预期用途，标记并指定仅用于该目的；
- b) located in a designated area;  
放置在指定区域；
- c) designed to be regularly and effectively emptied.  
定期有效清空。

Provision must be made for the segregation, storage and removal of waste. Removal frequencies from production areas must be managed to avoid accumulations. Waste accumulation in general must be limited as it poses a risk of pest infestation. Waste must be managed in a manner that prevents attraction and harbouring of pests.

必须提供隔离、存储和转移废弃物用的容器。规定从生产区域转移的频率，避免废弃物累积。规定废弃物累积的总体上限，避免导致害虫孳生的危害。废弃物须以预防吸引和滋生害虫的方式进行管理。

Materials (bulk or packaged) designated as waste must be disposed of in a manner that prevents unauthorised use.  
作为废弃物的物料（散装或包装）必须以防止未经授权使用的方式处置。

Waste and materials not suitable as feed should be isolated and identified. Any such materials including those containing hazardous levels of veterinary drugs, contaminants or other hazards must be disposed of in an appropriate way and not used as feed.

废弃物和不适合用作饲料的物料应被隔离和标识。包括那些含有危险等级的兽药、污染物或其他危害的任何这类物料，必须以适宜的方式处置，不得用作饲料。

### 7.5.2. Drains and drainage 排水系统

Drains must be designed, constructed and maintained so that contamination is prevented. Drains must flow freely and have sufficient capacity to handle expected loads.

排水沟必须设计、建造并维护，以防止污染。排水沟须通畅，有足够的容量处理预期的负荷。

Drains should not leak and be located in such a way that materials would not be contaminated if a leak occurred. Drainage direction must not be from a contaminated area to a clean area.

排水沟不应泄露，并应按照发生泄漏时不造成物料污染的方式布置。排水方向不得从污染区流向洁净区。

Sewage, waste and rainwater must be disposed of according to local regulations and in a manner which ensures that equipment and the safety and quality of feed is not affected.

生活污水、废弃物和雨水的处置必须符合当地法规要求，确保设备及饲料的安全和质量不受影响。

## 7.6. Equipment suitability 设备适宜性

### 7.6.1. Measuring devices 测量装置

All measuring, metering and dosing devices used in the manufacture of specialty feed ingredients must be fit for purpose.

所有用于特殊饲料成分生产的测量、计量、定量装置必须适合其预期目的。

The Operator must establish processes to ensure that monitoring and measurement can be carried out in a manner consistent with documented procedures and must retain appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources.

经营者必须建立过程，确保监视和测量的执行符合文件化程序的要求，并保留适当的成文信息作为监视和测量资源适用性的证据。

Measuring and dosing devices essential to quality and feed safety must be identified and must meet the following conditions:

用于质量和饲料安全方面的测量和定量装置必须被识别，并符合下列要求：

- a) be calibrated or verified, at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards. Where no standards exist, the basis for calibration or verification must be recorded;  
对照能溯源到国际或国家标准的测量标准，按照规定的时间间隔或在使用前进行校准或检定。当不存在上述标准时，必须记录校准或验证的依据；
- b) be adjusted or re-adjusted as necessary;  
必要时进行调整或再调整；
- c) be identified to show the calibration status;  
予以识别，以确定其校准状态；
- d) be safeguarded from adjustments that would invalidate the measurement result;  
防止可能使测量结果失效的调整；
- e) be protected from damage and deterioration during handling, maintenance and storage.  
在处理、维护和存储期间防止损坏或失效。

In case of external calibration, the laboratory must be accredited against ISO/IEC 17025 or equivalent. In case of internal calibration, all the reference materials must be certified.

如需外部校准，实验室必须通过 ISO/IEC 17025 认可或具有同等的资格。进行内部校准时，所用的全部标准物质/标准样品必须经过认证。

In addition, the Operator must assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The Operator must take appropriate action on the equipment and any product that might have been affected. Records of the results of calibration and verification must be maintained.  
此外，当发现设备不符合要求时，经营者必须对以往测量结果的有效性进行评估和记录。经营者必须对该设备和任何可能受影响的产品采取适当的措施。校准和验证结果的记录须予以保持。

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application should be verified. This verification should be undertaken prior to initial use and reconfirmed if necessary. For existing software, verification can be based on legacy data/performance. If a computer software is used to control a CCP, its ability to satisfy the intended application should be validated.

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。确认应在初次使用前进行，必要时再确认。已有应用的软件，验证可依据以往的数据/表现。如果计算机软件用于控制 CCP，其满足预期用途的能力应进行确认。

### 7.6.2. Maintenance 维护保养

A documented preventive maintenance programme must be in place and must include manufacturing equipment, and all devices used to monitor and/or control feed safety hazards.

必须建立文件化的预防性维护保养计划，包括制造设备及所有用于监视和/或控制饲料安全危害的装置。

Sanitary requirements must apply to maintenance activities. Maintenance personnel must be trained in the feed hazards associated with their activities.

维护保养活动必须考虑卫生要求。维护保养人员须接受与其活动相关的饲料危害的培训。

Maintenance requirements that affect product quality and safety must be given priority. Maintenance activities must be performed in a manner that prevents contamination. Maintenance activities in production process areas must be recorded.

须优先制定影响产品质量和安全的维护保养要求。维护保养活动的实施必须以防止污染的方式进行。生产加工区域的维护保养活动必须被记录。

A procedure for the release of the equipment under maintenance must exist and must specify cleaning and pre-use inspection measures.

必须制定设备维护保养后放行的程序，且必须明确清洁和使用前的检查措施。

Temporary fixes must not put feed safety at risk. A request for replacement by a permanent repair must be included in the maintenance schedule.

临时维修不得造成饲料安全风险。维护保养计划中必须包括彻底修复的要求。

Lubricants and heat transfer fluids must be fit for purpose and meet appropriate statutory requirements, where relevant, wherever there is a risk of direct or indirect contact with feed.

润滑油和导热液体必须符合使用目的，且符合适当的法规要求，因为任何直接或间接接触饲料都会有风险。

## 7.7. Measures for prevention of cross-contamination 防止交叉污染的措施

Programmes must be in place to prevent, control and detect potential cross-contamination.

必须建立预防、控制和查明潜在交叉污染的方案。

Where appropriate, a zoning plan (e.g. different levels of sanitation requirements) must be implemented to prevent cross-contamination.

在适当情况下，必须实施分区规划（如不同卫生要求等级）以防止交叉污染。

Based on risk assessment(s), procedures to prevent potential physical, chemical and/or biological cross-contamination must be implemented. Cross-contamination must be prevented or controlled by use of dedicated lines, cleaning, line changeover practices (such as flushing) and/or product sequencing.

根据风险评估，必须实施预防潜在物理、化学和/或生物交叉污染的程序。通过使用专用线路、清洁、线路转换操作（如冲洗）和/或产品生产顺序来防止或控制交叉污染。

Effectiveness of procedures must be verified and documented. Verification that procedures are followed as well as validation studies must be recorded.

程序的有效性必须被验证和记录。验证该程序依照确认的方法落实，必须记录验证结果。

## 7.8. Cleaning and sanitation 清洁和卫生

### 7.8.1. Cleaning and sanitizing programmes 清洁和消毒计划

Cleaning programmes must be established to maintain sanitary conditions and documented.

必须制定文件化的清洁计划，以保持卫生条件。

Where identified in the risk assessment, sanitizing programmes must be established and documented. Programmes must be monitored for continuing suitability and effectiveness.

根据风险评估的识别，必须制定文件化的消毒计划。必须对该计划进行监视，以确保持续的适宜性和有效性。

Facilities and equipment must be maintained in a condition which facilitates wet or dry cleaning and/or sanitation. 设施和设备必须保持在便于湿或干洗和/或卫生的条件下。

Cleaning, and when applicable, sanitizing programmes must specify, as a minimum:

清洁计划（适用时，消毒计划）须至少明确下列内容：

- a) areas, items of equipment and tools to be cleaned and/or sanitized;  
拟清洁和/或消毒的区域、设备部件和工具；
- b) training of cleaning staff;  
清洁人员的培训；
- c) responsibility for the tasks specified;  
具体工作的职责；
- d) cleaning/sanitizing agents;  
清洗剂/消毒剂；
- e) method and frequency;  
方法和频率；
- f) monitoring and verification.  
监视和验证。

### 7.8.2. Cleaning agents and tools 清洗剂和工具

Cleaning agents must be used and stored according to the manufacturer's instructions, clearly labelled, separately stored from raw materials and finished products and applied properly to avoid contamination of raw materials and finished products. The material safety data sheet (MSDS) of the cleaning agent must be available.

清洗剂必须依据制造商的说明书使用和储存，标识清晰，与原料和终产品分开存放，适当使用，避免污染原料和终产品。必须收集清洗剂的化学品安全技术说明书（MSDS）。

After a wet cleaning procedure, the machinery coming into contact with feed must be dry enough for the next production.

经过湿洗后，与饲料接触的机器须足够干燥以便后续生产。

Where appropriate, disinfection may be necessary after cleaning, but traces of detergents and disinfectants must be minimised.

适当时，清洗后可能需要消毒，但清洗剂和消毒剂的残留须减至最低。

Chemicals that are strongly scented or could give rise to taint and odour contamination must not be used.  
不得使用有强烈气味或可能引起污染和气味污染的化学品。

Materials and equipment used for cleaning toilets must be segregated from those used elsewhere.  
用于清洗厕所的材料和设备必须与在其他地方所使用的材料和设备分开。

## 7.9. Pest control 虫害控制

Sanitation, cleaning, incoming materials inspection, storage and monitoring procedures must be designed and implemented to avoid creating an environment conducive to pest activity.

必须建立和实施卫生、清洁、来料检验、存储和监视程序，以避免产生有利于有害生物活动的环境。

Feed production and storage buildings must be maintained in a manner to prevent pest access. Windows and other openings must, where necessary, be proofed against pests. Doors must be close-fitting and proofed against pests when closed.

饲料生产和存储的建筑必须保持防止害虫进入的状态。必要时，窗户和其他开口处必须密封以防虫。关闭时，门应能关紧，且密封以防虫。

Storage and material handling practices must be designed to avoid the availability of feed and water to pests. Spilled materials and waste must be efficiently managed to prevent availability to pests.

存储和原料处理的操作，必须考虑避免为害虫提供饲料和水。必须有效管理溢出的物料和废弃物，避免被害虫利用。

A preventive pest control programme must:

预防性虫害控制计划必须：

- a) be maintained at manufacturing, storage and transport facilities under the Operator's control;  
在经营者控制范围内的制造、存储、运输设施得以保持；
- b) have description of periodic reviews including physical inspections and their frequency of inspections must be determined by risk assessment and must be documented;  
有包括物理检查在内的定期评审的描述，该检查应形成记录，检查频率由风险评估决定；
- c) be clearly defined and reflect the activities of the site, targeted pests, preventive plans and control procedures for prevention;  
明确地规定和反映现场活动、目标害虫、预防计划和预防性控制程序；
- d) be reviewed for effectiveness;  
评审其有效性；
- e) assure the qualification of the external pest controller.  
确保外包虫害控制人员的资格。

The hazard analysis must consider the risk of contamination due to infestation or use of pesticides.  
危害分析必须考虑由于虫害或使用杀虫剂导致的污染风险。

The results of the pest control must be regularly reviewed and necessary actions taken.

Pest monitoring programmes must include the placing of pest control devices in key locations to identify pest activity. A map of pest control devices must be maintained. Pest control devices must be designed and located so as to prevent potential contamination of materials, products, equipment or facilities.

虫害控制的结果必须定期进行评审，必要时采取措施。

虫害监控计划必须识别虫害活动，包括在关键位置放置虫害控制装置。

必须保持虫害控制装置布置图。虫害控制装置必须设计和定位，防止对原料、产品、设备或设施的潜在污染。

Control and/or eradication measures must be put in place immediately after evidence of infestation is reported.

Pesticide use and application must be restricted to trained staff and must be controlled to avoid feed safety hazards.

在出现虫害侵扰后，必须立即实施控制和/或消灭措施。杀虫剂的使用和应用必须由经过培训的员工操作，必须受控，避免造成饲料安全危害。

Records of pesticide use must be maintained to show the type, quantity and concentrations used, where, when and how applied, and the target pest.

必须保持杀虫剂使用记录，记录使用杀虫剂的类型、数量、浓度、地点、时间、使用方法以及目标害虫。

## 7.10. Personnel hygiene 个人卫生

Requirements for personal hygiene and behaviour must be established and documented. All personnel, visitors and contractors must be required to comply with the documented requirements.

个人卫生和行为的要求必须制定并形成文件。所有员工、访客和承包方都应遵守该文件的要求。

The Operator must inform visitors and contractors about hygiene and health requirements before being allowed into feed production and storage areas.

在被允许进入饲料生产和存储区域前，经营者须告知访客和承包方有关卫生和健康的要求。

### 7.10.1. Personal behaviour and cleanliness 个人行为和清洁

A documented procedure must describe required personal behaviour. The procedure must, as a minimum, cover:  
文件化的程序应描述个人行为要求。程序要求须至少包括：

- a) permissibility of eating, drinking, gum chewing and tobacco use in designated areas. All human food must be stored, prepared and consumed in designated areas;  
在指定区域内吃饭、喝水、嚼口香糖和吸烟。所有食物必须在指定的区域存储、准备和食用；
- b) control measures to avoid hazards presented by jewellery and other items carried by a person;  
为避免人员佩戴首饰和携带其他物品而出现危害的控制措施；
- c) staff hygiene, sanitary facilities and toilets must be available, clearly designated and maintained;  
员工卫生、消毒设施和厕所必须可用，设计得当，维护方便；
- d) permissibility of personal items, such as smoking materials and medicines, in designated areas;  
在指定区域内存放个人物品，如吸烟材料和药品；
- e) availability of separate lockers for private clothes and working clothes to avoid a contamination. Maintenance of the personal lockers so that they are kept free from rubbish and in an acceptable state;  
提供单独的储物柜存放私人衣物和工作服，以避免污染。维护个人储物柜，使其不受垃圾污染，处于可接受状态；
- f) instructions on unacceptable behaviour. These include sneezing or coughing over open product or product contact surfaces and no spitting allowed. Fingernails must be kept clean and trimmed.

说明不可接受的行为。这些行为包括在开放的产品或产品接触面上方打喷嚏或咳嗽，不允许吐痰。指甲必须保持整洁。

Staff in feed production and storage areas must maintain personal hygiene to prevent contamination. Hand washing must be conducted before starting any working shift, after using the toilet and immediately after handling different products and or potential contaminants that could lead to a feed safety risk.

饲料生产和存储区域的员工必须保持个人卫生以防止污染。每班班前，使用厕所后，以及处理不同产品和/或潜在的可能导致饲料安全危害的污染物后时，必须洗手。

### 7.10.2. Clothing and protective equipment 工作服和防护装备

The Operator must provide staff who work in areas where feed is handled, with appropriate workwear such as protective clothing, safety footwear and other protective equipment that does not pose a feed safety risk.

经营者必须为饲料操作区域的员工提供适当的工作服，如防护服、安全鞋和其他防护装备，且不导致饲料安全风险。

If gloves are worn, control is needed to ensure that there is no risk of contamination of the finished product from them.

如果手套磨损，需要控制以确保不对终成品造成污染的危害。

Clothing and protective equipment must be maintained in hygienic conditions.

工作服和防护装备必须保持卫生。

The Operator must define appropriate dress code for visitors and contractors.

经营者必须确定针对访客和承包方的适当的着装规范。

### 7.10.3. Health status 健康状况

Operator must have a written procedure regarding medical care. Where permitted by law, staff must inform the Operator of any condition, disease or illness that may be transmissible through feed.

经营者必须建立书面的医疗救护程序。在法律允许情况下，员工须告知经营者任何可能通过饲料传播的传染病、疾病。

## 7.11. Transport 运输

An Operator must include the below stated requirements in their communication with the transporters.  
经营者与运输方的沟通须包括下列规定的要求。

However, a FAMI-QS Operator is exempted from these requirements when using a transporter certified against one of the FAMI-QS recognised standards for transport. To verify which standards are recognized by FAMI-QS, regarding transports, please consult the Document P-MS-003, available in FAMI-QS website.

当然，当运输商通过了 FAMI-QS 认可的运输标准的认证，FAMI-QS 经营者可免除这些要求。关于运输，为证实 FAMI-QS 认可的标准有哪些，请参阅在 FAMI-QS 网站上提供的文件 P-MS-003。

### 7.11.1. Driver Responsibility 司机职责

The transport company must ensure that the driver in charge of transport:

运输公司须确保负责运输的司机：

- a) is aware of her/his responsibility in terms of product preservation during cleaning, loading, transport and unloading activities;  
在清洁、装载、运输和卸货活动中，知晓他/她在产品防护方面的责任；
- b) if necessary, takes preventive actions to avoid any kind of contamination during cleaning, loading, transport and unloading activities;  
必要时，在清洁、装载、运输和卸货活动中，采取预防措施避免任何污染；
- c) informs the Operator as agreed, directly or via own organisation, of any nonconformity that could compromise the safety of the goods.  
依照约定，直接或通过自己的组织，通知经营者任何可能危害产品安全的不符合。

The transport company must document and maintain evidence of education and training of driver personnel.  
运输公司须记录和保持对司机进行与饲料运输相关的教育和培训的证据。

### 7.11.2. Transport of packed goods 包装产品的运输

Transports should be fit for purpose. Operator must ensure that product integrity is maintained during transportation.

运输应符合其目的。经营者必须确保在运输过程中保持产品完整。

Note: Products must not be transported, even if sealed, with goods that might compromise the safety of the raw material or the finished product. The chosen transport vehicle must be designed to protect the packaged goods against adverse effects (e.g. humidity, scratches in package). The transport vehicle must be designed to avoid any risk of cross-contamination with impurities coming from other goods loaded on the same vehicle at the same time or in a previous loading.

备注：即使密封的产品也不得与可能导致安全危害的原料或产品同时运输。选择的运输车辆需按照保护包装货物免受不利影响（如潮湿、刮伤）的方式设计。运输车辆的设计需能够避免来自本次或前次装载在同一车辆上其他货物的杂质产生交叉污染的风险。

### 7.11.3. Transport of bulk products 散装产品运输

#### 1) Prerequisites前提条件

The transport company must ensure that the containers for transport:  
运输公司必须确保运输容器：

- a) can be effectively cleaned and maintained to avoid contamination of the feed. This applies in particular to materials and surfaces which come into direct contact with feed;  
被有效清洁和维护，避免饲料受到污染，尤其适用于直接与饲料接触的物料和表面；
- b) are in good technical condition;  
有良好的技术条件；
- c) are appropriate for the intended use and function;  
适合其预期的用途和功能；

When transport requirements are changed, the transport company must ensure that:  
当运输要求变更时，运输公司必须确保：

- d) relevant documents are amended;  
相关文件被修订;
- e) relevant persons, including the Operator's representative, are made aware of the changes made to documents and associated requirements.  
相关人员, 包括经营者的代表, 都知晓文件和相关要求的变更。

## 2) Cleanliness and contamination prevention 清洁和污染预防

Before loading takes place, the container must be: empty, clean, odourless and dry (especially where solid or powdery product(s) is/are to be loaded). When applicable, preload restrictions must be observed.

The discharge equipment must be clean and this includes piping, hoses and pumps on vehicles, where applicable. The cleaning must be recorded.

装载前, 容器必须是空的, 清洁的, 无味并且干燥 (特别是装载固体或粉末产品)。适用时, 必须遵守装载限制。

卸货设备 (包括车辆上的管道、软管和泵) 必须进行清洁, 适用时, 清洁情况必须被记录。

Note: Four basic principles can be distinguished with respect to cleaning and disinfection: dry cleaning, cleaning with water, cleaning with water and cleansing agent and disinfection immediately or after one of the previous cleaning regimes. The choice of a minimum necessary cleaning regime is established on the basis of the characteristics of the previous product. If the loading compartment is not clean after the chosen cleaning regime, additional cleaning must take place and the choice of cleaning regime must be reconsidered.

备注: 清洗和消毒的四种类型: 干洗, 水洗, 水洗、清洗剂洗后立即消毒, 或在前次清洗方式后消毒。根据前次运输产品的特点, 选择并制定最基本的清洗方式。如果在实施所选择的清洗方式后, 装载容器还是不干净, 必须实施额外的清洗, 并且必须重新考虑清洗方式的选择。

## 3) Traceability of containers and loads 容器和装货的可追溯性

For each delivery the transport company must:

在每次交付过程中, 运输公司必须:

- a) record the previous load-product information, including associated container identification, as well as any associated cleaning operations;  
记录前次装载产品的信息, 包括相关容器的标识, 以及任何有关的清洗操作;
- b) record the loaded product information, including associated container identification;  
记录装载产品信息, 包括有关容器的标识;
- c) keep the recorded information available for an appropriate period of time.  
记录的信息保存适当的时间。

## 7.12. Feed packaging information and customer communication 饲料包装信息及顾客沟通

Information on content and intended use of feed products must be communicated to customers (via label or any other written document accompanying the goods) to ensure proper and safe use. Procedures must be in place detailing the correct labelling of products. Nonconforming or expired labels must be managed in a manner to prevent unauthorised use.

有关饲料产品的内容和预期用途的信息必须与顾客沟通（通过标签或任何其他伴随产品的书面文件），以确保正确和安全的使用。必须建立一个程序，详细说明正确的产品标签。不符合或失效的标签须管理得当，以防止未经授权的使用。

Label must fulfil the legal requirements of the country of the destination. A process to obtain the necessary documented information for the content of the label must be in place.

标签必须符合目的国的法律要求。获取关于标签内容必要成文信息的过程必须建立。

### 7.13. Competence and training 能力和培训

The Operator must:

经营者必须:

- a) determine the necessary competence of staff involved in feed safety and quality management and the general operations;  
确定与饲料安全、质量管理、常规操作有关的员工所需具备的能力;
- b) ensure that the staff is competent on the basis of appropriate education, training, periodic retraining or experience and, where necessary, evaluate the effectiveness of any training undertaken;  
基于适当的教育、培训、定期培训或经验，确保员工是胜任的，必要时，评价培训的有效性;
- c) ensure that the staff is trained in the relevant policies and procedures of the Feed Safety and Quality Management System;  
确保员工接受了饲料安全和质量管理体系有关政策和程序的培训;
- d) document, maintain and retain appropriate documented information as evidence of competence.  
保持和保留适当的成文信息作为人员能力的证据。

### 7.14. Awareness 意识

Relevant staff must be aware of:

相关员工必须知晓:

- a) their contribution to the effectiveness of the Feed Safety and Quality Management System, including the benefits of improved performance;  
他们对饲料安全和质量管理体系有效性的贡献，包括改进绩效的益处;
- b) the implications of not conforming with the Feed Safety and Quality Management System requirements.  
不符合饲料安全和质量管理体系要求的后果。

### 7.15. Communication 沟通

The Operator must consider the need for both internal and external communications relevant to the Feed Safety and Quality Management System. Responsibility for communication must be established.

经营者须考虑与饲料安全和质量管理体系相关的内部和外部沟通的需求。必须制定沟通的相关职责。

### 7.16. Complaint handling system 投诉处理系统

A formalised documented procedure on complaint handling must:

一个正式的形成文件的投诉处理程序，必须:

- a) allocate responsibility for controlling and adequate follow up of complaints;  
分配有关管理及跟进投诉的职责;
- b) unequivocal tracking of each complaint;  
明确跟进每个投诉;
- c) record name of complaining customer;  
记录投诉顾客的名称;
- d) record product name and identification code;  
记录产品名称和识别代码;
- e) reason for complaint;  
投诉的原因;
- f) identify and record each complaint;  
识别和记录每个投诉;
- g) reply to the complaining customer;  
回复投诉的顾客;
- h) identify if other customers could be involved.  
识别可能涉及的其他顾客。

Corrective actions must be carried out in a timely and effective manner, with consideration given to the frequency and seriousness of complaints.

考虑到投诉的频率及严重性，必须及时采取有效的纠正措施。

Where possible, complaint information must be used to avoid recurrence and implement ongoing improvements.  
可能时，投诉信息必须用于避免重复发生和实施持续改进。

### 7.16.1. Feed Safety Incident Communication (Crisis Management) 饲料安全事件沟通（危机管理）

If an Operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the defined feed safety or statutory requirements, it must immediately initiate procedures to recall the feed in question from the market and inform the competent authorities, if applicable.

It is required that:

如果经营者认为或有理由相信，其进口、生产、加工、制造或分销的饲料不符合规定的饲料安全或法规要求，必须立即启动程序从市场上召回存在问题的饲料并告知主管当局。适用时，要求：

- a) the crisis management procedure is documented and meets the requirements of the FAMI-QS Feed Safety Incident Procedure (P-CM-001);  
建立书面的危机管理程序，并且符合FAMI-QS饲料安全事件程序 (P-CM-001) 的要求;
- b) the responsibility is defined for notifying customers and regulatory authorities (where applicable);  
规定告知顾客和监管机构（适用时）的职责;
- c) the responsibility within the operation for product recall(s) is defined;  
规定执行产品召回的职责;
- d) the test of the Feed Safety Incident Communication is performed at regular intervals, defined by the company, and documented.  
按照公司规定，定期进行饲料安全事件沟通的测试，并形成记录。

Note: A crisis may result in a Rapid Alert situation (RASFF or equivalent) or originate from such.

备注：危机可能导致快速预警 (RASFF 或等同) 或与此相关的情况。

### 7.16.2. Recall procedures 召回程序

Systems must be in place in such way that products failing to meet the required Feed Safety standards can be identified, located and removed from all necessary points of the supply chain.

必须建立召回系统，确保不符合饲料安全标准的产品能被识别、定位并从供应链的所有必要环节中移除。

A documented product recall programme must be established and maintained, including a list of internal and external key contacts.

必须制定和保持文件化的产品召回计划，包括内部和外部关键联系人的清单。

Where products are withdrawn due to immediate health hazards, the safety of other products produced under the same conditions must be evaluated. The need for public warnings, notification of customers, and/or regulatory authorities must be considered.

由于急性健康危害而撤回产品时，须评价在同样条件下生产的其他产品的安全性。必须考虑是否需要警告公众，通知顾客和/或主管当局。

The product recall programme must be evaluated periodically, at least annually, to ensure effectiveness. Records must be maintained.

产品召回计划须定期进行评价，至少每年一次，以确保有效性，必须保持相关记录。

## 8. Operation 运行

### 8.1. Operational planning and control 运行的策划和控制

The Operator must plan, implement and control the processes needed to meet requirements, and to implement the actions determined in the Feed Safety and Quality Management System, by:

为满足要求，并实施饲料安全和质量管理体系所确定的措施，经营者必须通过以下措施对所需的过程进行策划、实施和控制：

- a) establishing criteria for the processes;  
建立过程的准则；
- 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 confidence that the processes have been carried out as planned.  
在必要的程度上，保持成文信息，以确信过程已经按策划进行。

The Operator must control planned changes, including relevant updates of the HACCP programme, and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

经营者必须控制策划的变更，包括 HACCP 计划相关的更新，并且评审非预期变更的后果，必要时，采取措施减轻不利影响。

### 8.2. Determination of requirements for products 与产品有关要求的确定

The Operator must determine:

经营者必须确定：

- a) the statutory and regulatory requirements related to the product;  
与产品有关的法律法规要求；
- b) the requirements specified by the customer, including requirements related to delivery and post-delivery activities;  
顾客规定的要求，包括与交付及交付后活动有关的要求；
- c) the requirements not stated by the customer but necessary for specified or intended use, where known;  
顾客虽然没有明示，但规定的用途或已知的预期用途所必须的要求；
- d) the contract or order requirements differing from those previously expressed.  
与以前表述不一致的合同或订单的要求。

The Operator must determine and implement effective arrangements for communicating with customers in relation to product information, enquiries, contracts or order handling, customer feedback, including complaints, and crisis management.

经营者必须确定并实施与顾客沟通（产品信息、问询、合同或订单的处理、顾客反馈，包括抱怨和危机管理）的有效安排。

A review must be conducted prior to the Operator's commitment to supply products to the customer and must ensure contract or order requirements differing from those previously defined are resolved.

评审必须在经营者向顾客作出提供产品的承诺之前进行，并必须确保与以前表述不一致的合同或订单的要求已得到解决。

Where requirements for products are changed, the Operator must ensure that relevant documented information is amended and that relevant staff is made aware of the changed requirements.

若产品要求发生变更，经营者必须确保相关的成文信息得到修改，并确保相关人员了解已变更的要求。

### 8.3. Design and development 设计和开发

The Operator must establish, implement and maintain a design and development process. A design and development process must be established also in the case that the already existing requirements of the product change.

经营者必须建立、实施和保持一个设计和开发过程。在已经存在的产品要求变更的情况下，也必须建立一个设计和开发过程。

The safety of products must be assured during the developmental stages of a new product through application of HACCP principles.

应用 HACCP 原理，确保新产品在开发阶段的产品安全性。

The Operator must plan and control the design and development of products or processes, with clearly identified requirements. The development plan must consider risks related to feed safety and quality. The Operator must ensure new developments are fit for intended purpose and their safe and proper use, and conforms to specified requirements.

经营者必须策划和控制产品或工艺的设计和开发，并有明确的要求。开发计划必须考虑到与饲料安全和质量有关的风险。经营者必须确保新的开发符合预期目的以及安全合理的使用，并符合规定的要求。

Design and development process is applied to any new ingredient/product or any change to an existing ingredient/product.

设计和开发过程适用于任何新成分/产品或任何现有成分/产品的变更。

The Operator must retain the documented information resulting from the design and development process. 经营者必须保留由设计和开发过程所产生的成文信息。

#### 8.3.1. Design and development planning 设计和开发策划

In determining the stages and controls for design and development, the Operator must consider:

在确定设计和开发的各个阶段和控制时，经营者必须考虑：

- a) the nature, duration and complexity of the design and development activities;  
设计和开发活动的性质、持续时间和复杂程度；
- b) the requirements that specify particular process stages, including applicable design and development reviews;  
所需的特定工艺阶段的要求，包括适用的设计和开发评审；
- c) the required design and development verification and validation;  
所需的设计和开发验证、确认活动；
- d) the responsibilities and authorities involved in the design and development process;  
设计和开发过程涉及的职责和权限；
- e) the need to control interfaces between individuals and parties involved in the design and development process;  
设计和开发过程参与人员和相关方之间接口的控制要求；
- f) the need for involvement of customer and user groups in the design and development process;

顾客及使用群体参与设计和开发过程的需求;

g) the necessary documented information to confirm that design and development requirements have been met.

证实已经满足设计和开发要求所需的成文信息。

### **8.3.2. Design and development Inputs** 设计和开发输入

The Operator must determine:

经营者必须确定:

- a) requirements essential for the specific type of products and services being designed and developed, including, as applicable, functional and performance requirements;  
针对所设计和开发的具体类型的产品和服务, 确定必需的要求, 适用时包括功能和性能要求;
- b) applicable statutory and regulatory requirements;  
适用的法律法规要求;
- c) standards or codes of practice that the Operator has committed to implement;  
经营者承诺实施的标准或操作规范;
- d) internal and external resource needs for the design and development of products and services;  
产品和服务的设计和开发所需的内部、外部资源;
- e) the potential consequences of failure, due to the nature of the products and services;  
由产品和服务性质所导致的潜在的失效后果;
- f) the level of control expected of the design and development process by customers and other relevant interested parties.

顾客和其他相关方所期望的对设计和开发过程的控制水平。

Inputs must be adequate for design and development purposes, complete, and unambiguous. Conflicts among inputs must be resolved.

针对设计和开发的目的, 输入必须是充分和适宜的, 且应完整、清楚, 相互矛盾的设计和开发输入必须得到解决。

### **8.3.3. Design and development controls** 设计和开发控制

The controls applied to the design and development process must ensure that:

对设计和开发过程进行控制, 必须确保:

- a) the results to be achieved by the design and development activities are clearly defined;  
明确规定通过设计和开发活动拟获得的结果;
- b) design and development reviews are conducted as planned;  
按策划实施设计和开发的评审;
- c) verification is conducted to ensure that the design and development outputs have met the design and development input requirements;  
实施验证活动, 以确保设计和开发输出已满足设计和开发输入的要求;
- d) validation is conducted to ensure that the resulting products are capable of meeting the requirements for the specified application or intended use (when known).  
实施确认活动, 以确保形成的产品能够满足规定的使用要求或预期用途 (已知时)。

### **8.3.4. Design and development outputs** 设计和开发输出

The Operator must ensure that design and development outputs:

经营者必须确保设计和开发输出:

- a) meet the input requirements for design and development;  
满足设计和开发输入的要求;
- b) are adequate for the subsequent processes for the provision of products and services;  
满足后续产品和服务提供过程的需求;
- c) include or reference monitoring and measuring requirements, and acceptance criteria, as applicable;  
包括或引用监视和测量的要求, 适当时, 包括接收准则;
- d) ensure products to be produced, or services to be provided, are fit for intended purpose and their safe and proper use.  
确保产品的生产或提供的服务, 符合预期的目的和他们的安全和适当的使用。

The Operator must retain the documented information resulting from the design and development process.

经营者必须保留设计和开发过程结果的成文信息。

#### **8.4. Change control 变更控制**

Any change after the development process and the placing of the product on the market must be reviewed, controlled and approved before implementation, to ensure that there is no adverse impact on product safety and conformity to requirements.

在开发过程和产品投放市场后的任何变更必须在实施前进行评审、控制和批准, 确保这些变更对产品安全和满足要求不会产生不利影响。

Following the establishment of the Good Manufacturing Practice (GMP) and HACCP programme, the Operator must update these documents with following information, if necessary, in case of a change:

在建立良好操作规范 (GMP) 和HACCP计划后, 当发生变更时, 如有必要, 经营者必须更新这些文件的以下信息。

- a) characteristics of raw materials, ingredients and product-contact materials;  
原材料、配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, process steps, equipment and control measures.  
流程图, 过程步骤, 设备和控制措施。

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

必须保留评审的结果和任何必要措施的记录。

#### **8.5. Control of externally provided products and services 外部提供的产品和服务的控制**

The Operator must identify externally provided processes, products, and services, which may have an impact on feed safety and quality, and ensure that they conform to specified requirements.

经营者必须识别外部提供的过程、产品和服务（这可能影响饲料安全和质量）, 并确保他们符合规定的要求。

The Operator must communicate to external providers, applicable requirements related to the product, process or services and to the FAMI-QS Code. Those requirements must be mutually agreed, approved and documented.

经营者必须与外部供方沟通与产品、过程或服务有关的适用要求和 FAMI-QS 规范要求。这些要求必须相互认同并形成文件。

The Operator must establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with specified requirements, based on this document.

经营者必须基于外部供方按照本文件确定的要求提供过程、产品和服务的能力，制定并实施对外部供方的评价、选择、绩效监视以及再评价的准则。

The Operator must retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers.

对外部供方进行评价，绩效监视和再评价的结果，经营者必须保留适当的成文信息。

### **8.5.1. Type and extent of control of external provision – Contract Manufacturers 外部提供（合同制造商）控制类型和程度**

Processes or functions of the Operator which have been outsourced to a contract manufacturer remain within the scope of the Operator's Feed Safety and Quality Management System. The Operator must define both the controls it intends to apply to the contract manufacturer and those it intends to apply to the resulting output.

被外包给合同制造商的过程或职能保持在经营者的饲料安全和质量管理体系范围中。经营者必须规定对合同制造商的控制及其输出结果的控制。

The Operator has to demonstrate that it exercises sufficient control to ensure that the process is performed according to the relevant requirements of FAMI-QS, and any other requirements of the Operator's Feed Safety and Quality Management System.

经营者必须证实实施了充分的控制，以确保过程是按照 FAMI-QS 相关要求和经营者的饲料安全和质量管理体系的要求进行的。

There are two situations that frequently need to be considered when deciding the appropriate level of control of an outsourced process:

当确定外包过程适当控制级别时，通常需要考虑两种情况：

- a) When the Operator has the competence and ability to carry out a process, but chooses to outsource that process (for commercial or other reasons). In this situation the process control criteria must already have been defined, and can be transposed into requirements for the supplier of the outsourced process, if necessary.

当经营者有能力去完成某个过程，但选择外包此过程（商业或其他原因）。在这种情况下，过程控制准则必须明确，如果有必要，可以将外包过程的要求转换成对供应商的要求。

- b) When the Operator does not have the competence to carry out the process itself, and chooses to outsource it. In this situation the Operator has to ensure that the controls proposed by the supplier of the outsourced process are adequate. In some cases, it may be necessary to involve external specialists in making this evaluation.

当经营者没有能力自己去完成某个过程而选择外包。在这种情况下，经营者必须确保对提供外包过程的供应商的控制是充分的。在某些情况下，可能有必要让外部专家参与评价。

If the contract manufacturer is not FAMI-QS certified or is not certified by any other recognized standard, the Operator must evaluate the risk associated to the Operator's product and perform an audit, in order to ensure that the contract manufacturer meets the FAMI-QS requirements. The audit must be performed by an appropriately trained auditor. A report must be written and accessible.

如果合同制造商不是获得 FAMI-QS 认证的也不是获得其他被认可标准认证的，经营者必须评价与经营者产品相关的风险并实施审核，以确保合同制造商符合 FAMI-QS 要求。审核必须由经过适当培训的审核员完成，必须编写审核报告并可获取。

During the Operator's certification and surveillance audits, the Certification Body must check the audit report of the contract manufacturer, and if deemed necessary also audit the external contract manufacturer.

在经营者的认证和监督审核期间，认证机构必须检查针对合同制造商的审核报告，如果认为有必要也可以审核外部合同制造商。

If the contract manufacturer is certified according to FAMI-QS or any recognized feed, food or pharmaceutical standard, no additional FAMI-QS audit by the Operator may be required, as long as the applicable product falls under the scope of that certification. To verify which standards are recognized by FAMI-QS, regarding assured sources, please consult the Document P-MS-003, available in FAMI-QS website.

如果合同制造商按照 FAMI-QS 或其他认可的饲料，食品或药品标准获得认证，只要相应的产品在认证范围内，经营者不需要额外的 FAMI-QS 审核。为证实哪些标准是被 FAMI-QS 认可的，关于有保证的来源，请参考文件 P-MS-003，该文件可从 FAMI-QS 官网上获取。

Note: Adequate training of auditor normally includes knowledge in the FAMI-QS code, auditing techniques and the scope of the external provider (process, product or service).

注：对审核员的适当培训包括 FAMI-QS 规范的知识，审核技巧和外部提供的范围（过程，产品或服务）。

## 8.6. Purchased materials 原料采购

Purchasing of materials must be managed in such a way that the suppliers used have the capability to meet specified feed safety and quality requirements.

原料的采购必须以供应商有能力满足规定的饲料安全和质量要求的方式进行管理。

The compliance of incoming materials to specified purchase requirements must be verified.

必须验证购进原料是否符合规定的采购要求。

### 8.6.1. Selection and management of suppliers 供应商的选择和管理

The Operator must define a process for the selection, approval and monitoring of suppliers. The Operator must evaluate and select suppliers based on their ability to supply products in accordance with the Operator's requirements. The Operator must maintain a list of internally approved suppliers including the purchased raw material and their status as assured or non-assured.

经营者必须为选择，批准和监视供应商确定一个过程。经营者必须基于供应商按经营者的要求供应产品的能力评价和选择供应商。经营者必须保留一份内部批准的供应商名录，名录中包括采购的原料及对应供应商的状态（如有保证的和非保证的）。

If a supplier is not FAMI-QS certified or is not certified by any other recognized standard, it is considered a non-assured source. On the contrary, if it is FAMI-QS certified or certified by any other recognized standard, it is considered an assured source.

如果一个供应商不是 FAMI-QS 认证的也不是其他被认可的标准认证的，其则被认为是非保证的来源。与此相反，如果是 FAMI-QS 认证的或被其他认可的标准认证的，其则被认为是有保证的来源。

**Note: To verify which standards are recognized by FAMI-QS, regarding assured sources, please consult the Document P-MS-003, available in FAMI-QS website.**

注：为证实哪个标准是被 FAMI-QS 所认可的，关于有保证的来源，请参考文件 P-MS-003，可从 FAMI-QS 网站获取。

Each supplier, either assured or non-assured, must be subject to periodical review. The Operator must define the intervals for the supplier evaluation based on its own risk assessment.

对每个供应商，不管是有保证还是非保证的，都必须定期进行评审。经营者必须基于各自的风险评估确定供应商评价的时间间隔。

The raw materials that enter the production process must be defined according to both their type and their use.

The following information must be documented for each raw material:

进入生产过程的原料必须根据他们的类型和用途来界定。对每一种原料，下列信息必须形成文件：

- a) specification for the purchased product;  
采购产品的规格；
- b) product description;  
产品描述；
- c) method of production;  
生产方式；
- d) analytical characteristics;  
分析特性；
- e) details of any undesirable substance with which the raw material may be typically associated, appropriate certification and any other hazards or limitations associated with the raw material, which have been considered in the Operator's HACCP programme, etc.  
与原料相关的不良物质的详细信息，已包含在经营者 HACCP 计划等文件中的适当的认证和与原料有关的其他任何危害或限值。

Selection and approval of all raw materials must also include their origin, transport, storage, processing and handling.

所有原料的选择和批准也必须包括其来源，运输，存储，加工和处理。

Feed safety-related acceptance criteria or specifications of purchased materials and ingredients must be appropriate to their intended use.

饲料安全相关的验收标准或采购原料和成分的规格必须与其预期用途相适宜。

**The Operator must:**

经营者必须：

- f) record any relevant analytical and monitor results and records of the evaluations on the supplier and necessary actions arising from that evaluation;  
记录所有相关的分析、监视结果、对供应商的评价以及评价所引起的任何必要的措施；
- g) establish a process to provisionally qualify supplier in emergency situations.  
建立一个过程，为了批准紧急情况下的供应商。

In case the supplier is a non-assured source, an audit at the supplier's premises is required, in addition to the above requisites. In that case, the audit needs to be conducted at least within six months after the raw material's delivery. Operators must present a realistic audit plan for their non-assured suppliers. They have to audit all their suppliers at least once, during the three years of the certification cycle.

如果供应商是非保证的来源，除了上述必要条件外，要求对供应商进行现场审核。这种情况下，审核至少在原材料交付后的六个月内进行。经营者对他们非保证来源的供应商审核必须有一份切实可行的审核计划。在三年认证周期内，经营者必须对所有该类供应商至少审核一次。

As an alternative to the audit of a non-assured supplier, the Operator must perform a separate risk assessment based on the criteria described on this chapter (8.6.1 (a-g)), which must justify the use of the raw material, without a FAMI-QS audit, at the supplier's premises.

作为对非保证来源供应商审核的替代方法，经营者必须基于本章（8.6.1（a-g））标准要求进行单独的风险评估，经营者必须能够证明，没有在供应商生产现场进行基于 FAMI-QS 的审核，使用这种原料是合理的。

The auditor must assess the implementation of the suppliers' audit programme and/or the risk assessment. 审核员必须评估对供应商审核方案的实施情况和/或风险评估情况。

### 8.6.2. Verification of incoming materials 购进原料的验证

Each batch entering the site must be uniquely registered by means of a batch number, full name of product, date of receipt, quantity received as well as manufacturing and/or expiry date. Any damage must be reported to an appropriate responsible unit, e.g. the quality assurance and procurement unit.

每批进入现场的原料必须根据批号、产品的全称、接收日期和接收数量进行唯一登记，同时需记录生产和/或保质期。如有任何损坏必须向相关的责任部门（如质量保证和采购部门）报告。

Incoming materials must be checked and formally approved prior to use, according to written procedures. In case of hazardous raw materials used in the process, health and safety risks must be taken into consideration.

购进原料在使用前必须根据书面程序进行检查和正式批准。在生产过程中使用危险原料时，必须考虑健康和安全风险。

If the incoming material is delivered in bulk, a receipt and storage procedure must be in place and necessary checks performed before unloading.

如果购进的原料是散装交付，必须建立接收和存储程序，并在卸货前进行必要的检查。

Where appropriate, a retention sample of adequate size must be retained for the duration of the shelf life of the raw material concerned, either at the supplier or the Operator's facilities. The samples must be appropriately stored, in a manner that must maintain the integrity of the product.

适当时，在供应商或经营者处进行留样，留样要有足够的数量，留样期限要考虑原料的保质期。对样品必须进行适当储存，保持产品的完整性。

Handling of incoming materials must be in accordance with its status and storage conditions. For example, a received material which is deemed unfit for use must be identified as such and segregated from those materials released for use.

购进产品的处理应当根据其状况和存储条件，如，被认为不适合使用的已接收原料必须标识并与那些放行使用的原料隔离开来。

If incoming materials are rejected and thus not incorporated because of noncompliance with the specification or for any reason related to product quality and safety, their disposal, destination or return to supplier must be recorded.

如果购进原料由于不符合规格或任何与产品质量和安全有关的原因被拒收，必须记录其处置、去向或退回供应商的情况。

## 8.7. HACCP Programme HACCP 计划

The Operator must establish, implement and maintain a HACCP programme.  
经营者必须建立、实施和保持HACCP计划。

The HACCP programme must be maintained as documented information and must include the following:  
HACCP计划必须保持成文信息，并包括以下内容：

- a) information for each identified Critical Control Points (CCP);  
每个确定的关键控制点（CCP）的信息；
- b) feed safety hazard(s) to be controlled at the CCP;  
CCP控制的饲料安全危害；
- c) control measure(s);  
控制措施；
- d) critical limit(s);  
关键限值；
- e) monitoring procedure(s);  
监视程序；
- f) corrections and corrective action(s) to be taken if critical limits are exceeded;  
如果超出关键限值，采取的纠正和纠正措施；
- g) list of responsibilities, designated responsible personnel, including for certain authorisations;  
职责清单，指定的负责人员，包括某些授权；
- h) records of monitoring.  
监视的记录。

The Operator must use the guidance for application of HACCP programme provided in the *Codex Alimentarius Guidelines*.

经营者必须使用《食品法典》提供的 HACCP 计划的应用指南。

The implementation of the HACCP programme must follow the applicable FAMI-QS Process Documents, depending on the scope of the Feed Safety and Quality Management System.

HACCP 计划的实施必须遵循适用的 FAMI-QS 过程文件，这取决于饲料安全和质量管理体系的范围。

HACCP programme must be reviewed when:

当出现以下情况时，必须对 HACCP 计划进行评审：

- a significant process change takes place (e.g. equipment, strain, supplier, process upgrade etc.);  
重要的过程发生了变化（如：设备、菌株、供应商、工艺改进等）；
- there is an update of the feed safety hazards.  
饲料安全危害发生变化。

The HACCP team must re-evaluate the HACCP programme at least every three (3) years. In the event that other provisions arise, the HACCP programme must be subject to a more frequent evaluation.

HACCP 小组必须至少每 3 年重新评价 HACCP 计划。如果有其他规定时，对 HACCP 计划必须更频繁的评价。

Note: HACCP programme for Feed Safety must be approached from the perspective of animal and human health.  
注：必须从动物和人类健康的角度来考虑饲料安全 HACCP 计划。

### 8.7.1. Determination of critical limits for critical control points and monitoring 关键限值的确定和关键控制点监视

Critical limits must be determined for the monitoring established for each CCP. Critical limits must:  
必须对每个CCP点所设定的监视确定其关键限值。关键限值必须：

- a) be established to ensure that the identified acceptable level of the feed safety hazard in the end product is not exceeded;  
确保终产品的饲料安全危害不超过已知的可接受水平；
- b) be measurable (quantitatively and qualitatively) and the rationale for their determination must be supported by scientific or other documented information.  
可测量的（定量和定性），并且其确定的理由必须得到科学或其他成文信息的支持。

For each CCP, a monitoring system must be established to demonstrate that the critical limits are controlled. The system must include all scheduled measurements or observations relative to the critical limit(s).

对每个CCP点，必须建立监视系统以证实关键限值是受控的。该系统必须包括所有针对关键限值的、有计划的测量或观察。

The monitoring system must consist of documented information including procedures, instructions and records and should include, but are not limited to the following:

监视系统必须由程序、指导书和记录等成文信息构成，包括但不限于以下内容：

- c) measurements or observations that provide results within an adequate time frame;  
在适当的时间范围内，可提供结果的测量或观察；
- d) monitoring devices used;  
所用的监视装置；
- e) applicable calibration methods;  
适用的校准方法；
- f) monitoring frequency;  
监视频率；
- g) monitoring results;  
监视结果；
- h) responsibilities and authorities for monitoring and evaluation of all data.  
与监视和评价监视结果有关的职责和权限。

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

当监视程序是基于主观信息的（如对产品和/或加工过程的视觉检验），必须有作业指导书、规范作为支持。必须对负责监视活动的人员进行培训。

The monitoring procedure and frequency of monitoring must be capable of determining when the critical limits have been exceeded in time for the product to be isolated, before it is used or consumed.

监视的方法和频次必须能够及时确定关键限值何时超出，以便在产品使用或消费前对产品进行隔离。

### 8.7.2. HACCP team leader HACCP 小组组长

The HACCP team leader must:

HACCP 小组组长必须:

- a) Appoint (where possible) and manage a HACCP team and organise its work;  
任命 (可能时) 和管理 HACCP 小组，并组织其工作;
- b) ensure relevant training, and periodic retraining of the HACCP team members;  
确保相关培训，并定期对 HACCP 小组成员进行再培训;
- c) report to the top management on the effectiveness of the HACCP programme.  
向最高管理者报告 HACCP 计划的有效性。

Note: The responsibility of the HACCP team leader may include liaison with external parties on matters relating to the Feed Safety and Quality Management system.

注: HACCP 小组组长的职责可包括与饲料安全和质量管理体系有关事宜的外部联络。

## 8.8. Control of Production 生产过程的控制

The Operator must plan and carry out production under controlled conditions. Controlled conditions must include, as applicable:

经营者必须策划并在受控条件下进行生产。适用时，受控条件必须包括:

- a) the availability of information that describes the characteristics of the finished product;  
获得描述终产品特性的信息;
- b) a written specification, which is amended when any change takes place for each product;  
书面的规格要求，当产品发生变化时予以修订;
- c) a unique name or code for each product;  
每种产品唯一的名称或代码;
- d) details of packaging and labelling. Product labelling must be in accordance with the relevant feed legislation;  
包装和标签的详细信息。产品标签必须符合相关的饲料法规;
- e) for each packaged unit: labelling in order to allow traceability to the batch to which it belongs, if necessary, identified with a unique code (or combination of codes);  
对每一个包装单元，贴标签是为了追溯其所属的批次，必要时，用唯一的代码（或代码的组合）进行识别;
- f) production being carried out according to written procedures aimed at defining, controlling and monitoring the critical points in the manufacturing process. These must include procedures to address the risk of carry-over, if applicable;  
根据书面程序进行生产，以确定，控制和监视制造过程的关键点。适用时，必须包括应对残留风险的程序;
- g) inspection of all finished products prior to dispatch, in accordance with written procedures, to ensure they meet specification;  
所有成品在放行前应当根据书面程序进行检验以确保符合规格要求;
- h) Retention sample must be kept for a minimum the shelf life of the product.  
留样必须至少保存至产品的保质期。

### 8.8.1. Identification and traceability 标识和可追溯性

To ensure traceability, the Operator must:

为确保可追溯性，经营者必须：

- I. identify and record the process output by suitable means throughout product realisation;  
在产品实现的全过程中使用适宜的方法识别和记录过程输出；
- II. retain any documented information necessary to maintain traceability, including but not limited to:  
保留任何必要的成文信息以保持可追溯性，包括但不限于：
  - a) the names and addresses of manufacturers of incoming materials, specialty feed ingredients or intermediates (including batch number information);  
购进原料，特殊饲料成分或中间体的制造商的名称与地址（包括批号信息）；
  - b) the flow of materials within its control in a manner which meets the objectives of the traceability system;  
满足可追溯系统要求，在其控制下的物料流转；
  - c) the nature and quantity of the products produced;  
所生产产品的性质和数量；
  - d) the respective dates of manufacture and, where appropriate, the number of the batch;  
各自的生产日期，适当时，批次的数量；
  - e) the names and addresses of the intermediaries, manufacturers or users to whom products have been delivered.  
已交付产品的中间商、制造商或用户的名称和地址。

The Operator must identify the relevant regulatory and policy requirements (if applicable) to be met by its traceability system.

经营者必须识别相关的法规和政策要求（如适用），以满足其可追溯系统的要求。

The traceability system must be verifiable and the Operator must establish a monitoring scheme for the traceability system.

可追溯系统必须是可验证的，经营者必须建立一个可追溯系统的监视计划。

**Note 1:** Process outputs are the results of any activities which are ready for delivery to the Operator's customer or to an internal customer (e.g. receiver of the inputs to the next process); they can include products, services, intermediate parts, components, etc.

**注 1：**过程输出是准备交付给经营者的顾客或内部顾客的任何活动的结果（如下一过程输入的接收者）；它们包括产品，服务，中间部分，组件等。

**Note 2:** Operator must define the batch according to the specificity of his process (batch or continuous production).

**注 2：**经营者必须根据其工艺（批次或连续生产）的特性来定义批次。

### **8.8.2. Preservation of product 产品防护**

The Operator must establish the shelf life of a product and preserve the conformity of the product during production, to the extent necessary to maintain conformity to the requirements.

经营者必须确定产品的保质期，并在生产过程中保持产品的符合性，并在必要程度上保持与要求的符合性。

Preservation measures must include product identification, handling, packaging, storage and protection.

防护措施必须包括标识、处理、包装、存储与保护。

### **8.8.3. Post-delivery activities 交付后的活动**

The Operator must meet requirements for post-delivery activities associated with the products.  
经营者必须满足与产品相关的交付后活动的要求。

In determining the extent of post-delivery activities that are required, the Operator must consider:  
在确定所要求的交付后活动的覆盖范围和程度时，经营者必须考虑：

- a) the risks associated with the products;  
与产品相关的风险；
- b) the nature, use and intended lifetime of the products;  
产品的性质、使用和预期寿命；
- c) customer feedback;  
顾客反馈；
- d) statutory and regulatory requirements.  
法律法规要求。

Note: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services and supplementary services such as recycling or final disposal.

注：交付后活动可包括保证条款所规定的措施、合同义务（如维护服务等）、附加服务（如回收最终处置等）。

#### 8.8.4. Release of products 产品的放行

The Operator must implement the planned arrangements at appropriate stages to verify that product requirements have been met. Evidence of conformity with the acceptance criteria must be retained.  
经营者必须在适当阶段实施策划的安排，以验证产品的要求已得到满足。必须保留符合接收准则的证据。

The release of products to the customer must not proceed until the planned arrangements for verification of conformity have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

除非得到有关授权人员的批准，适用时得到顾客的批准，否则在策划的符合性验证安排已圆满完成之前，不应向顾客放行产品。

Documented information must provide traceability to the person(s) authorising release of products for delivery to the customer. If appropriate, an authorised document should be provided stating the compliance of the delivered batch with the agreed requirements, such as Certificate of Analysis.

必须保留成文信息，以追溯到授权放行产品交付给顾客的人员信息。适用时，应提供一份授权文件（如分析报告），说明交付的批次符合约定的要求。

#### 8.8.5. Control of nonconforming process outputs and products 不合格的输出和产品的控制

The Operator must ensure that process outputs/products that do not conform to the requirements are identified and controlled, to prevent their unintended use or delivery.

经营者必须确保对不符合要求的过程输出/产品进行识别和控制，以防止非预期的使用或交付。

The Operator must establish a documented procedure for dealing with products which do not comply with intended requirements. The procedure must include:

经营者必须制定一个文件化的程序来处理不符合预期要求的产品。程序必须包括：

- a) identification of product and batch code;  
产品和批次的识别;
- b) documentation of any nonconformity, corrective action(s) and verification steps;  
任何不合格、纠正措施和验证步骤的记录;
- c) evaluation of the cause of the nonconformity, including other potentially affected batches;  
不合格原因的评价，包括其他可能受影响的批次;
- d) segregation of affected batch or batches;  
受影响批次的隔离;
- e) provision for disposal, reprocess or rework of products where appropriate;  
适当时，提供对产品的处置，再加工或返工;
- f) verification of conformity to the requirements after correction, if applicable;  
适用时，纠正后符合要求的验证;
- g) informing the customer and obtaining authorisation for release, following corrective actions, or release certain provisions, where applicable.  
适用时，通知顾客并获得放行的授权，后续的纠正措施或发布的某些规定。

Responsibility for review and disposal of the nonconforming product must be defined. The Operator must take appropriate corrective action based on the nature of the nonconformity and its impact on the conformity of products. This applies also to nonconforming products detected after delivery of the products.

必须规定评审与处置不合格品的职责。经营者必须根据不符合的性质和对产品符合性的影响采取适当的纠正措施。这也适用于产品交付后发现的不合格品。

The Operator must retain documented information of actions taken on nonconforming process outputs and products, including any concessions obtained and the person or authority that made the decision regarding dealing with the nonconformity.

经营者必须保留对不合格过程输出和产品采取纠正措施的成文信息，包括获得的让步接收，以及做出处置不合格决定的人或主管部门。

#### 8.8.5.1. Rework 返工

The approval and use of reworks (e.g. from rejects, customer returns or spillage) must be considered within the HACCP programme.

Rework must be managed in such a way that feed safety, quality and traceability are not compromised. Rework management must include criteria and conditions for acceptance, storage, identification, traceability and processing. Product returned from distribution must be assessed for feed safety hazards and handled accordingly. Defective products must be stored separately and secured.

返工（例如，来自拒收、顾客退回或损坏）的批准和使用必须在 HACCP 计划中加以考虑。

返工必须以保证饲料安全、质量和可追溯性的方式进行管理。返工管理必须包括接收、存储、标识、可追溯性和处理的准则和条件。分销后返回的产品必须评估饲料安全危害并进行相应处理。有缺陷的产品必须分开存放和保管。

## 9. Performance Evaluation 纪效评价

### 9.1. Monitoring 监视

The Operator must determine:

经营者必须确定

- a) what needs to be monitored and measured;  
需要监视和测量什么;
- b) the methods for monitoring, measurement, analysis, evaluation and verification, as applicable, to ensure validated results;  
需要用什么方法进行监视、测量、分析、评价和验证, 适用时, 以确保结果有效;
- c) when the monitoring and measuring must be performed;  
何时必须实施监视和测量;
- d) when the results from monitoring and measurement must be analysed and evaluated.  
何时必须对监视和测量结果进行分析和评价。

The Operator must retain appropriate documented information as evidence of the results.

经营者必须保留适当的成文信息, 以作为结果的证据。

### 9.2. Internal audit 内部审核

The Operator must conduct internal audits, at planned intervals, to provide information on whether the Feed Safety and Quality Management System:

经营者必须按照策划的时间间隔进行内部审核, 以提供有关饲料安全和质量管理体系的下列信息:

#### I. conforms to:

是否符合:

- a) the Operator's own requirements for its Feed Safety and Quality Management System;  
经营者自身的饲料安全和质量管理体系要求;
- b) the requirements of the FAMI-QS Code;  
FAMI-QS 规范的要求;
- c) regulatory and other defined requirements.  
法规和其他规定的要求。

#### II. is effectively implemented and maintained.

是否得到有效的实施和保持。

The Operator must:

经营者必须:

- d) have a documented program that plans, establishes, implements and maintains an audit programme including the frequency, methods, responsibilities, planning requirements, scope & criteria and reporting, which must take into consideration the importance of the processes concerned and the results of previous audits. The audit programme may be used to identify potential opportunities for improvement;

有一个书面的程序，依据有关过程的重要性和以往的审核结果，策划、制定、实施和保持审核方案，审核方案包括频次、方法、职责、策划要求，审核范围、准则和报告。审核方案可用于识别潜在的改进机会；

- e) select trained, competent and independent auditors to conduct audits in order to ensure the objectivity and the impartiality of the audit process;  
选择经过培训、有能力且独立的审核员实施审核，以确保审核过程客观公正；
- f) ensure that corrective actions are scheduled and verified when completed;  
确保纠正措施按计划进行，并在完成时进行验证；
- g) retain documented information as evidence of the implementation of the audit programme and the audit results.  
保留成文信息，作为实施审核方案以及审核结果的证据。

### 9.3. Management review 管理评审

Top management must review the Operator's Feed Safety and Quality Management System, at planned intervals (at least yearly), to ensure its continuing suitability, adequacy and effectiveness. Records of this review must be maintained.

最高管理者必须按照策划的时间间隔（至少每年）对经营者的饲料安全和质量管理体系进行评审，以确保其持续的适宜性、充分性和有效性。必须保持管理评审的记录。

The management review must take into consideration:

管理评审必须考虑下列内容：

- a) the status of actions from previous management reviews;  
以往管理评审所采取措施的情况；
- b) changes in the relevant external and internal risks and the need to update or change the Feed Safety and Quality Management;  
相关外部和内部风险的变化以及饲料安全和质量体系更新或变更的需要；
- c) information on the Feed Safety and Quality Management System performance, including but not limited to trends in:  
下列有关饲料安全和质量管理体系绩效的信息，包括其趋势但不限于：
  - i. recalls, nonconformities, customer complaints and corrective actions;  
召回，不合格，顾客投诉和纠正措施；
  - ii. monitoring and measurement results;  
监视和测量结果；
  - iii. audit results;  
审核结果；
- d) the opportunities for continual improvement;  
持续改进的机会；
- e) the need for updating the Feed Safety and Quality Policy.  
更新饲料安全和质量体系方针的需求。

The results of the management review must include decisions related to continual improvement opportunities and any need for changes to the Feed Safety and Quality Management System. Decisions to change any aspect of the Feed Safety and Quality Management System must be communicated to key staff.

管理评审的结果必须包括与持续改进机会相关的决定和对饲料安全和质量管理体系所需变更的决定。对饲料安全和质量管理体系任何方面变更的决定必须传达给关键员工。

**The Operator must retain documented information as evidence of the results of management reviews.**  
经营者必须保留成文信息，作为管理评审结果的证据。

## 10. Improvement 改进

### 10.1. Nonconformity and corrective action 不合格和纠正措施

When a nonconformity occurs, the Operator must:

当出现不合格时, 经营者必须:

- a) react to the nonconformity as appropriate;  
适当时, 对不合格做出应对;
- b) evaluate the need for action to eliminate the immediate causes of the nonconformity, in order that it does not recur or occur elsewhere;  
评价是否需要采取措施, 以消除产生不合格的直接原因, 避免其再次发生或者在其他场合发生;
- c) implement any action needed, including short/ long term corrective and preventative actions, as well as changes to the Feed Safety and Quality System, where applicable;  
实施所需要的措施, 包括短期或长期的纠正以及预防措施, 适用时, 变更饲料安全和质量管理体系;
- d) document any actions or solutions;  
对所采取的措施或解决方案形成文件;
- e) communicate solution(s) internally and/or externally, if applicable;  
适用时, 在内和或外部沟通解决方案;
- f) review the effectiveness of any corrective action(s) taken.  
评审所采取的纠正措施的有效性。

Corrective actions must be appropriate to the severity of the nonconformities encountered.

纠正措施必须与不合格的严重程度相适应。

The Operator must retain documented information as evidence of actions taken and their effectiveness.

经营者必须保留成文信息, 作为采取措施和有效性的证据。

### 10.2. Continual improvement 持续改进

The Operator must continually improve the suitability, adequacy and effectiveness of the Feed Safety and Quality Management System. This should not be limited to the Feed Safety and Quality objectives.

经营者必须持续改进饲料安全和质量管理体系的适宜性、充分性和有效性。这不应仅限于饲料安全和质量目标。

Evidence of continual improvement activities must also be documented to enable the revision by any relevant third parties.

持续改进活动的证据必须形成文件, 使相关的第三方能够进行修订。