TECHNICAL SPECIFICATION

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Prerequisite programmes on food safety —

Part 6: Feed and animal food production

Programmes prérequis pour la sécurité des denrées alimentaires —

Partie 6: Production des aliments pour animaux

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 34 *Food products*, Subcommittee SC 17 *Management systems for food safety*.

ISO/TS 22002 contains the following parts under the general title *Prerequisite programmes on food safety*:

— *Part 1: Food manufacturing*

— *Part 2: Catering*

— *Part 3: Farming*

— *Part 4: Food packaging manufacturing*

— *Part 6: Feed and animal food production*

Introduction

ISO 22000 sets out specific food safety requirements for organizations in the food chain. One such requirement is that organizations establish, implement and maintain prerequisite programmes (PRPs) to assist in controlling food safety hazards.

This Technical Specification does not duplicate the requirements given in ISO 22000 and is intended to be used when establishing, implementing and maintaining the PRPs specific to the organization(s) in conjunction with ISO 22000.

ISO/TC 34/SC 17 acknowledged the PAS 222:2011 as a starting point for the development of this Technical Specification.

Prerequisite programmes on food safety —

Part 6:
Feed and animal food production

1 Scope

This Technical Specification specifies requirements for establishing, implementing and maintaining prerequisite programmes (PRPs) to assist in controlling feed safety hazards in feed and animal food and in materials intended for use in the production of feed and animal food. Feed safety hazards in this context relate to attributes that have a potential to affect adversely animal and/or human health.

Prerequisite programmes are intended to ensure feed safety and to prevent, control and detect potential contamination including cross-contamination that could occur under the responsibility of the organization.

This Technical Specification is applicable to all organizations regardless of size, location or complexity that are involved in the manufacturing and/or supply of feed and animal food and wish to implement a PRP. Feed and animal food operations are diverse in nature and not all of the requirements specified in this Technical Specification necessarily apply to an individual organization or process. Where exclusions are made or alternative measures are implemented, these need to be justified by a hazard assessment and verified to be effective. Any exclusions or alternative measures adopted should not affect the ability of an organization to comply with other requirements contained in this Technical Specification.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 22000, *Food safety management systems — Requirements for any organization in the food chain*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 22000 and the following apply.

3.1
feed
any single or multiple products, whether processed, semi-processed or raw, which is intended to be fed to food producing animals

[SOURCE: CAC/GL 81-2013 — modified]

3.2
animal food
any single or multiple products, whether processed, semi-processed or raw, which is intended to be fed to non-food producing animals

[SOURCE: CAC/GL 81-2013 — modified]

3.3
feed safety
concept that *feed* (3.1) and *animal food* (3.2) will not cause harm to animals and/or lead to *contamination* (3.5) of human food products

3.4
feed safety hazard
biological, chemical or physical agent in *feed* (3.1) and *animal food* (3.2), with the potential to cause an adverse health effect in animals and/or humans

3.5
contamination
introduction or occurrence of a *contaminant* (3.6) in *feed* (3.1) and *animal food* (3.2) or the production environment

[SOURCE: CAC/RCP 1-1969:1997, 2.3 — modified]

3.6
contaminant
any substance not intentionally added to *feed* (3.1) or *animal food* (3.2), which is present as a result of the production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such feed or animal food, or as a result of environmental *contamination* (3.5)

[SOURCE: CAC/GL 81-2013 — modified]

3.7
cross-contamination
contamination (3.5) from one type, item or lot or batch of *feed* (3.1) and *animal food* (3.2) to another

3.9
materials
any constituent part of *feed* (3.1) and *animal food* (3.2) and packaging materials

3.10
representative sample
sample in which any particular characteristics of the lot or batch from which it is drawn are maintained, in particular in the case of a simple random sample where each of the items or increments of the lot or batch has been given the same probability of entering the sample

3.11
rework
nonconforming and/or returned products suitable for reprocessing

EXAMPLE Pellet fines, screenings, quality defects and customer returns.

3.12
medications
substances applied or administered to any animal for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour or the combination of such substances with *feed* (3.1) or *animal food* (3.2)

[SOURCE: Codex Alimentarius Commission Procedural Manual, 23: 2015 — modified]

3.13
zoning
defined area within an establishment where specific operating, hygiene or other practices may be applied to minimize the potential for *contamination* (3.5)

[SOURCE: PAS 222:2011 — modified]

4 Generic PRPs

4.1 Establishment

4.1.1 General requirements

Establishments shall be designed, constructed and maintained in a manner that

a) facilitates satisfactory performance of all operations,

b) eliminate or minimize to acceptable level the feed safety hazards associated with those operations, and

c) prevent contamination from the surroundings.

Establishments shall be maintained in good order. Vegetation shall be tended, removed or otherwise managed to address feed safety hazards. Establishments shall be designed, constructed and maintained to allow adequate drainage and cleaning to prevent contamination.

The establishment boundaries shall be defined and documented. Access to the establishment shall be managed to address feed safety hazards. Access by non-employees shall 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 shall be taken.

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

4.1.2 Environment

Potential sources of contamination from the local environment shall be considered. Measures taken to protect against potential sources of contamination shall be documented and reviewed for effectiveness.

4.2 Layout and workspace

4.2.1 General requirements

Processes and workspaces shall be designed, constructed and maintained to control feed safety hazards.

4.2.2 Internal design and layout

The establishment shall be designed so the movement of materials, products and people do not contribute to contamination.

Testing areas and laboratories shall be designed, located and operated to prevent contamination of materials and production areas of the establishment.

4.2.3 Internal structures and fittings

Walls, floors and floor-wall junctions shall be cleanable and resistant to the cleaning system applied.

Standing water shall be prevented and/or removed.

Openings shall be designed and managed to prevent entry of foreign matter, precipitation and pests. This includes external openings for the transfer of materials within the establishment.

Roofs in manufacturing and storage locations shall be self-draining and shall not leak.

Ceilings and overhead fixtures shall be designed and maintained to prevent damage and build-up of dirt and condensation.

4.2.4 Equipment

Equipment shall be designed and located to permit access for operation, cleaning and maintenance.

All equipment used for producing or processing feed and animal food shall be fit for the purpose for which it is used.

4.2.5 Mobile structures and equipment

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

4.2.6 Storage

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

Storage conditions shall be appropriate for the intended use of the material.

Temperature and humidity shall be controlled where necessary.

Storage areas for dry materials shall be kept dry and appropriately ventilated.

Measures shall be taken to prevent contamination when materials are stored directly on the floor.

Sufficient space shall be maintained between packaged materials and walls to allow inspection and pest control activities to be carried out.

Packaging shall be fit for purpose.

Hazardous compounds not intended for inclusion in feed and animal food shall be segregated and secured when not in use. Materials with restricted use shall be stored segregated to avoid cross-contamination or unintended use.

4.3 Utilities

4.3.1 General requirements

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

4.3.2 Water supply

All forms of water that come into direct contact with product contact surfaces or are included in feed and animal food, shall not introduce a feed safety hazard. When available, potable water should be used.

Use of reclaimed or recycled water shall be justified by a risk assessment. Reclaimed or recycled water shall have a separate supply system, identified and not connected to or otherwise prevented from refluxing into the primary or potable water systems.

Facilities for storage and distribution of water shall be designed to meet specified water quality requirements.

4.3.3 Ventilation

Production and storage areas shall be appropriately ventilated to prevent contamination.

Measures shall be taken to remove excess humidity and moisture appropriate to the type of facility.

Ventilation systems including intake ports and filters shall be inspected and maintained.

4.3.4 Air and other gases

Air and gases that come into direct contact with feed and animal food, including those used for transferring, blowing or drying, shall not compromise feed safety.

Gases from combustion intended for direct contact with feed and animal food shall not compromise feed safety. The fuel used as the combustion source shall be fit for purpose.

4.3.5 Lighting

Lighting shall allow personnel to carry out assigned feed safety responsibilities.

Light fixtures shall be designed in such a way to prevent contamination in the case of breakages.

4.4 Waste disposal

4.4.1 General requirements

Systems shall be in place such that waste is identified, collected, removed and disposed of to prevent contamination. Waste shall be managed in a manner that prevents attraction and harbouring of pests.

4.4.2 Waste handling

Containers for waste shall be

a) clearly identified for their intended use,

b) located in a designated area, and

c) designed to be effectively emptied.

Provision shall be made for the segregation, storage and removal of waste. Removal frequencies from production areas shall be managed to avoid accumulations. Waste accumulation shall occur only in designated areas.

Materials designated as waste shall be disposed of in a manner that prevents unauthorized use.

4.4.3 Drains and drainage

Drains shall be designed, constructed and maintained so that contamination is prevented.

Drains shall have sufficient capacity to handle expected loads.

Drains should not be located such that materials would be contaminated if a leak occurred.

Open drainage direction shall not be from a contaminated area to a clean area.

Closed drainage direction should not be from a contaminated area to a clean area.

4.5 Equipment suitability, cleaning and maintenance

4.5.1 General requirements

Equipment shall be fit for purpose, installed, maintained and managed to facilitate cleaning and maintenance.

4.5.2 Hygienic design

Product contact surfaces and tools shall be constructed from suitable materials and be able to resist repeated cleaning and where applicable sanitizing.

4.5.3 Measuring and dosing devices

All measuring and dosing devices used in the manufacture of feed and animal food shall be fit for purpose.

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

a) calibrated prior to initial use and recalibrated at specified intervals, against measurement standards traceable to international or national measurement standards; where no standards exist, the basis for calibration shall be documented;

b) adjusted or readjusted as necessary;

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

d) safeguarded from adjustments that would invalidate the measurement result;

e) protected from damage and deterioration when appropriate.

4.5.4 Maintenance

A preventive maintenance programme shall be in place and shall include all devices used to monitor and/or control feed safety hazards.

Hygiene requirements shall apply to maintenance areas and maintenance activities.

Maintenance requests that affect feed safety shall be given priority.

Maintenance activities shall be performed in a manner that prevents contamination.

Maintenance activities in process areas shall be recorded.

Temporary repairs shall not compromise feed safety. Replacement by a permanent repair shall be included in the maintenance schedule.

The procedure for releasing maintained equipment back to production shall specify sanitation and pre-use inspection measures.

Lubricants and heat transfer fluids shall be fit for purpose where there is potential for direct or indirect contact with materials.

4.6 Management of purchased materials and services

4.6.1 General requirements

Purchasing of materials and services shall be managed such that the suppliers have the capability to meet specified feed safety requirements.

The conformance of services and incoming materials to specified purchase requirements shall be verified.

4.6.2 Selection and management of suppliers

A documented risk-based process for the selection, approval and monitoring of suppliers shall be in place. The process shall include the following:

a) an assessment of the supplier's ability to meet feed safety requirements and specifications for each material from suppliers;

   EXAMPLES Supplier assessment may include the following:

   — audit of the supplying site prior to accepting materials for production;

   — appropriate third party certification;

   — required approvals or registrations.

b) monitoring the performance of the suppliers to ensure continued approval status.

   EXAMPLES Monitoring may include the following:

   — conformity with materials or product specification;

   — fulfillment of certificate of analysis requirements;

   — satisfactory audit outcomes.

A process to provisionally qualify an unapproved supplier in emergency situations shall be defined. Provisionally qualified suppliers shall be formally approved before continued use.

4.6.3 Incoming materials

Documentation shall be evaluated and materials shall be examined prior to unloading to verify the identity and suitability of the material. Records shall be maintained for an appropriate period of time.

Conveyances and materials shall be examined prior to unloading to verify that the integrity of the material has not been compromised.

A representative sample of each incoming material for inclusion in a lot or batch shall be maintained for an appropriate period of time.

Bulk conveyances shall be checked and recorded to ensure that previous loads do not compromise feed safety.

When a material is covered by a certificate of analysis, a certificate of analysis validation programme shall be in place, and the method of validation shall be documented.

Materials that do not conform to relevant specifications shall be handled under a documented procedure designed to prevent unintended use.

4.7 Measures for prevention of cross-contamination

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

Based on a risk assessment, procedures to prevent cross-contamination shall be implemented.

Where appropriate, a zoning plan shall be defined and managed.

Cross-contamination by medication shall be prevented or controlled by use of dedicated lines, cleaning, line changeover practices and/or product sequencing.

Effectiveness of procedures shall be validated and documented. Verification activities shall be monitored and recorded.

EXAMPLES Procedures used alone or in combination to prevent cross-contamination:

— physical cleaning;

— flushing;

— sequencing.

4.8 Cleaning and sanitation

4.8.1 General requirements

Cleaning programmes shall be established and documented to maintain hygienic conditions.

Where identified in the risk assessment, sanitizing programmes shall be established and documented. Programmes shall be monitored, verified and where appropriate validated for continuing suitability and effectiveness.

Facilities and equipment shall be maintained in a condition which facilitates wet or dry cleaning and/or sanitation.

Dry process areas shall be dry after wet cleaning or sanitation.

4.8.2 Cleaning and sanitizing programmes

Cleaning and, when applicable, sanitizing programmes shall specify, as a minimum, the following:

a) areas, items of equipment and tools to be cleaned and/or sanitized;

b) responsibility for the tasks specified;

c) cleaning/sanitizing method and frequency.

Measures shall be taken to prevent contamination when compressed air is used to “blow down” debris in a facility.

4.8.3 Cleaning and sanitizing agents and tools

Cleaning and sanitizing agents shall be fit for purpose, clearly identified, stored separately and used only in accordance with documented instructions.

Tools shall be fit for purpose, maintained and stored to prevent contamination.

4.9 Pest control

4.9.1 General requirements

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

4.9.2 Pest control programs

Pest control programmes shall identify target pests, address preventive plans, control procedures and be reviewed for effectiveness.

The organization shall have a nominated person to manage pest control programme and/or deal with qualified contractors at the establishment.

The pest control programme shall include a list of approved pesticides for use in specified areas of the establishment.

Requirements relating to the storage of hazardous materials shall apply to all pesticides used at the establishment.

4.9.3 Preventing access

Feed and animal food production and storage buildings shall be maintained in a manner to prevent pest access.

4.9.4 Harbourage and infestations

Storage and material handling practices shall avoid the availability of materials and water to pests.

Spilled materials and waste shall be controlled to prevent availability to pests.

Material found to be infested shall be handled in such a way as to prevent contamination of other materials, products or the establishment.

Potential pest harborage shall be removed.

EXAMPLES Burrows, undergrowth, and stored items.

4.9.5 Monitoring and detection

Pest monitoring programmes shall include the placing of detectors or traps in key locations to identify pest activity. A map of detectors and traps shall be maintained. Detectors and traps shall be designed and located to prevent potential contamination of materials or facilities.

Detectors and traps shall be effective for the target pest and application.

The detectors and traps shall be inspected at a frequency intended to identify new pest activity.

Records of inspections shall be maintained and reviewed to ensure programme effectiveness.

4.9.6 Control and eradication

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

Pesticide use and application shall be restricted to qualified individuals and shall be controlled to avoid feed safety hazards.

Records of pesticide use shall be maintained to show the type, quantity and concentrations used. Target pest and method of application shall be identified.

4.10 Personnel hygiene

4.10.1 General requirements

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

4.10.2 Personal behaviour

A documented policy shall describe required personal behaviours. The policy shall, as a minimum, cover the following:

a) permissibility of smoking, eating and chewing in designated areas only;

b) control measures to avoid hazards presented by jewellery and other items carried on a person;

c) permissibility of personal items, such as smoking materials and medicines, in designated areas only;

d) maintenance of personal lockers so that they are kept free from rubbish and in an acceptable state;

e) spitting shall be prohibited in feed and animal food production and storage areas.

4.10.3 Personal hygiene facilities and toilets

Personal hygiene facilities and toilets shall be located, available, clearly designated and maintained to prevent contamination.

4.10.4 Designated eating areas

All human food shall be stored, prepared and consumed in designated areas.

4.10.5 Clothing and protective equipment

Personnel who work in, or enter into, areas where feed and animal food is handled shall wear clothing and protective equipment that does not pose a feed safety risk.

4.10.6 Personal cleanliness

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

4.11 Rework

4.11.1 General requirements

Rework shall be managed in such a way that feed safety is not compromised and traceability is maintained. Rework management shall include criteria and conditions for acceptance, storage, identification, traceability and processing.

Product returned from distribution shall be assessed for feed safety hazards and handled accordingly. Defective products shall be stored in a separate and secure area to prevent unintended use.

4.11.2 Storage, identification and traceability

Stored rework shall be protected from contamination and shall not attract or harbour pests.

Segregation requirements for rework shall be established and documented.

Rework shall be identified and recorded to maintain traceability.

4.11.3 Rework usage

The quantity, type and conditions of rework (including “in process” rework) used shall be specified. All process steps and methods of addition shall be defined.

Where rework activities involve removing a product from filled or wrapped packages, controls shall be in place for the removal and segregation of packaging materials and to avoid contamination of the product with extraneous matter.

Rework containing medication(s) shall be managed appropriately to avoid compromising feed safety.

