

**PAS 222**

**Prerequisite programmes on food safety for manufacturing food and feed for animals**

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## Foreword

This Publicly Available Specification, PAS 222, was sponsored by SSAFE and developed through the British Standards Institution.

Acknowledgement is given to the following organizations that were consulted in the development of this PAS:

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- Cargill
- Food and Agriculture Organization of the United Nations
- Foundation for Food Safety Certification
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## Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

*Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.*

## **Introduction**

Prerequisite programmes (PRPs) assist in controlling food safety hazards that may arise across the food supply chain. The animal food, feed and ingredient industries play an important role in safeguarding the food supply chain for both humans and animals. This PAS is intended to assist organizations in setting out requirements that are specific to the manufacture of commercial animal food, feed and ingredients.

This PAS intends to be consistent with relevant publications, referenced in the bibliography, from the Food and Agriculture Organization and Codex Alimentarius Commission. The development of this PAS builds upon the work of these organizations and from the work completed in the form of BS EN PAS 220, which was used as a template.

The public availability of the document ensures that all organizations (regardless of size, location or complexity) that operate in the animal food space have access to the PRPs.

Use of PAS 222 is voluntary. This PAS may be used alone or in conjunction with a food safety management system such as BS EN ISO 22000.

## 1 Scope

This Publicly Available Specification (PAS) specifies requirements for establishing, implementing and maintaining prerequisite programmes (PRPs) to assist in controlling food safety hazards in commercially manufactured food for animals and in ingredients intended for use in the production of commercial animal food. "Food safety hazards" in this context relate to attributes that are likely to adversely affect animal and/or human health either directly or indirectly.

*NOTE The term "animal food" is synonymous with "animal feed" in this document. Animal food refers to products intended to provide nourishment to non-human terrestrial and aquatic animals, including food-producing animals, companion animals and pets, work (draft) animals, laboratory animals, captive (zoo) animals and non-captive (wild) animals. In addition, ingredients utilized in the manufacture of commercial products are considered "animal food" and are within the scope of this document.*

*NOTE The term "animal health" in the context of this document refers to the well-being of animals with respect to absence of disease, including abnormal metabolic conditions. Animal health can be adversely impacted by a multitude of conditions unrelated to animal food. Biological, chemical and/or physical attributes of an animal food that are likely to adversely affect animal health when the intended use of a product is followed constitute a food safety hazard. Protecting animal health through the production of safe animal food encompasses a broad array of measures, many outlined in this document. Adverse animal productivity by itself is not considered an animal health matter in this document unless attributed to a specific hazard or combination of hazards contained within an animal food product. For example, a complete feed product for swine that does not optimize growth is a product quality, not a food safety, matter unless the reduced growth is caused by a severe nutrient deficiency or toxicity, or from a hazard present in the product.*

This PAS is applicable to all organizations, regardless of size, location or complexity, that are involved in the supply and manufacturing (including storage, distribution and/or transportation) steps related to compound animal food and ingredients utilized in the manufacture of such animal food and that wish to implement a PRP.

The PRPs contained in this PAS may be implemented alone or in such a way as to address the requirements specified in BS EN ISO 22000:2005, Clause 7.

This PAS is neither designed nor intended for use in other parts of the food supply chain.

Animal food and animal food ingredient operations are diverse in nature, and not all of the requirements specified in this PAS apply to an individual establishment or process.

*NOTE Where exclusions are made or alternative measures are implemented, these need to be justified by a hazard assessment. Any exclusions or alternative measures adopted should not affect the ability of an organization to comply with these requirements. Examples of such exclusions include the additional aspects relevant to manufacturing operations listed below.*

This PAS specifies detailed requirements to be considered, specifically:

- a) establishment and associated utilities;
- b) processes, including workspace and employee facilities;
- c) supplies of air, water, energy and other utilities;
- d) supporting services, including waste and sewage disposal;
- e) suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance;
- f) management of ingredients;
- g) management of medications
- h) measures for the prevention of cross-contamination;
- i) cleaning and sanitizing;

- j) pest control;
- k) personnel hygiene;

In addition, this PAS adds other aspects that are considered relevant to animal food and feed manufacturing operations:

- a) rework;
- b) product withdrawal procedures;
- c) warehousing;
- d) specifications/formulation of products;
- e) specifications for services;
- f) training and supervision of personnel;
- g) documentation and record-keeping;
- h) product information and consumer awareness;
- i) food defence, biovigilance and bioterrorism.

## **2 Normative references**

The following referenced documents may be useful for the application of this PAS. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN ISO 22000:2005, Food safety management systems – Requirements for any organization in the food chain, Clause 7

## **3 Terms and definitions**

For the purposes of this PAS, the following terms and definitions apply.

The terms and definitions given in BS EN ISO 22000:2005 also apply.

### **3.1**

#### **contamination**

introduction or occurrence of a contaminant (see 3.2) in food or a food environment

[Adapted from Codex Alimentarius, 2.3]

### **3.2**

#### **contaminant**

any biological or chemical agent, foreign matter or other substances not intentionally added to food that may compromise food safety or suitability

[After Codex Alimentarius, Food hygiene, Basic texts, 4th ed, 2.3]

*NOTE Measures for prevention of malicious contamination are outside the scope of this PAS. For further information and guidance on approaches to the protection of food businesses from all forms of malicious attack, see PAS 96.*

### **3.3**

#### **establishment**

any building or area in which food is handled, and the surroundings, under the control of the same management

[After Codex Alimentarius, Food hygiene, Basic texts, 4th ed, 2.3]

**3.4****materials**

raw materials, packaging materials, ingredients, process aids, cleaning materials and lubricants

**3.5****cleaning**

removal of soil, food residue, dirt, grease or other objectionable matter

[After Codex Alimentarius, Food hygiene, Basic texts, 4th ed, 2.3]

**3.6****product contact**

all surfaces that are in contact with the product or the primary package during normal operation

**3.7****material/product specification**

detailed documented description or enumeration of parameters, including permissible variations and tolerances, that are required to achieve a defined level of acceptability or quality

**3.8****food grade**

lubricants and heat transfer fluids formulated to be suitable for use in animal food processes where there may be incidental contact between the lubricant and the animal food

**3.9****disinfection**

reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability

[After Codex Alimentarius, Food hygiene, Basic texts, 4th ed, 2.3]

**3.10****sanitizing**

process of cleaning followed by disinfection

**3.11****sanitation**

all actions dealing with cleaning or maintaining hygienic conditions in an establishment, ranging from cleaning and/or sanitizing of specific equipment to periodic cleaning activities throughout the establishment (including building, structural and grounds cleaning activities)

**3.12****certificate of analysis****COA**

document provided by the supplier that indicates results of specific tests/analysis, including test methodology, performed on a defined lot of the supplier's product

**3.13****zoning**

demarcation of an area within an establishment where specific operating, hygiene or other practices may be applied to minimize the potential for microbiological cross-contamination

*NOTE Examples include: clothing change on entry/exit, positive air pressure, modified traffic flow patterns.*

**3.14**

**label**

printed matter that is part of the finished product package conveying specific information about the contents of the package, the food ingredients and any storage and preparation requirements

*NOTE This includes but is not limited to:*

*the package itself, printed matter attached to the package, or a sticker used for over-labelling;*

*multi-packs that have an inner label on the individual product and an outer combined label for the whole contents;*

*documents that accompany bulk shipments such as bills of lading, weigh tickets and other printed matter descriptive of the product;*

*all information that is required by regulation to be printed on the package or documents required to accompany bulk shipments.*

**3.15**

**product withdrawal**

removal of a nonconforming product from the market, trade and warehouses, distribution centres and/or customer warehouses because it does not meet specified standards

*NOTE Product withdrawal includes recalls.*

**3.16**

**first expired, first out**

**FEFO**

stock rotation based on the principle of despatching earliest expiration dates first

**3.17**

**first in, first out**

**FIFO**

stock rotation based on the principle of despatching earliest received products first

**3.18**

**conveyance**

the physical means of transporting an animal food product or ingredient from one location to another (e.g. truck, railcar/train, barge, ship, bags).

## **4 Establishments**

### **4.1 General requirements**

Establishments shall be designed, constructed and maintained in a manner that is fit for purpose.

### **4.2 Buildings**

Buildings shall be designed, constructed and maintained in a manner appropriate to the nature of the processing operations to be carried out, the food safety hazards associated with those operations and the potential sources of contamination from the plant environs. Buildings shall be of durable construction that presents no hazard to the product.

*NOTE For example, roofs should be self-draining and should not leak.*

### **4.3 Environment**

Potential sources of contamination from the local environment shall be avoided.

*NOTE Animal food production should not be carried out in areas where potentially harmful substances could enter the product. Where appropriate, environmental assessments should be conducted, such as in the case of manufacturing facilities that were previously used for the production or handling of industrial or nuclear products or in locations where waste products are produced, handled or stored (industrial, municipal or agricultural wastes).*

The effectiveness of measures taken to protect against potential contaminants shall be periodically reviewed.

### **4.4 Locations of establishments**

The site boundaries shall be clearly identified.

Access to the site shall be controlled.

The site shall be maintained in good order. Vegetation shall be tended or removed. Roads, yards and parking areas shall be drained to prevent standing water and shall be maintained.

## 5 Processes and workspaces

### 5.1 General requirements

Processes and workspaces shall be designed, constructed and maintained to facilitate good hygiene and manufacturing practices. The movement patterns of materials, products and people, and the layout of equipment, shall be designed to protect against potential contamination sources.

### 5.2 Traffic patterns

The establishment shall provide adequate space, with a logical flow of materials, products and personnel. Physical separation of raw materials from products where microbial control measures have been applied shall be provided.

*NOTE Examples of physical separation may include walls, barriers or partitions, equipment enclosure, or sufficient distance to minimize risk.*

Openings intended for transfer of materials shall be designed and maintained to minimize entry of foreign matter and pests.

### 5.3 Structures and fittings

Process area walls and floors shall be cleanable, as appropriate for the process or product hazard. Materials shall be resistant to the cleaning system applied.

Wall floor junctions and corners shall be designed to facilitate cleaning.

*NOTE It is recommended that wall–floor junctions are rounded in processing areas.*

Floors shall be designed to avoid standing water.

In wet-process areas, floors shall be sealed and drained. Drains shall be trapped and covered.

Ceilings and overhead fixtures shall be designed to minimize build-up of dirt and condensation.

External opening windows, roof vents or fans, where present, shall be appropriately screened.

External opening doors shall be closed or appropriately screened when not in use.

### 5.4 Location of equipment

Equipment shall be designed and located so as to facilitate good hygiene practices and monitoring.

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

### 5.5 Laboratory facilities

Inline and online test facilities shall be controlled to minimize risk of product contamination.

Microbiology laboratories shall be designed, located and operated so as to prevent contamination of people, plant and products.

### 5.6 Temporary and/or mobile structures and equipment

Temporary and/or mobile structures and equipment (e.g. storage containers, conveyances, construction equipment) shall be designed, located and constructed to avoid pest harbourage and potential contamination of products.

Additional hazards associated with temporary and/or mobile structures and equipment shall be assessed and controlled.

**5.7 Storage of animal food, packaging materials, ingredients and non-food chemicals**

Facilities used to store ingredients, packaging and products shall provide protection from dust, condensation, drains, waste and other sources of contamination.

Storage areas for dry animal food products and ingredients shall be kept dry and well ventilated. Monitoring and control of temperature and humidity shall be applied where specified.

Storage areas shall be designed or arranged to allow segregation of ingredients, work in progress and finished products.

All materials and products shall be stored off the floor and with sufficient space between the material and the walls to allow inspection and pest control activities to be carried out.

The storage area shall be designed to allow maintenance and cleaning, prevent contamination and minimize deterioration.

A separate, secure (locked or otherwise access-controlled) storage area shall be provided for both hazardous and non-hazardous chemicals not intended for product inclusion (e.g. cleaning materials, pesticides).

Exceptions for bulk or agricultural crop materials shall be documented.

## 6 Utilities

### 6.1 General requirements

The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination. Utilities' quality shall be monitored to minimize product contamination risk where appropriate.

### 6.2 Water supply

The supply of potable water shall be sufficient to meet the needs of the production process(es). Facilities for storage, distribution and, where needed, temperature control of the water shall be designed to meet specified water quality requirements.

*NOTE Potable water should conform to the World Health Organization's Guidelines for drinking-water quality. Use of non-potable, reclaimed or recycled water should be justified by a risk assessment.*

Water used as a product ingredient, or in contact with products or product surfaces, including steam (e.g. during pellet conditioning), shall meet specified quality and microbiological requirements relevant to the product.

Water for cleaning or applications where there is a risk of indirect product contact shall meet specified quality and microbiological requirements relevant to the application.

Non-potable water shall have a separate supply system, labelled, not connected to the potable water system and prevented from refluxing into the potable system.

*NOTE It is recommended that water that can come into contact with the product should flow through pipes that can be disinfected.*

### 6.3 Boiler chemicals

Boiler chemicals, if used, shall be either:

- a) approved food additives that meet relevant additive specifications; or
- b) additives that have been approved by the relevant regulatory authority as safe for use in water intended for human and/or animal consumption.

Boiler chemicals shall be stored in a separate, secure (locked or otherwise access-controlled) area when not in immediate use.

### 6.4 Air quality and ventilation

Requirements for filtration, relative humidity and microbiology of air used as an ingredient or for direct product contact shall be established where applicable. Where temperature and/or humidity are deemed critical by the organization, a control system shall be put in place and monitored.

Ventilation (natural or mechanical) shall be provided to remove excess or unwanted steam, dust and odours, and to facilitate drying after wet cleaning.

*NOTE Environmental air-scrubbing systems may be considered a form of ventilation if designed to serve that purpose.*

Room air supply quality shall be controlled to minimize risk from airborne contamination where applicable.

Ventilation systems shall be designed and constructed such that air does not flow from contaminated or raw areas to clean areas in buildings that are zoned. Systems shall be accessible for cleaning, filter changing and maintenance.

Exterior air intake ports shall be examined periodically for physical integrity.

## 6.5 Compressed air and other gases

Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing (including those used for transporting, blowing or drying materials, products or equipment) shall be suitable to prevent contamination.

*NOTE Special consideration should be given to prevent the introduction of hazards in applications that use compressed air to convey materials and/or fill product containers.*

Where oil is used for compressors and there is potential for the air to come into contact with the product, the oil used shall be fit for purpose.

*NOTE Use of oil-free compressors is recommended.*

Compressed air shall not be used for dry cleaning in process areas.

*NOTE Use of compressed air to “blow down” debris can spread potential contaminants throughout a facility.*

Requirements for filtration, relative humidity and microbiology shall be specified where appropriate.

*NOTE Filtration of the air should be as close to the point of use as is practicable.*

## 6.6 Lighting

The lighting provided (natural or artificial) shall allow personnel to operate in a hygienic manner.

*NOTE The intensity of the lighting should be appropriate to the nature of the operation.*

Light fixtures shall be protected or equipped in such a way that materials, product or equipment are not contaminated in the case of breakages.

## 7 Waste disposal

### 7.1 General requirements

Systems shall be in place such that waste materials are identified, collected, removed and disposed of in a manner that prevents contamination of products or production areas.

### 7.2 Containers for waste or hazardous substances

Containers for waste and hazardous substances shall be:

- a) clearly identified for their intended purpose;
- b) located in a designated area;
- c) constructed of impervious material that can be readily cleaned;
- d) closed when not in immediate use;
- e) locked where the waste may pose a risk to the product.

*NOTE Waste materials produced in the manufacture of animal food can attract animals, including insects, rodents and wild birds. It is important to prevent animal access to such materials.*

### 7.3 Waste management and removal

Provision shall be made for the segregation, storage and removal of waste.

Accumulation of waste shall not be allowed in processing areas. Removal frequencies (from processing areas) shall be managed to avoid accumulations. Waste accumulation shall occur only in designated storage areas and not pose risk of product contamination.

Labelled materials, products or printed packaging designated as waste shall be disfigured or destroyed so that trademarks cannot be reused. Records of destruction shall be retained.

**7.4 Drains and drainage**

Drains shall be designed, constructed and located so that the risk of contamination of materials or products is avoided. Drains shall have capacity sufficient to remove expected flow loads. Drains shall not pass over-exposed processing lines or be located in a manner that would contaminate product if a leak occurred.

Drainage direction shall not be from a contaminated area to a clean area.

## **8 Equipment suitability, cleaning and maintenance**

### **8.1 General requirements**

Animal food contact equipment shall be designed and constructed to facilitate cleaning and maintenance. Contact surfaces shall not affect, or be affected by, the intended product or cleaning system.

Animal food contact equipment shall be constructed of durable materials able to resist repeated cleaning.

### **8.2 Hygienic design**

Equipment shall meet established principles of hygienic design, including:

- a) smooth, accessible, cleanable surfaces, self-draining in wet process areas;
- b) use of materials compatible with intended products and cleaning or flushing agents;
- c) framework not penetrated by holes or nuts and bolts.

Piping and ductwork shall be cleanable and drainable, with no dead ends.

Equipment shall be designed to minimize contact between the operator's hands and the products.

### **8.3 Product contact surfaces**

Product contact surfaces shall be constructed from materials suitable for animal food use. They shall be impermeable and corrosion-free.

### **8.4 Temperature control and monitoring equipment**

Equipment used for thermal processes shall meet the temperature gradient and holding conditions given in relevant product specifications.

Equipment shall provide for the monitoring and control of temperature.

### **8.5 Cleaning programmes**

Wet and/or dry cleaning programmes shall be implemented and documented.

The programmes shall specify what is to be cleaned, the responsible agent, the method and frequency of cleaning, the use of dedicated cleaning tools, removal or disassembly requirements, and methods for verifying the effectiveness of the cleaning.

All cleaning activities shall be recorded.

Compressed air shall not be used for dry cleaning in process areas.

*NOTE This requirement is also contained in 6.5. Use of compressed air to "blow down" debris can spread potential contaminants throughout a facility.*

### **8.6 Preventive and corrective maintenance**

A preventive maintenance programme shall be in place.

The preventive maintenance programme shall include all devices used to monitor and/or control food safety hazards.

*NOTE Examples of such devices include screens and filters (including air filters), magnets and metal detectors.*

Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination.

Maintenance requests that impact product safety shall be given priority.

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

Lubricants and heat transfer fluids shall be food grade where there is a risk of direct or indirect contact with the product.

The procedure for releasing maintained equipment back to production shall include clean-up, sanitizing, where specified in process sanitation procedures, and pre-use inspection.

Local area PRP requirements shall apply to maintenance areas and maintenance activities in process areas. Maintenance personnel shall be trained in the product hazards associated with their activities.

### **8.7 Measuring devices**

All scales and metering devices used in the manufacture of animal food shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly according to the risks.

Where necessary to ensure valid results, measuring equipment shall be:

- a) 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 shall be recorded;
- b) adjusted or re-adjusted 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 during handling, maintenance and storage.

*NOTE This section was adapted from FAMI-QS Code of Practice section 6.4.*

## **9 Management of ingredients**

### **9.1 General requirements**

Purchasing of materials that impact on food safety shall be controlled so that the suppliers used have the capability to meet the specified requirements. The conformance of incoming materials to specified purchase requirements shall be verified.

*NOTE This section is applicable to the management of materials and processing aids used in the production of ingredients and to the management of commercially prepared ingredients utilized by commercial animal food manufacturers.*

### **9.2 Selection and management of suppliers**

There shall be a defined process for the selection, approval and monitoring of suppliers. The process used shall be justified by hazard assessment, including the potential risk to the final product, and shall include:

- a) assessment of the supplier's ability to meet food safety expectations, requirements and specifications;
- b) description of how suppliers are assessed;

*NOTE Examples of a description of how suppliers are assessed include:*

*review of supplier food safety management systems, including PRPs;*

*audit of the supplier establishment prior to accepting materials for production;*

*appropriate third-party certification.*

- c) monitoring the performance of the supplier to confirm continued approval status.

*NOTE* Monitoring may include conformance to material or product specifications, meeting certificate of analysis (COA) requirements and satisfactory audit outcomes.

### **9.3 Incoming material requirements (ingredients/packaging)**

Conveyances, documentation and materials shall be inspected prior to unloading to verify the integrity of the material has been maintained.

*NOTE 1* Receiving personnel should evaluate every load on a case-by-case basis. Possible questions include: Is this the correct material? Is it free from infestation or other contamination? Is the conveyance suitable and in good repair? Have dry ingredients and packaging been maintained dry or do they show evidence of contamination from water that was introduced during transit?

*NOTE 2* Bulk conveyances should at the point of acceptance show evidence of previous loads carried on the conveyance together with details of any relevant cleaning/sanitizing operations conducted prior to loading. Previous loads should be checked against a list of prohibited materials that represent a contamination risk to the product. The number of previous loads checked should be based on a risk assessment or regulatory directive.

When an ingredient is covered by a COA, a COA verification programme shall be in place, and the method of verification shall be documented.

*NOTE* The inspection frequency and scope should be based on potential hazards presented by the material and a risk assessment of the specific supplier.

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

Access points to bulk material receiving lines shall be identified and secured from unintended use and contamination. Discharge into such systems shall take place only after approval and verification of the material to be received.

### **9.4 Communications on product/process attributes**

Ingredient suppliers shall be required prior to shipment to notify customers of relevant changes in product composition due to changes in source materials and/or processing aids and/or the production process used in the manufacture of an animal food ingredient. Records of such communications shall be retained.

*NOTE* Changes in product composition or processing method can impact the manner in which an ingredient can be safely used in an animal feed product. Such changes may require a supplier to be reassessed, require modification of product formulas and/or affect intended use of animal food products.

A real-life example is as follows: a compound feed manufacturer routinely purchased a wheatfeed ingredient (middlings) from a specific supplier because it was high in fibre content (40%). This ingredient supplied the majority of the fibre in a complete finished feed for a specific animal class. Unexpectedly and without notification, the wheatfeed supplier mixed wheat flour that was out of specification for a bakery into the wheatfeed ingredient. The resulting drop in fibre content adversely affected the health and welfare of the livestock that consumed the compound feed product. Communication of such a change would have prevented the situation.

## **10 Management of medications**

### **10.1 General requirements**

Medications present in the product shall be declared. The declaration shall be on the label for finished products, and on the label or the accompanying documentation for products intended for further processing.

Products shall be protected from unintended medication cross-contact by use of dedicated lines, cleaning and line change-over practices (such as flushing) and/or product sequencing.

*NOTE* Manufacturing cross-contact may arise from either:

*a) traces of product from the previous production run that cannot be adequately cleaned from the product line due to technical limitations; or*

*b) when contact is likely to occur, in the normal manufacturing process, with products or ingredients that are produced on separate lines, or in the same or adjacent processing areas.*

Rework containing medication(s) shall be used only:

- a) in products that contain the same medication by design; and
- b) in accordance with statutory and regulatory requirements.

*NOTE 1 For general rework requirements, see Clause 15.*

*NOTE 2 Animal food handling employees should receive specific training in medication awareness and associated manufacturing practices.*

## **10.2 Prevention of cross-contact**

Procedures to prevent cross-contact shall be documented. Effectiveness of procedures shall be validated. Verification that procedures are followed shall occur. Validation studies and verification activities shall be recorded.

*NOTE Use of dedicated equipment/lines, physical cleaning, flushing and/or sequencing are examples of procedures used alone or in combination to prevent cross-contact.*

## **10.3 Storage**

Medications shall be stored in a dedicated room or area dedicated for such purpose. Access to medications shall be restricted to authorized personnel.

## **11 Measures for prevention of cross-contamination**

### **11.1 General requirements**

Programmes shall be in place to prevent, control and detect cross-contamination. Measures to prevent physical, chemical and biological (including microbiological) cross-contamination shall be included.

### **11.2 Physical cross-contamination**

Where brittle materials are used, periodic inspection requirements and defined procedures in case of breakage shall be put in place.

*NOTE Glass and brittle material (such as hard plastic components in equipment) should be avoided where possible.*

Based on hazard assessment, measures shall be put in place to prevent, control or detect potential cross-contamination.

*NOTE 1 Examples of such measures include:*

*adequate covers over equipment or containers for exposed materials or products;*

*use of screens, magnets, sieves or filters;*

*use of detection/rejection devices such as metal detectors.*

*NOTE 2 Sources of potential contamination include wooden pallets and tools, rubber seals, personal protective clothing and equipment (e.g. elevator buckets).*

### **11.3 Chemical cross-contamination**

Situations where potential for chemical cross-contamination exists shall be identified and programmes to prevent, control and detect cross-contamination shall be in place.

Procedures to prevent cross-contamination shall be documented. Effectiveness of procedures shall be validated. Verification that procedures are followed shall occur. Validation studies and verification activities shall be recorded.

*NOTE Physical cleaning, flushing an/ or sequencing are examples of procedures used alone or in combination to prevent cross-contamination.*

#### **11.4 Biological cross-contamination**

Areas where potential for cross-contamination of biological hazards exist (airborne or from traffic patterns) shall be identified and a segregation (zoning) plan implemented where appropriate. A hazard assessment shall be carried out to determine potential contamination sources, susceptibility of the product and control measures suitable for these areas as follows:

- a) separation of raw from finished products;
- b) structural segregation: physical barriers, walls, separate buildings;
- c) access controls with requirements to change into required work wear;
- d) traffic patterns or equipment segregation: people, materials, equipment and tools (including use of dedicated tools);
- e) air pressure differentials.

*NOTE Microbial hazards are specific to the intended use of an animal food product or ingredient. Animal species, production class and/or age along with the method or location of use (residential versus commercial application, contact with immunocompromised populations) should be considered during hazard assessment.*

## **12 Cleaning and sanitizing**

### **12.1 General requirements**

Cleaning and sanitizing programmes shall be established to ensure that the food processing equipment and environment are maintained in a hygienic condition. Programmes shall be monitored for continuing suitability and effectiveness.

### **12.2 Cleaning and sanitizing agents and tools**

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

Cleaning and sanitizing agents and chemicals shall be clearly identified, food grade, stored separately and used only in accordance with the manufacturer's instructions.

Tools and equipment shall be of hygienic design and maintained in a condition that does not present a potential source of extraneous matter.

### **12.3 Cleaning and sanitizing programmes**

Cleaning and sanitizing programmes shall be established and validated by the organization to ensure that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule.

Cleaning and/or sanitizing programmes shall specify at a minimum:

- a) areas, items of equipment and utensils to be cleaned and/or sanitized;
- b) responsibility for the tasks specified;
- c) cleaning/sanitizing method and frequency;
- d) monitoring and verification arrangements;
- e) post-clean inspections;
- f) pre-start-up inspections.

## 12.4 Monitoring effectiveness

Cleaning and sanitation programmes shall be monitored, at frequencies specified by the organization, to ensure their continuing suitability and effectiveness.

## 13 Pest control

### 13.1 General requirements

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

### 13.2 Pest control programmes

The establishment shall have a nominated person to manage pest control activities and/or deal with appointed expert contractors.

Pest management programmes shall be documented, identify target pests and address plans, methods, schedules, control procedures and, where necessary, training requirements. Programmes shall include a list of chemicals that are approved for use in specified areas of the establishment.

Requirements relating to the storage of hazardous chemicals contained in 5.7 shall apply to all pesticides used at an establishment.

### 13.3 Preventing access

Process and warehouse buildings shall be maintained in good repair. Holes, drains and other potential pest access points shall be sealed.

External doors, windows or ventilation openings shall be designed and maintained to minimize the potential for entry of pests.

*NOTE* Doors should be tight fitting and close without gaps to prevent pest ingress.

Programmes shall address access of all animals, whether wild, feral or domestic.

*NOTE* Outer walls should have as few ledges as possible to discourage birds from perching or building nests.

### 13.4 Harbourage and infestations

Storage and material handling practices shall be designed to minimize the availability of food and water to pests. Spilled materials 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 harbourage (e.g. burrows, undergrowth, stored items) shall be removed.

Where outside space is used for storage, stored items shall be protected from weather or pest damage (e.g. bird droppings).

### 13.5 Monitoring and detection

Pest monitoring programmes shall include the placing of detectors and 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 so as to prevent potential contamination of materials, products or facilities.

*NOTE* Bait stations should not be located in process areas.

Detectors and traps shall be of robust, tamper-resistant construction. They shall be appropriate for the target pest.

The detectors and traps shall be inspected at a frequency intended to identify new pest activity. The results of inspections shall be analysed to identify trends.

### **13.6 Control and eradication**

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

Pesticide use and application shall be restricted to trained operatives and shall be controlled to avoid product safety hazards.

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

## **14 Personnel hygiene and employee facilities**

### **14.1 General requirements**

Requirements for personal hygiene and behaviours proportional to the hazard posed to the process area or product shall be established and documented. All personnel, visitors and contractors shall be required to comply with the documented requirements.

### **14.2 Personnel hygiene facilities and toilets**

Personnel hygiene facilities shall be available so that the degree of personal hygiene required by the organization can be maintained. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated.

Establishments shall:

- a) provide adequate numbers, locations and means of hygienically washing, drying and, where required, sanitizing hands (including wash basins, supply of soap and water, and/or sanitizer);
- b) have sinks designated for hand washing, separate from sinks for food use and equipment cleaning stations;
- c) provide an adequate number of toilets of appropriate hygienic design, each with hand washing, drying and, where required, sanitizing facilities;
- d) have employee hygiene facilities that do not open directly onto production, packing or storage areas;
- e) have adequate changing facilities for personnel.

### **14.3 Staff canteens and designated eating areas**

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

Designated areas for human food storage, preparation and consumption shall be situated so that the potential for cross-contamination of production areas is minimized.

### **14.4 Work wear and protective clothing**

Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear work clothing that is fit for purpose, clean and in good condition (e.g. free from rips, tears or fraying material).

Work wear shall be laundered at intervals suitable for the intended use of the garments.

Where gloves are used for product contact, they shall be clean and in good condition.

Shoes for use in processing areas shall be fully enclosed.

Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.

### 14.5 Health status

Employees in animal food contact operations (including site catering) shall undergo ongoing health monitoring (subject to legal restrictions in the country of operation), unless documented hazard or medical assessment indicates otherwise.

### 14.6 Illness and injuries

Where permitted by law, people known or suspected to be infected with, or carrying, a disease or illness transmissible through animal food intended for feeding inside homes shall be prevented from handling animal food or food contact materials.

*NOTE For example, individuals with diarrhoea should not come in contact with pet foods during manufacturing.*

### 14.7 Personal cleanliness

Personnel in animal food production and storage areas shall be required to wash and, where required, sanitize hands:

- a) before starting any working shift;
- b) immediately after using the toilet;
- c) immediately after handling any potentially contaminating material (e.g. pesticides).

Spitting (expectorating) shall be prohibited in animal food production and storage areas.

### 14.8 Personal behaviour

A documented policy shall describe the behaviours required of personnel in receiving, processing, packaging, loading and storage areas. The policy shall, as a minimum, cover:

- a) permissibility of smoking, eating and chewing in designated areas only;
- b) control measures to minimize hazards presented by permitted jewellery;  
*NOTE Permitted jewellery includes specific types of jewellery that may be worn by the personnel in processing and storage areas on account of religious, ethnic, medical or cultural imperatives.*
- 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 soiled clothing;
- e) prohibition of storage of product contact tools and equipment in personal lockers.

## 15 Rework

### 15.1 General requirements

Rework shall be stored, handled and used in such a way that product safety, quality, traceability and regulatory compliance are maintained.

### 15.2 Storage, identification and traceability

Stored rework shall be protected from exposure to microbiological, chemical or extraneous matter contamination and shall not provide a source of food to pests.

Segregation requirements for rework (e.g. medications, materials prohibited or toxic to certain species) shall be documented and met.

Rework shall be clearly identified and/or labelled to allow traceability. Traceability records for rework shall be maintained.

The rework classification or the reason for rework designation shall be recorded (e.g. product name, production date, shift, line of origin, shelf-life).

### **15.3 Rework usage**

Where rework is incorporated into a product as an “in-process” step, the acceptable quantity, type and conditions of rework use shall be specified. The process step and method of addition, including any necessary preprocessing stages, shall be defined.

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

## **16 Product withdrawal procedures**

### **16.1 General requirements**

Systems shall be in place such that products failing to meet required food safety standards can be identified, located and removed from all necessary points of the supply chain.

### **16.2 Product withdrawal requirements**

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

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

The product withdrawal programme shall be tested through conduct of a “mock recall” a minimum of once per year. Records of mock recalls shall be maintained.

## 17 Warehousing

### 17.1 General requirements

Materials and products shall be stored in clean, dry, well-ventilated spaces protected from dust, condensation, fumes, odours or other sources of contamination.

### 17.2 Warehousing requirements

Effective control of warehousing temperature, humidity and other environmental conditions shall be provided where required by product or storage specifications.

*NOTE It is recommended that, where products are stacked, consideration is given to measures necessary to protect the lower layers.*

Waste materials and chemicals (cleaning products, lubricants and pesticides) shall be stored separately.

A separate area or other means of segregating materials identified as nonconforming shall be provided.

Specified stock rotation systems (FIFO/FEFO) shall be observed.

### 17.3 Vehicles, conveyances and containers

Vehicles, conveyances and containers shall be maintained in a state of repair, cleanliness and condition consistent with requirements given in relevant specifications.

Vehicles, conveyances and containers shall provide protection against damage or contamination of the product. Control of temperature and humidity shall be applied and recorded where required by the organization.

A list of materials that are an acceptable (positive) and/or unacceptable (negative) prior use of bulk conveyances and containers shall be maintained. A hazard analysis shall be conducted to determine when cleaning is required. Cleaning procedures shall be documented, and cleaning actions between loads shall be recorded. Where required by the organization, bulk containers and conveyances shall be dedicated to a specified material, class of materials or animal food and/or ingredient use only.

### 17.4 Product returns

Product returned from distribution shall be assessed for signs of infestation and handled accordingly. Defective products shall be stored in a separate and secure area. Exceptions for bulk or agricultural crop materials shall be documented.

## 18 Formulation of products

Compounded animal food shall be formulated in a manner that is consistent with the intended use of the product. Formulation procedures shall ensure the appropriate use of ingredients that contain nutrients that can be deleterious to certain classes of animals.

*NOTE Some nutrients can cause illness in certain classes of animals when provided in excess (e.g. copper toxicity in sheep).*

## 19 Specifications for services

The animal food manufacturing organization shall ensure that all services (including utilities, transport and maintenance) that are provided and may have an impact on food safety:

- a) shall have specified requirements;
- b) shall be described in documents to the extent needed to conduct hazard analysis;

c) . shall be managed in conformance with the requirements of Clause 9.

## **20 Training and supervision of personnel**

The organization shall ensure the effective training and supervision of personnel, including contractors and visitors, in the correct application of the animal food safety principles and practices commensurate with their activity.

Training of personnel with respect to animal food safety principles and practices shall be documented.

## **21 Documentation and record-keeping**

Prerequisite programmes shall be documented. Records of changes to such programmes shall be maintained.

## **22 Product information/consumer awareness**

### **22.1 Product information**

Information shall be presented to customers and consumers in such a way as to enable them to understand its importance and make informed choices.

*NOTE Information may be provided by labelling or other means, such as company websites and advertisements, and may include storage, preparation and feeding instructions applicable to the product.*

### **22.2 Labelling of products**

Procedures shall be in place detailing the correct labelling of products in accordance with applicable regulations.

## **23 Food defence, biovigilance and bioterrorism**

### **23.1 General requirements**

Each establishment shall assess the hazard to products posed by potential acts of sabotage, vandalism or terrorism and shall put in place proportional protective measures.

*NOTE For further information and guidance on approaches to the protection of food businesses from all forms of malicious attack, see PAS 96.*

### **23.2 Access controls**

Potentially sensitive areas within the establishment shall be identified, mapped and subjected to access control.

*NOTE Where feasible, access should be physically restricted by use of locks, electronic card key or alternative systems.*

## **Bibliography**

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

### Standards publications

PAS 96, Defending food and drink. Guidance for the deterrence, detection and defeat of ideologically motivated and other forms of malicious attack on food and drink and their supply arrangements

PAS 220:2008, Prerequisite programmes on food safety for food manufacturing

### Other publications

Codex Alimentarius, Recommended international code of practice – General Principles of Food Hygiene

<http://www.fao.org/docrep/w6419e/w6419e03.htm#the%20codex%20general%20principles%20of%20food%20hygiene>:

Codex Alimentarius, Code of Practice on Good Animal Feeding

[http://www.codexalimentarius.net/download/standards/10080/CXP\\_054e.pdf](http://www.codexalimentarius.net/download/standards/10080/CXP_054e.pdf)

FAO/IFIF, Food and Agriculture Organization and International Feed Industry Federation – Good Practices for the Feed Industry. <http://www.fao.org/docrep/012/i1379e/i1379e00.htm>

WHO, World Health Organization – Guidelines for drinking-water quality

[http://www.who.int/water\\_sanitation\\_health/dwq/gdwq3rev/EN/](http://www.who.int/water_sanitation_health/dwq/gdwq3rev/EN/)

### Further reading

BIP 2128, ISO 22000 Food safety – Guidance and workbook for food manufacturers

BS EN ISO 22005, Traceability in the feed and food chain – General principles and basic requirements for system design and implementation

ISO/TS 22003, Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems

ISO/TS 22004:2005, Food safety management systems – Guidance on the application of ISO 22000:2005