

PAS 222:2011

Prerequisite programmes for food safety in the manufacture of food and feed for animals



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Foreword

This Publicly Available Specification (PAS) has been prepared by the British Standards Institution (BSI) to specify requirements for prerequisite programmes (PRPs) to assist in controlling animal food and feed safety hazards

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Technical Author representing SSAFE: David Harlan (Cargill)

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Publishing information

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This PAS is not to be regarded as a British Standard, European Standard or International Standard. In the event that this PAS is put forward to form the

basis of a full British Standard, European Standard or International Standard, it will be withdrawn.

Use of this document

It has been assumed in the preparation of this PAS that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

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.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Use of PAS 222 is voluntary unless required by legislation, regulation or contract. This PAS may be used alone or in conjunction with a food safety management system such as BS EN ISO 22000:2005, Clause 7.

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 those industries by setting out requirements that are specific to the manufacture and provision of animal food, feed and ingredients.

In some respects, animal food safety is a more complex topic than human food safety in that the feeding of multiple and diverse species is involved, many of which are engaged in the production of human food in the form of meat, milk and eggs. However, the core principles and approaches used to assess and prevent potential hazards in food and feed for animals are similar to those deployed during the manufacture of food for humans, despite differences in production practices and levels of hygiene deployed.

Biological, chemical and/or physical attributes of an animal food that are likely to adversely affect animal and/or human health when the intended use of a product is followed constitute an animal food safety hazard. Therefore, animal food safety PRPs, such as those outlined in this document, must both address the protection of the health of animals and outline measures necessary to safeguard the human food supply.

Potential hazards can adversely impact animal health or lead to contamination of human food products (in food-producing animals), or both. It must also be noted that animal health can be impacted by a multitude of conditions completely unrelated to animal food. Thus, poor animal health is not necessarily an indicator of safety problems with animal food.

As a result of the complexities surrounding the intended uses of products fed to animals, some sections of this PAS highlight the need to conduct a hazard assessment (see Annex A).

This PAS intends to be consistent with relevant publications, referenced in the Bibliography, such as PAS 220:2008 and those published by the Food and Agriculture Organization (FAO) and Codex Alimentarius.

The public availability of PAS 222:2011 ensures that all organizations (regardless of size, location or complexity) that operate in the animal food and feed industries have access to the PRPs.

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 manufactured food for animals and in ingredients intended for use in the production of animal food. "Food safety hazards" in this context relate to attributes that have a potential to adversely affect animal or human health.

NOTE For the purposes of this PAS, the term "animal food" is synonymous with "animal feed".

This PAS applies to products intended to provide nourishment to non-human terrestrial and aquatic animals, including food-producing animals, companion animals and pets, work animals, laboratory animals, zoo animals and wild animals. In addition, ingredients utilized in the manufacture of such products are considered "animal food" and are within the scope of this document.

For the purpose of this PAS, the term "animal health" refers to the well-being of animals with respect to absence of disease, including abnormal metabolic conditions. 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.

NOTE Attributes of animal food that cause reduced animal productivity are a product quality, not a food safety, matter unless the reduced productivity is caused by a severe nutrient deficiency or toxicity, or results from a hazard present in the animal food product.

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

Animal food and animal food ingredient operations are diverse in nature, and not all of the requirements specified in this PAS necessarily apply to an individual site 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 do not affect the ability of an organization to comply with other requirements contained in this PAS.

This PAS specifies requirements to be considered, specifically addressing:

- a) site and associated utilities;
- b) processes, including workspaces and employee facilities;
- c) supplies of air, water and other utilities;
- d) supporting services, including waste 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 contamination;
- i) sanitation;
- j) pest control;
- k) personnel hygiene;

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

- l) rework;
- m) product withdrawal procedures;
- n) warehousing and transportation;
- o) formulation of products;
- p) specifications for services;
- q) training and supervision of personnel;
- r) product information;
- s) food defence, biovigilance and bioterrorism.



2 Terms and definitions

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

2.1 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

2.2 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, *Recommended international code of practice – General principles of food hygiene*, 2.3]

NOTE For measures related to the prevention of malicious contamination, see 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.

2.3 contamination

introduction or occurrence of a contaminant (see 2.2) in food or a food environment

[After Codex Alimentarius, *Recommended international code of practice – General principles of food hygiene*, 2.3]

2.4 cleaning

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

[After Codex Alimentarius, *Recommended international code of practice – General principles of food hygiene*, 2.3]

2.5 conveyance

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



2.6 cross-contamination

contamination (see 2.3) from one type, item or batch of food to another

2.7 disinfection

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

[After Codex Alimentarius, *Recommended international code of practice – General principles of food hygiene*, 2.3]

2.8 first expired, first out (FEFO)

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

2.9 first in, first out (FIFO)

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

2.10 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

2.11 hazard assessment

evaluation to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of a safe product, and whether its control is needed to enable the defined acceptable levels to be met

NOTE *In hazard assessment (see Annex A), possible severity of adverse health effects and the likelihood of occurrence of identified hazards are considered.*

[Derived from ISO 22000, 7.4.3]

2.12 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 preparation, storage and use requirements

NOTE *This includes but is not limited to:*

- a) *the package itself, printed matter attached to the package, or a sticker used for over-labelling;*
- b) *multi-packs that have an inner label on the individual product and an outer combined label for the whole contents;*
- c) *documents that accompany bulk shipments, such as bills of lading, weigh tickets and other printed matter descriptive of the product;*
- d) *all information that is required by regulation to be printed on the package or documents required to accompany bulk shipments.*

2.13 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

2.14 materials

raw materials, packaging materials, ingredients, medications, processing aids, cleaning materials and lubricants

2.15 product contact

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

2.16 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.*

2.17 rework

utilization of nonconforming and returned materials suitable for reprocessing (e.g. pellet fines, screenings, quality defects and customer returns)

2.18 sanitation

all actions dealing with cleaning or maintaining hygienic conditions at a site, ranging from cleaning (see 2.4) and/or sanitizing (see 2.19) of specific equipment to periodic cleaning activities throughout the site (including building, structural and grounds cleaning activities)

2.19 sanitizing

process of cleaning (see 2.4) followed by disinfection (see 2.7)

2.20 site

area in which animal food is handled, together with any immediate surrounding area under which prerequisite programmes apply

2.21 zoning

demarcation of an area within a site where specific operating, hygiene or other practices may be applied to minimize the potential for microbiological contamination (see 2.3)

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

3 Sites



3.1 General requirements

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

Sites shall be maintained in good order. Vegetation shall be tended, removed or otherwise managed to address animal food safety hazards. Roads, yards and parking areas shall be drained to prevent standing water and shall be maintained.

3.2 Buildings

Where used in manufacturing and storage locations, roofs shall be self-draining and shall not leak.

3.3 Environment

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

NOTE 1 Animal food production should not be carried out at sites where potentially harmful substances from the environment could enter the product. Where appropriate, environmental assessments should be conducted, such as in the case of sites that were previously used for the production or handling of industrial or radiological products or where waste products are produced, handled or stored (industrial, municipal or agricultural wastes).

NOTE 2 At sites where animal production is carried out in addition to animal food, feed or ingredient manufacturing, measures to prevent contamination of animal food with animal wastes should be in place.

3.4 Locations of sites

The site boundaries shall be defined and documented.

Access to the site shall be managed to address animal food safety hazards. Where it is not feasible to control access to the site, measures to prevent the introduction of hazards shall be taken.

NOTE Where animal food production sites include areas accessible to the public, such as roadways, sidewalks, rail lines or other rights-of-way, measures such as locking doors, securing receiving pits and fencing particular high-risk areas may be used to prevent the introduction of animal food safety hazards.

4 Processes and workspaces

4.1 General requirements

Processes and workspaces shall be designed, constructed and maintained to control animal food safety risks.

4.2 Workflow

The movement patterns of materials, products and people shall be managed to protect against sources of contamination.

***NOTE** Where a hazard assessment has determined the need to zone different areas of the site, barriers should be in place to prevent particles or vectors representing a potential risk of contamination passing from a lower to a higher hygiene area. Examples of these barriers are walls, gates, segregated forklift traffic routes and segregated personnel traffic routes. Typical examples of potential contamination include dust from unprocessed materials, environmental dirt, pallets and packaging, microorganisms, foreign material, water, unfiltered air and pests (including pet animals).*

4.3 Structures and fittings

Process area walls, floors and floor-wall junctions shall be cleanable. Structural materials shall be resistant to the cleaning system applied.

External openings intended for transfer of materials shall be managed to prevent entry of foreign matter, moisture and pests.

In situations where wet-process areas exist, floors shall be sealed and drained to prevent standing water.

Ceilings and overhead fixtures shall be managed to prevent build-up of dirt and condensation.

4.4 Equipment

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

4.5 Laboratory facilities

Inline and online test facilities shall be managed to prevent product contamination.

Microbiology laboratories shall be designed, located

and operated so as to prevent contamination of people, plant and products.

4.6 Temporary and/or mobile structures and equipment

Temporary and/or mobile structures and equipment (e.g. storage containers, conveyances, construction equipment) shall be managed to prevent pest harbourage and contamination of products.

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

4.7 Storage of materials

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

Storage areas for dry animal food products and ingredients shall be kept dry and well ventilated.

All packaged materials 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 managed to allow maintenance and cleaning, prevent contamination and minimize deterioration.

Chemicals not intended for product inclusion (e.g. cleaning materials, pesticides) shall be stored in a separate and secure (locked or otherwise access-controlled) storage area when not in use.

Monitoring and control of temperature and humidity shall be applied where specified for stored ingredients (e.g. grain).

For bulk or agricultural crop materials, exceptions to 4.7 shall be justified and documented.

***NOTE** Ingredients and agricultural materials are sometimes stored in the open air in desert areas. In this situation, the provision of a roof not only is unnecessary, due to the lack of rainfall, but also could be counterproductive, should the large differentials between daytime and night-time temperatures lead to condensation.*

5 Utilities

5.1 General requirements

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

5.2 Water supply

Water used as a product ingredient, including steam (e.g. during pellet conditioning), or in contact with materials, products or product-contact surfaces shall meet specified animal food safety requirements relevant to the product.

Water for cleaning or applications where there is a risk of indirect product contact shall meet specified animal food safety requirements relevant to the application.

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

NOTE *Potable water should be used when available.*

Use of reclaimed or recycled water shall be justified by a hazard assessment.

NOTE *Reclaimed or recycled water should have a separate supply system, labelled and not connected to or otherwise prevented from refluxing into the primary or potable water systems.*

5.3 Boiler chemicals

For boilers that supply water or steam for product contact or direct inclusion (e.g. during extrusion, conditioning and solvent recovery processes), the boiler chemicals, if used, shall be either:

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

5.4 Ventilation

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

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

5.5 Air and compressed gas systems

Air and compressed gas systems, including those used for transferring, 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 or fill product containers.*

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

NOTE *Use of oil-free compressors is recommended. Where oil compressors are used, food-grade oil should be used.*

5.6 Lighting

The lighting provided (natural or artificial) shall allow personnel to operate in a hygienic manner and to carry out assigned animal food safety responsibilities.

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.



6 Waste disposal



6.1 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.

6.2 Containers for waste

Containers for waste shall be:

- a) clearly identified for their intended purpose;
- b) located in a designated area;
- c) designed to be effectively emptied.

6.3 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 a risk of product contamination.

Waste shall be managed in a manner that prevents it from becoming a source of food to pests.

***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.*

Products (bulk or packaged) and product labels designated as waste shall be disposed of in a manner that prevents unauthorized use.

6.4 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 be located in a manner that would contaminate products if a leak occurred.

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

7 Equipment suitability, cleaning and maintenance

7.1 General requirements

Animal food equipment shall be fit for purpose and designed and constructed to facilitate cleaning and maintenance.

Product contact surfaces shall be constructed from materials suitable for animal food and able to resist repeated cleaning.

Product contact equipment shall be smooth, accessible, cleanable and constructed of materials compatible with the intended use.

7.2 Temperature control and monitoring equipment

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

Thermal process equipment shall provide for the monitoring and control of temperature.

7.3 Preventive and corrective maintenance

A preventive maintenance programme shall be in place and 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 affect 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 fit for purpose where there is a risk of direct or indirect contact with the product.

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

Site-specific 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.

7.4 Measuring devices

All scales and metering devices used in the manufacture of animal food shall be fit for purpose for the range of weight or volume to be measured and shall be tested for accuracy regularly according to the risks.

Where necessary to verify 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 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 during handling, maintenance and storage.

NOTE This subclause was adapted from the FAMI-QS, European code of practice for feed additive and premixture operators, section 6.4.

8 Management of ingredients

8.1 General requirements

Purchasing of materials that affect animal food safety shall be managed 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.

NOTE 1 Monitoring may include conformance to material or product specifications, meeting certificate of analysis (CoA) requirements and satisfactory audit outcomes.

NOTE 2 In the case of agricultural commodities sourced from multiple suppliers, monitoring for potential hazards (e.g. pesticides, mycotoxins, drying methods) on a regional basis or at points of physical accumulation (e.g. grain elevators) may be more practical than approval of individual farm suppliers.

- c) a process to decertify a previously approved supplier;
- d) a process to provisionally approve a supplier in emergency situations.

8.2 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 an animal food safety hazard assessment and shall include:

- a) an assessment of the supplier's ability to meet food safety expectations, requirements and specifications;
- b) monitoring the performance of the supplier to confirm continued approval status;

8.3 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 Incoming materials should be evaluated. Possible questions include: Is this the correct material? If seals are used, are they intact? Are materials 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 prior to acceptance show evidence of previous loads carried on the conveyance together with details of any relevant cleaning or sanitizing operations conducted prior to loading. Previous loads should be checked to ensure

that they do not represent a contamination risk to the product.

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.

8.4 Communications on product/process attributes

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

NOTE 1 *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 or affect the intended use of animal food products.*

NOTE 2 *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.*

9 Management of medications



9.1 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 changeover 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 14.

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

9.2 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 sequencing are examples of procedures used alone or in combination to prevent cross-contact.

9.3 Storage

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

10 Prevention of contamination

Programmes shall be in place to prevent, control and detect potential contamination that could occur at a site.

Based on a hazard assessment, measures to prevent potential physical, chemical, biological and radiological contamination (including cross-contamination) shall be addressed by the programmes.

Measures shall be put in place to prevent, control or detect potential contaminants identified by the hazard assessment.

NOTE 1 *Examples of measures to control physical contaminants 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 physical contamination include wooden pallets, elevator buckets, tools, rubber gaskets, conveyance seals, personal protective clothing and parts from equipment.*

Procedures to prevent 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 and sequencing are examples of procedures used alone or in combination to prevent contamination.*

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

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

Where identified by the hazard assessment, a zoning plan (see 2.21) shall be implemented.

NOTE 1 *Microbial hazards are specific to the intended use of an animal food product or ingredient. Animal species, production class and age, along with the method or location of product use (residential versus commercial application, contact with immunocompromised populations), should be considered during hazard assessment.*

NOTE 2 *Control measures suitable for zoning facilities may include:*



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

Where identified by the hazard assessment:

- a) *room air supply shall be managed to prevent airborne contamination;*
- b) *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;*
- c) *air supply systems shall be accessible for cleaning, filter changing and maintenance;*
- d) *temperature and/or humidity shall be monitored and controlled.*

NOTE *Air pressure differentials should be considered when developing a zoning plan.*

11 Sanitation

11.1 General requirements

Cleaning programmes shall be established and documented to maintain hygienic conditions. Programmes shall be monitored for continuing suitability and effectiveness.

Where identified in the hazard assessment, sanitizing programmes shall be established and documented for wet cleaning and for wet-process areas.

11.2 Cleaning and sanitizing agents and tools

Cleaning and sanitizing agents shall be fit for purpose, clearly identified, stored separately and not adversely affect animal food safety.

Cleaning and sanitizing tools shall be designed and maintained in a condition that does not present a potential source of extraneous matter.

11.3 Cleaning and sanitizing programmes

Cleaning and sanitizing programmes shall specify, as 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 (e.g. post-cleaning and/or pre-start-up inspections).

NOTE Care should be taken to prevent product contamination when compressed air is used to “blow down” debris in a facility. For example, mixer openings should be covered to prevent entry of blown-down debris. Debris that have been blown down to ground level (i.e. the floor) should be removed through traditional methods (e.g. sweeping, vacuuming) for cleaning to be effective.

Periodic cleaning and sanitizing activities shall be recorded.

NOTE Routine housekeeping activities are not considered periodic and do not need to be recorded.

Cleaning and sanitizing programmes shall be verified for their continuing suitability and effectiveness.

12 Pest control

12.1 General requirements

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

12.2 Pest control programmes

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

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 site.

Requirements relating to the storage of hazardous chemicals contained in 4.7 shall apply to all pesticides used at the site.

12.3 Preventing access

Animal food production and storage buildings shall be maintained in good repair. Holes, drains and other potential pest access points shall be sealed.

External doors, windows and ventilation openings shall be designed and maintained to prevent the entry of target pests.

NOTE 1 Screens are appropriate means to prevent entry of pests and can be utilized for ventilation purposes.

NOTE 2 Programmes should address access of all animals, whether wild, feral or domestic.

NOTE 3 Outer walls should have as few ledges as possible, to discourage birds from perching or building nests.

12.4 Harbourage and infestations

Storage and material handling practices shall be designed to avoid the availability of food and water to pests. Spilled materials shall be controlled to prevent availability to pests.

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.

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.

12.5 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 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 effective 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 analyzed to identify trends.

12.6 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.

13 Personnel hygiene and employee facilities

13.1 General requirements

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

13.2 Personnel hygiene facilities

Personnel hygiene facilities shall be available, clearly designated and maintained as necessary for animal food safety.

13.3 Designated eating areas

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

13.4 Workwear and personal protective equipment

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

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

Personal protective equipment, where required, shall be designed to prevent product contamination.

NOTE *For example, ear plugs should be on cords attachable to the person or headgear so that when removed they cannot fall into the product.*

13.5 Health status

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 and material contact surfaces.

14 Rework

13.6 Personal cleanliness

Personnel in animal food production and storage areas shall be required to wash and, where viewed as necessary by the organization, sanitize hands:

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

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

13.7 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 (e.g. gum, tobacco) in designated areas only;
- b) control measures to avoid hazards presented by jewellery;
- 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.



14.1 General requirements

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

NOTE Rework includes nonconforming and returned materials suitable for reprocessing (e.g. pellet fines, screenings, quality defects and customer returns).

14.2 Storage, identification and traceability

Stored rework shall be protected from 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 established and documented.

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

The source and description of rework shall be recorded (e.g. product name, production date, shift, line of origin).

14.3 Rework usage

Where rework is incorporated into a product as an "in-process" step, the 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 for the removal and segregation of packaging materials and to avoid contamination of the product with extraneous matter.



15 Product withdrawal procedures

15.1 General requirements

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

15.2 Product withdrawal requirements

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

NOTE Availability of accurate key contact lists assists in the timely management of product withdrawals.

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.

NOTE Effective traceability of materials can minimize the quantity of product subject to a withdrawal.

16 Warehousing and transportation

16.1 General requirements

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

16.2 Warehousing

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 (e.g. FIFO or FEFO) shall be observed.

16.3 Vehicles, conveyances and containers

Vehicles, conveyances and containers shall be maintained in a state of repair, cleanliness and condition consistent with material and product 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 programme shall be in place to determine, evaluate and record the material handled in prior loads, to prevent animal food safety hazards.

NOTE *A list of materials or classes of materials that are an acceptable (positive) or unacceptable (negative) prior use of bulk conveyances and containers can be used as part of a programme to determine suitable use. However, limitations on the use of lists exist: for example, negative lists will never identify all unacceptable materials.*

A hazard assessment 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 or ingredient use only.

16.4 Product returns

Product returned from distribution shall be assessed for animal food safety hazards and handled accordingly.

Defective products shall be stored in a separate and secure area. Exceptions for bulk or agricultural crop materials shall be documented.



17 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 be in place to manage the 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).



18 Specifications for services

For services that have an impact on animal food safety, the animal food manufacturing organization shall have specified requirements and manage the services in conformance with the requirements of Clause 8.

NOTE Examples of service providers include water utilities and maintenance, scale calibration, transportation, external storage, transloading and pest control providers.



19 Training and supervision of personnel

The organization shall train and supervise personnel, including contractors and visitors, in the 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.

20 Product information

Information on content and intended use of animal food products shall be communicated to customers (e.g. on a product label).

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



21 Food defence, biovigilance and bioterrorism

21.1 General requirements

The organization shall assess animal food safety hazards reasonably expected to occur by potential acts of sabotage, vandalism or terrorism and shall put in place protective measures.

NOTE 1 *CARVER plus Shock is a prioritization tool that can be used to assess the food defence vulnerabilities within a system or infrastructure in the animal food industry.*

NOTE 2 *For further information and guidance on approaches to the protection of food businesses from all forms of malicious attack, see 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.*

21.2 Access controls

Sensitive areas within the site shall be identified, mapped and subjected to access control.

NOTE *Examples of access controls include physical restriction by use of locks, electronic card key or alternative systems, signage and employee policy restrictions.*



Annex A (informative)

Hazard assessment

Some sections in this PAS call out the need to conduct a hazard assessment. A hazard assessment (see 2.11) is a fundamental process used in animal food safety management systems to assist in establishing the risks from potential hazards and what control measures should be in place.

BS EN ISO 22000:2005 defines a food safety hazard as a “biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect”.

A hazard assessment is intended to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of a safe food, or whether additional control measures should be deployed to meet the defined acceptable levels.

Each hazard identified should be evaluated based on the severity of the possible adverse health effects and the likelihood of occurrence. Furthermore, hazard assessments should document the methodology used to conduct the assessment and record results.

While PAS 222:2011 deals with PRPs, the hazard assessment may identify the need for additional control measures, such as an operational PRP (defined in ISO 22000:2005, 3.9) or critical control point (defined in ISO 22000:2005, 3.10), to be deployed to adequately reduce the hazard.

Figure A.1 shows an example hazard assessment template for use in documenting the hazard assessment process and recording outcomes.

Figure A.1 – Example hazard assessment template

Hazard Assessment							
Plant name:		Reviewed date:		Reviewer(s):			
Hazard Assessment Scope:							
What is the POTENTIAL Food Safety RISK to the finished product and environment: (Describe the biological, chemical or physical risk)							
SITUATION ASSESSMENT: (Why, who, what, when, where)							
OUTCOME SUMMARY: Review the data from Part 2 and summarize the overall direction and actions to be taken							

Part 2 – Column legend for details and support data							
A. Identify item to be assessed from the process. Walk around the plant and review plant/process areas to gather the data							
B. Define the consequences of the hazard in all applicable areas (biological, chemical, physical). What is the consequence of this hazard to product and environment if not controlled?							
C. Describe in detail any past occurrences for this item/area. Include cost implication							
D. Describe what control strategies are in place. If control strategies need to be established, include action to be taken, desired final outcome and cost(s) to implement							
E. Risk evaluation: Likelihood of the hazard to occur with control measures in place : H = High, M = Medium, L = Low							
F. Risk evaluation: Severity of the hazard if it were to occur: H = High, M = Medium, L = Low							
G. Rank the risk with control measures in place : H = High: Take action, M = Medium: Discuss & determine timing, L = Low: No action							
H. Rationale and assessment comments							

A	B		C	D	E	F	G	H
Item	Hazard/consequence Bold the hazard(s)		History/occurrences/associated costs	Control strategies	Likelihood	Severity	Risk rank	Rationale and assessment comments
	Biological							
	Chemical							
	Physical							
	Biological							
	Chemical							
	Physical							

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

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

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

CARVER plus Shock method for food sector vulnerability assessments

<http://www.fsis.usda.gov/PDF/Carver.pdf>

Codex Alimentarius, *Code of practice on good animal feeding*

http://www.codexalimentarius.net/download/standards/10080/CXP_054e.pdf

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>

FAMI-QS, *European code of practice for feed additive and premixture operators*

<http://www.fami-qs.org/documents/codeofpractice.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>

ISO/IEC, *Guide 51, Safety aspects – Guidelines for their inclusion in standards*

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*



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389 Chiswick High Road
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United Kingdom
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