PAS 420:2014

Product safety management system for the manufacturing of home and/or personal care products and the raw/packaging materials used for their manufacture – Specification



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Foreword

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Presentational conventions

The provisions of this PAS are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall". Its recommendations are expressed in sentences in which the principal auxiliary verb is "should". The use of the auxiliary verb "can" indicates that something is technically possible when the auxiliary verb "may" indicates permission.

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

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Introduction

In response to the success of the food industry pre-requisite programme (PRP) standards in support of BS EN ISO 22000, several global industry players have expressed a desire to take a similar risk-based approach, incorporating a management system, to the manufacture of home and/or personal care (HPC) products.

Issues currently facing HPC manufacturers include:

- incidents of unsafe products being released onto the market, resulting in large recalls and reputational damage;
- high costs associated with:
  - recalls;
  - inspections (regulators);
  - multiple audits (retailers and other customers);
- controls, systems and regulation varying greatly:
  - throughout countries/regions;
  - across the industry;
  - within organizations themselves;
- lack of uniformity in method of ensuring product safety within the organization (especially for companies with a global footprint and manufacturing sites in different countries).

Accordingly, this PAS looks to establish:

i) a fully integrated, risk-based approach to the manufacture of HPC products;

ii) consistency in the manufacturing process across all product streams and countries;

iii) benefits of implementation and consistency in approach such as fewer product recalls, better management of staff, improved competence of key personnel, and reduction of costs;

iv) a verifiable framework, enabling organizations to measure performance against concrete criteria;

v) a reduced need for surveillance/inspection by authorities.

This PAS seeks to set out requirements for the development and implementation of a HPC product safety management system, including pre-requisite programmes (PRP), for the production of HPC products used daily by consumers and the raw/packaging materials used to manufacture these products. It takes a risk-based approach to help manufacturers identify hazards and critical control points, and develop plans to mitigate against those hazards and risks .

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1 Scope

This PAS specifies requirements for establishing, implementing and maintaining a home and/or personal care (HPC) product safety management system and associated prerequisite programmes (PRP) to assist in the manufacture of HPC products and the raw/packaging materials used to manufacture these products.

Examples of home care products include, but are not limited to:

- bleach;
- table polish;
- bathroom cleaner;
- kettle de-scaler;
- limescale remover; and
- antibacterial wipes.

This PAS does not address vacuum cleaners, washing machines or any other electric devices designed for household cleaning.

Examples of personal care products include, but are not limited to:

- shampoo;
- hair conditioner;
- deodorant;
- moisturiser;
- nail polish;
- toothpaste;
- soap; and
- hand cream.

This PAS is applicable to all organizations, regardless of size or complexity, involved in manufacturing HPC products or the raw/packaging materials used to manufacture these products, who wish to implement a HPC product safety management system and associated PRPs.

HPC product, raw and packaging material manufacturing operations are diverse in nature and not all of the requirements specified in this PAS apply to an individual organization or process. Accordingly:

- Manufacturers of raw and / or packaging materials are to comply with the main requirements of this PAS.
- Manufacturers of home care products are to comply with the main requirements of this PAS, and in addition, the requirements of Annex A.
- Manufacturers of personal care products are to comply with the main requirements of this PAS, and in addition, the requirements of Annex A and Annex B.

NOTE *Where a customer specifies additional requirements, as outlined in Annex A or Annex B, then the organization is to consider these when developing and implementing their product safety management system.*

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2 Normative references

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

BS EN ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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 9000:2005 also apply.

3.1 certificate of analysis (CoA)

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

3.2 cleaning

removal of soil, dirt, grease or other objectionable matter

3.3 cleaning in place (CIP)

system that, without dismantling any equipment, cleans solely by circulating and/or flowing chemical detergent solutions and water rinses by mechanical means onto and over surfaces to be cleaned

3.4 cleaning out of place (COP)

system where equipment is disassembled and cleaned in a tank or in an automatic washer by circulating a cleaning solution and maintaining a minimum temperature throughout the cleaning cycle

3.5 contaminant

any biological and/or chemical agent, foreign matter, potential allergen or other substance, which may compromise the safety and integrity of the HPC product

3.6 contamination

introduction or unintended occurrence of a contaminant (see **3.5**) or process which causes adulteration in raw or packaging materials, HPC product or HPC production environment

NOTE *Measures for prevention of malicious contamination are outside the scope of this PAS.*

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3.7 HPC product safety

concept that product will not cause harm to the consumer when used according to its intended use

3.8 HPC product safety hazard

biological, chemical or physical agent in product, or condition of product, with the potential to cause an adverse health effect when used according to its intended use

3.9 HPC product safety policy

overall intention and direction of an organization related to HPC product safety (**3.7**) as formally expressed by top management

3.10 first expired first out (FEFO)

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

3.11 first in first out (FIFO)

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

3.12 hazard analysis

first step in a process necessary to assess risk

3.13 intended use

reasonably expected handling of the end product

3.14 label

printed matter that is part of the finished product package conveying specific information about the contents of the package, the product or the raw material and any storage and preparation 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 which have an inner label on the individual product and an outer combined label for the whole contents.

3.15 material/product specification

detailed documented description or enumeration of parameters, including permissible variations and tolerances, which are required to achieve a defined level of product safety and acceptable quality

3.16 materials

general term used to indicate raw materials, packaging materials, ingredients, process aids, tools, cleaning materials and lubricants

3.17 product contact

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

3.18 product recall

removal of a non-conforming product from the market, including recovery from consumers, trade and warehouses, distribution centres and/or customer warehouses because it does not meet specified standards

3.19 product withdrawal

removal of a non-conforming product from the supply chain because it does not meet specified standards

3.20 realization

activities that culminate in the delivery of safe HPC products

3.21 risk assessment

process to determine which hazards need to be controlled, the degree of control required to ensure HPC product safety, and which combination of control measures is required

3.22 risk management

identification, assessment and prioritization of risks followed by the coordination and application of resources to minimize, monitor, and control the probability and/or impact of unfortunate events

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3.23 sanitization

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

3.24 sensitizer

chemical that causes a substantial proportion of exposed people or animals to develop an adverse or unintended reaction in normal tissue after repeated exposure to the chemical

3.25 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 pattern. Negative air pressure recommended for microbiological laboratories when handling (potential) pathogens.*

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4 HPC product safety management system

4.1 General

The organization shall establish, document, implement and maintain an effective HPC product safety management system and update it when necessary in accordance with the requirements of this PAS.

The organization shall define the scope of the product safety management system. The scope shall specify the products or product categories, processes and production sites that are addressed by the product safety management system.

The HPC product safety management system shall conform to the mutually agreed requirements of customers.

NOTE *Attention is drawn to relevant statutory and regulatory requirements.*

Where an organization chooses to outsource any process that may affect end product conformity, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified and documented within the product safety management system.

4.2 Documentation

4.2.1 General

The HPC product safety management system documentation shall include:

a) documented statements of a product safety policy and related objectives (see **5.2**);

b) documented procedures and records required by this PAS; and

c) documents needed by the organization for the effective development, implementation and updating of the product safety management system.

4.2.2 Control of documents

Documents required by the HPC product safety management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in **4.2.3**.

All proposed changes shall be reviewed prior to implementation to determine their effects on product safety and their impact on the product safety management system.

A documented procedure shall be established to define the controls needed:

a) to approve documents for adequacy prior to issue;

b) to review and update documents as necessary, and re-approve documents;

c) so that changes and the current revision status of documents are identified;

d) so that relevant versions of applicable documents are available at points of use;

e) so that documents remain legible and readily identifiable;

f) so that relevant documents of external origin are identified and their distribution controlled; and

g) to prevent the unintended use of obsolete documents, and so they are identified as such if they are retained for any purpose.

4.2.3 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and evidence of the effective operation of the HPC product safety management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

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5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the HPC product safety management system and to continually improving its effectiveness by:

a) showing product safety is supported by the business objectives of the organization;

b) communicating to the organization the importance of meeting the requirements of this PAS, as well as customer requirements relating to product safety;

NOTE *Attention is drawn to any statutory and regulatory requirements applicable to the country where the product may be sold*

c) establishing the product safety policy;

d) conducting management reviews;

e) making resources available; and

f) addressing the root cause of any identified non-conformance against this PAS to prevent recurrence.

5.2 HPC product safety policy

Top management shall define, document and communicate its HPC product safety policy. This product safety policy shall:

a) be appropriate to the purpose of the organization in the supply chain;

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

c) address communication (see **5.5**);

d) be reviewed for continued suitability (see **5.7**); and

e) be supported by measurable objectives.

5.3 HPC product safety management system planning

Top management shall ensure that:

a) planning of the HPC product safety management system is carried out to meet the requirements given in **4.1** as well as the objectives of the organization that support product safety, and

b) the integrity of the product safety management system is maintained when changes to the product safety management system are planned and implemented.

5.4 Responsibility and authority

Top management shall define and communicate responsibilities and authorities within the organization to facilitate the effective operation and maintenance of the HPC product safety management system.

Top management shall ensure that there are an adequate number of properly trained personnel with regards to the defined activities in this document, according to the diversity of its production.

All personnel shall have responsibility to report problems with the product safety management system to identified person(s). Designated personnel shall have defined responsibility and authority to initiate and record actions, and release blocked product batches as appropriate.

Top management shall appoint a person who, irrespective of other responsibilities, shall have the responsibility and authority:

a) to manage a product safety team and organize its activities (see **8.2**);

b) to provide relevant training and education (see **6.2.3**) to the product safety team members;

c) to ensure that the product safety management system is established, implemented, maintained and updated; and

d) to report to the organization's top management on the effectiveness and suitability of the product safety management system.

NOTE *The responsibility of this person may include liaison with external parties on matters relating to the product safety management system.*

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5.5 Communication

5.5.1 External communication

To ensure that information on issues concerning HPC product safety is available throughout the supply chain, the organization shall establish, implement and maintain effective arrangements for communicating with its:

a) suppliers and contractors;
b) customers or consumers, in particular in relation to product information (including instructions regarding intended use, specific storage requirements and, as appropriate, shelf life), enquiries, contracts or order handling (including amendments), and customer feedback (including customer complaints);
c) statutory and regulatory authorities; and
d) other organizations that have an impact on, or are affected by, the effectiveness or updating of the product safety management system.

Records of communications shall be maintained.

NOTE *Attention is drawn to the consumer safety requirements of the relevant statutory and regulatory authorities, in addition to those of the customers.*

Designated personnel shall have defined responsibility and authority to communicate externally information concerning product safety. Information obtained through external communication shall be included as input to system updating (see **12.5**) and management review (see **5.7**).

5.5.2 Internal communication

The organization shall establish, implement and maintain effective arrangements for communicating with personnel on issues having an impact on HPC product safety.

In order to maintain the effectiveness of the product safety management system, the organization shall inform the product safety team (see **8.2.1**) in a timely manner, of changes, including but not limited to the following:

a) products or new products;
b) raw materials, ingredients and services;
c) production systems and equipment;
d) production premises, location of equipment, surrounding environment;
e) cleaning and sanitization programmes;
f) packaging, storage and distribution systems;
g) personnel qualification levels and/or allocation of responsibilities and authorizations;
h) statutory and regulatory requirements;
i) knowledge regarding product safety hazards and control measures;
j) customer, sector and other requirements that the organization observes;
k) relevant enquiries from external interested parties;
l) complaints indicating product safety hazards associated with the product; and
m) other conditions that have an impact on product safety.

The responsible person shall include this information in the updating of the product safety management system (see **12.5**). Top management shall include that relevant information as input to the management review (see **5.7**). The responsible person shall disseminate any relevant change information to those employees who have a direct impact on the integrity of the product safety management system.

5.6 Emergency preparedness and response

Top management shall ensure that procedures are established, implemented and maintained to manage potential emergency situations and accidents that can impact HPC product safety and which are relevant to the role of the organization in the supply chain.

5.7 Management review

5.7.1 General

Top management shall review the organization's HPC product safety management system at planned intervals regarding its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for change to the product safety management system, including the product safety policy. Records of management reviews shall be maintained (see **4.2.3**).

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5.7.2 Review input

The input to management review shall include, but is not limited to, information on:

a) follow-up actions from previous management reviews;

b) analysis of results of verification activities (see **12.4.2**);

c) changing circumstances that may affect product safety (see **5.5.2**);

d) emergency situations, accidents (see **5.6**) and withdrawals (see **11.4**);

e) reviewing results of system-updating activities (see **12.5**);

f) review of communication activities, including consumer and customer feedback (see **5.5.1**); and

g) external audits or inspections.

NOTE *The term "withdrawal" includes recall.*

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

5.7.3 Review output

The output from the management review shall include decisions and actions related to:

a) assurance of HPC product safety (see **4.1**);

b) improvement of the effectiveness of the product safety management system (see **12.5**);

c) resource needs (see **6.1**); and

d) revisions of the organization's product safety policy and related objectives (see **5.2**).

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6 Resource management

6.1 Provision of resources

The organization shall provide adequate resources for the establishment, implementation, maintenance and updating of the HPC product safety management system.

6.2 Human resources

6.2.1 General

The personnel carrying out activities having an impact on HPC product safety shall be competent and shall have appropriate education, training, skills and experience.

Where the assistance of external experts is required for the development, implementation, operation or assessment of the product safety management system, records of agreement or contracts defining the responsibility and authority of external experts shall be available.

Top management shall define and communicate the locations which authorized personnel are allowed to access.

6.2.2 Organization structure chart

The organizational structure shall be defined and communicated in order that the organization and personnel roles are understood.

6.2.3 Competence, awareness and training

Personnel, including newly recruited personnel, who perform work affecting HPC product safety in production, control, storage and shipment, shall have skills and competencies based on relevant training and experience acquired.

The organization shall:

a) identify the necessary competencies for personnel whose activities have an impact on HPC product safety;

b) identify training needs of all personnel, regardless of level or seniority in the organization, and develop and implement a corresponding training programme;

c) provide training or take other action to promote necessary competencies;

d) adequately train personnel responsible for monitoring, corrections and corrective actions of the product safety management system;

e) evaluate the implementation and the effectiveness of a), b), c) and d);

f) promote personnel awareness of the relevance and importance of their individual activities contributing to product safety;

g) promote understanding of the requirement for effective communication (see **5.5**) by all personnel whose activities have an impact on product safety; and

h) maintain appropriate records of training and actions described in c) and d).

Training shall be regarded as a constant and on-going process that is subject to regular updates.

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7 Planning and realization of safe products

7.1 General

The organization shall plan and develop the processes needed for the realization of safe products.

The organization shall implement, operate and monitor the effectiveness of the planned activities and any changes to those activities. This includes PRP(s) and/or the risk management plan.

7.2 Prerequisite programmes (PRPs)

7.2.1 General

The organization shall establish, implement and maintain PRP(s) to assist in controlling:

a) the likelihood of introducing HPC product safety hazards through the work environment;
b) biological, chemical and physical contamination of the product(s), including cross contamination between products and materials; and
c) product safety hazard levels in the product and product processing environment.

The PRP(s) shall:

a) be appropriate to the organizational needs with regard to product safety;
b) be appropriate to the size and type of the operation and the nature of the product(s) being manufactured and/or handled;
c) be implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or operational line; and
d) be approved by the product safety team.

When selecting and/or establishing PRP(s), the organization shall consider and utilize appropriate information.

NOTE *This information may include statutory and regulatory requirements, customer requirements, recognized guidelines, and codes of practices, national, international or sector standards.*

Verification of PRP(s) shall be planned (see Clause **9**) and PRP(s) shall be modified as necessary (see **11.2**). Records of verifications and modifications shall be maintained.

Documents shall specify how activities included in the PRP(s) are managed.

NOTE *Annex A describes the minimum PRPs required to effectively support a HPC product safety management system.*

When exclusions are made, these shall be justified by a risk assessment. Any exclusions or alternative measures adopted shall not affect the ability of the organization to comply with these requirements.

7.2.2 Construction of buildings

7.2.2.1 General

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

NOTE *For example, durable construction can include self-draining roofs which do not leak.*

7.2.2.2 Environment

Consideration shall be given to potential sources of contamination from the local environment.

7.2.2.3 Locations of establishments

The site boundaries shall be clearly identified. Access to the site shall be controlled. The site shall be maintained in a condition that protects products against contamination.

7.2.3 Layout of premises and workspace

7.2.3.1 General

Internal layouts 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 and unintended mixing of materials or products.

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7.2.3.2 Internal design, layout and traffic patterns

The building shall provide adequate space, with a logical flow of materials, products and personnel, to avoid the risk of mix-ups and cross contamination.

Based on a risk assessment, openings in the wall, floor or ceiling, intended for transfer of materials, shall be designed to minimize entry of foreign matter and pests.

7.2.3.3 Internal structures and fittings

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

Floors shall be designed to avoid standing water.

In wet process areas floors shall be sealed and drained.

7.2.4 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.

7.2.5 Storage of HPC products, raw and packaging materials

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

Storage areas shall be 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 blocked or quarantined products, raw materials, work in progress and finished products.

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

Cleaning materials, chemicals and other hazardous substances shall be stored in a manner that minimizes the risk of mix-ups and cross contamination.

The method of storage of bulk materials shall be documented in the HPC product safety management system.

7.2.6 Utilities – air, water, lighting

7.2.6.1 General

The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination.

7.2.6.2 Water supply

The supply of potable water or water suitably treated to prevent contamination of the product shall be able to meet the requirements of the manufacturing operation.

Where required due to potential product risk, water quality shall be verified by either testing and/or monitoring of process parameters.

Where product risk requires use of water treatment systems, they shall supply a specified quality of water and permit sanitization. Water treatment equipment shall be set up to avoid stagnation and risks of contamination. Materials used in water treatment equipment shall be selected to ensure that water quality is not affected.

7.2.6.3 Air quality and ventilation

Ventilation shall be sufficient for the intended production operations and product risk. Alternatively, specific measures shall be taken to protect the product.

Air quality shall be monitored to minimize product contamination risk. Air shall be treated when there is potential for it to have an impact on the safety or quality of the product.

7.2.6.4 Compressed air, steam and other gases

Compressed air, steam and other gas systems used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination.

7.2.6.5 Lighting

Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning.

7.2.7 Waste disposal

7.2.7.1 General

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

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Using findings from production and quality control laboratories, the organization shall define the different types of waste that could present a risk to the product.

7.2.7.2 Containers for waste and 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 which can be readily cleaned and sanitized; and
d) regularly cleaned.

7.2.7.3 Waste management and removal

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

Accumulation of waste shall not be allowed in HPC product handling or storage areas. Removal frequencies shall be managed to avoid accumulations.

Labelled materials, products or printed packaging designated as waste shall be disfigured or destroyed to ensure that trademarks cannot be reused. Removal and destruction shall be carried out by approved disposal contractors. The organization shall retain records of destruction.

NOTE *Local law should be considered with regards to licensing of third party waste disposal contractors.*

7.2.7.4 Drains and drainage

Drains shall be designed, constructed and located so that the risk of contamination of materials or products is avoided.

7.2.8 Equipment suitability, cleaning and maintenance

7.2.8.1 General

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

HPC product contact equipment shall be constructed of durable materials able to resist repeated cleaning.

7.2.8.2 Hygienic design

Equipment shall be able to 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 sanitization agents; and
c) piping and ductwork shall be cleanable, drainable, and with no dead ends.

7.2.8.3 Product contact surfaces

Product contact surfaces shall be constructed from materials designed for HPC products use. They shall be impermeable and rust or corrosion free.

7.2.8.4 Cleaning plant, utensils and equipment

Wet and dry cleaning programmes shall be documented so that all plant, utensils and equipment are cleaned at defined frequencies.

The programmes shall specify what is to be cleaned (including drains), the responsibility, the method of cleaning (e.g. CIP/COP), the use of dedicated cleaning tools, removal or disassembly requirements and methods for verifying the effectiveness of the cleaning.

7.2.8.5 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 HPC product safety hazards.

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

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

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7.2.9 Management of purchased materials

7.2.9.1 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 quality and HPC product safety expectations, requirements and specifications;

b) description of how suppliers are assessed; and

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

1) *audit of the supplying site prior to accepting materials for production;*

2) *third party certification against a defined list of standards.*

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

NOTE *Monitoring may include conformance to material or product specifications, meeting CoA requirements, satisfactory audit outcomes.*

7.2.9.2 Incoming material requirements (raw/packaging)

Delivery vehicles shall be checked prior to, and during, unloading to verify that the quality and safety of the material has been maintained during transit (e.g. seals are intact, free from infestation, temperature records exist).

Materials shall be inspected, tested or covered by CoA to verify conformance to specified requirements prior to acceptance or use. The method and result of verification, records of inspections and CoAs shall be documented.

NOTE *The inspection frequency and scope may be based on the hazard presented by the material and the risk assessment of the specific suppliers.*

Materials which do not conform to relevant specifications shall be handled under a documented procedure to avoid unintended use.

Access points to bulk material receiving lines shall be identified, capped and locked.

Discharge into such systems shall take place only after approval and verification of the material to be received.

7.2.10 Measures for prevention of cross contamination

7.2.10.1 General

A risk assessment shall be carried out to determine potential contamination (microbiological, chemical and physical – in accordance with Annex A) and a programme of measures shall be in place to prevent, control and detect contamination.

7.2.10.2 Chemical cross-contamination

Cleaning, line change-over practices and/or product sequencing (as required) shall protect products from chemical cross-contamination.

NOTE *Manufacturing cross-contamination can arise from either:*

a) traces of product from the previous production run which 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 raw materials that are produced on separate lines, or in the same or adjacent processing areas.

7.2.11 Pest control

7.2.11.1 General

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

7.2.11.2 Pest control programmes

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

Pest management programmes, to identify target pests, shall be documented, and address plans, methods, schedules, control procedures and, where necessary, training requirements.

Programmes shall include a list of chemicals which are approved for use in specified areas of the establishment.

7.2.11.3 Preventing access

Buildings shall be maintained in good repair.

Based on a risk assessment:

- holes, drains and other potential pest access points shall be sealed.
- external doors, windows or ventilation openings shall minimize the potential for entry of pests.

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7.2.11.4 Harbourage and infestations

Storage practices shall be designed to minimize the availability of food and water to pests.

7.2.11.5 Eradication

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. If pest control is managed by a third party, records shall be maintained by the organization.

7.2.12 Personnel hygiene and employee facilities

7.2.12.1 General

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.

7.2.12.2 Staff canteens and designated eating areas

Staff canteens and designated areas for food storage and consumption shall be situated so that the potential for cross contamination of production areas is minimized.

(Personnel) Employees' own food shall be stored and consumed in designated areas only.

7.2.12.3 Health status

Personnel shall undergo a medical assessment prior to employment in HPC product contact operations.

Additional medicals shall be carried out at intervals defined by the organization.

NOTE *These medicals may be subject to legal restrictions in the country of operation.*

7.2.13 Reworked product

7.2.13.1 General

Reworked products shall be stored, handled and used in such a way that product safety, quality, traceability are maintained.

7.2.13.2 Storage, identification and traceability

Stored rework shall be protected from exposure to chemical or extraneous matter contamination.

Segregation requirements for rework (e.g. chemicals or sensitizers) shall be documented and met.

Rework shall be clearly identified and/or labelled to allow traceability and include shelf life and approval as appropriate. 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).

7.2.13.3 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 pre-processing 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.

7.2.14 Product recall procedures

7.2.14.1 General

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

7.2.14.2 Product recall

A list of key contacts in the event of a recall shall be maintained. 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 shall be considered.

Product recall processes shall be tested on a regular basis to maintain their effectiveness. Records shall be maintained of any tests or real recalls that have taken place.

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7.2.15 Warehousing

7.2.15.1 General

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

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 non-conforming shall be provided.

Specified stock rotation systems (FIFO/FEFO) shall be observed. Products that have passed their use-by date/ expiry shall be blocked and not used.

If storage outside is necessary, items shall be protected from contamination, deterioration, moisture, excessive sunlight and damage.

Materials shall be stored off the floor and sufficiently far away from walls to enable inspection, pest control and prevent pest ingress. Lot coding and traceability shall be maintained

Tampering of product, damage to material packaging, cross contamination (including taint) and loss of product security shall be prevented

7.2.15.2 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.

7.2.16 Product information/consumer awareness

Information shall be presented to 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 organization websites and advertisements, and may include storage and usage instructions applicable to the product.*

7.2.17 HPC product defence, biovigilance and bioterrorism

7.2.17.1 General

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

NOTE *This should include consideration of transport and distribution, as well as onsite activities. It should include points such as:*

a) building and infrastructure design to prevent unauthorised entry;

b) reference checks for personnel;

c) control of confidential information;

d) security of storage and production areas;

e) management of security incidents.

7.2.17.2 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.*

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8 Risk assessment and ongoing risk management

8.1 General

All relevant information needed to conduct the risk assessment shall be collected, maintained, updated and documented. Records shall be maintained.

8.2 Preparation for risk assessment

8.2.1 HPC product safety team

The responsible person shall assemble a multi-disciplinary team. This team shall have specific knowledge and experience including, but not limited to:

- the organization's products;
- the organization's processes;
- equipment and product safety hazards within the scope of the product safety management system;
- identifying hazards; and
- assessing risks.

8.2.2 Product characteristics

8.2.2.1 Raw materials, ingredients and product-contact materials

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the risk assessment.

***NOTE** Examples of the descriptions required for hazard analysis are provided in Annex C.*

The organization shall identify statutory and regulatory HPC product safety requirements related to the above.

The descriptions shall be kept up-to-date including, when required.

8.2.2.2 Intended use

The intended use, the expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents to the extent needed to conduct the risk assessment.

Groups of HPC product users shall be identified for each product, and user groups known to be especially vulnerable to specific product safety hazards shall be considered.

***NOTE** Examples of groups:*

- *babies;*
- *children; or*
- *people with sensitive skin.*

The descriptions shall be kept up-to-date.

8.2.3 Flow diagrams, process steps and control measures

8.2.3.1 Flow diagrams

Flow diagrams shall detail all manufacturing process steps within the control of the organization. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase or introduction of product safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed, as per **C.3**.

In accordance with Clause **9**, the product safety team shall verify the accuracy of the flow diagrams by on-site checking. Verified flow diagrams shall be maintained as records.

8.2.3.2 Description of process steps and control measures

The existing control measures, process parameters and / or the rigorousness with which they are applied, or procedures that may influence HPC product safety, shall be described to the extent needed to conduct the risk assessment.

External requirements (e.g., from regulatory authorities or customers) that can impact the choice and the rigour of the control measures shall also be described.

8.2.3.3 Additional information for conducting a risk assessment

The additional information required for undertaking a risk assessment shall include, but is not limited to:

- customer complaints;
- product recalls;
- historical product safety issues; and
- test results of non-conforming products.

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8.3 Risk Assessment

8.3.1 General

The product safety team shall identify the hazards, assess the risks associated and determine the degree of control required to ensure HPC product safety, and which combination of control measures is required.

8.3.2 Hazard identification and determination of acceptable levels

All HPC product safety hazards that are reasonably expected to occur in relation to the type of product, type of process and processing facilities shall be identified and recorded. The identification shall be based on:

a) the preliminary information and data collected according to **8.2**; and

b) information from the supply chain on product safety hazards that may be of relevance for the safety of the end products, intermediate products and the product in use.

When identifying the hazards, consideration shall be given to:

1) the step(s) (from raw materials, processing and distribution) at which each product safety hazard may be introduced;

2) the step(s) preceding and following the specified operation;

3) the process equipment, utilities / services and surroundings; and

4) the preceding and following links in the supply chain.

For each of the product safety hazards identified, the acceptable level of the product safety hazard in the end product shall be determined.

NOTE *The determined level should take into account established statutory and regulatory requirements, customer safety requirements, and the intended use by the consumer.*

The justification for, and the result of, the determination shall be recorded.

8.3.3 Conducting the risk assessment

A risk assessment shall be conducted to determine, for each hazard identified (see **8.3.2**), 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.

Each hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. The methodology used shall be described, and the results of the hazard shall be recorded.

8.3.4 Selection and assessment of control measures

Based on the risk assessment of **8.3.3**, an appropriate combination of control measures shall be selected which are capable of preventing, eliminating or reducing these HPC product safety hazards to defined acceptable levels.

In this selection, each of the control measures as described in **8.2.3.2** shall be reviewed with respect to its effectiveness against the identified product safety hazards.

The control measures selected shall be categorized as to whether they need to be managed through operational PRP(s) or using the risk management plan (see **8.4**).

The selection and categorization shall be carried out using a defined approach in accordance with Annex C.

The methodology and parameters used for this categorization shall be described in documents, and the results of the assessment shall be recorded.

Control measures identified in a risk assessment shall be implemented.

8.4 Ongoing risk management

8.4.1 General

For each hazard that is to be controlled by the risk management plan, critical control point (CCP) shall be identified for the control measures identified (see **8.3.4**).

The risk management plan shall be documented and shall include the following information for each identified CCP:

a) HPC product safety hazard(s) to be controlled at the CCP (see **8.3.4**);

b) control measure(s) (see **8.3.4**);

c) critical limit(s) (see **8.4.2**);

d) monitoring procedures (see **8.4.3**);

e) corrections and corrective action(s) to be taken if critical limits are exceeded (see **8.4.4**);

f) responsibilities and authorities; and

g) record(s) of monitoring.

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8.4.2 Determination of critical limits for critical control points

Critical limits shall be determined for the monitoring established for each CCP.

Critical limits shall be established to ensure that the identified acceptable level of the product safety hazard in the end product (see **8.3.2**) is not exceeded.

Critical limits shall be measurable.

The rationale for the chosen critical limits shall be documented.

Critical limits based on subjective data (such as visual inspection of product, process, handling, etc.) shall be supported by instructions or specifications and / or education and training.

8.4.3 System for the monitoring of critical control points

A monitoring system shall be established for each CCP to demonstrate that the CCP is in control. The system shall include all scheduled measurements or observations relative to the critical limit(s).

The monitoring system shall consist of procedures, instructions and records that cover the following:

a) measurements or observations that provide results within an adequate time frame;
b) monitoring devices used;
c) applicable calibration methods (see **12.3**);
d) monitoring frequency;
e) responsibility and authority related to monitoring;
f) verification of monitoring results; and
g) record requirements and methods.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used.

8.4.4 Actions when monitoring results exceed critical limits

Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified in the risk management plan. The actions shall ensure that the cause of the non-conformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented (see **11.2**).

Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated (see **11.3**).

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9 Verification planning

Verification planning shall define the purpose, methods, frequencies and responsibilities for the verification activities. The verification activities shall confirm that:

a) the PRP(s) are implemented (see **7.2**) and are effective;

b) input to the hazard analysis (see Clause **8.2**) is continually updated;

c) the additional control measures (see **8.2.3.2**) are implemented and effective;

d) hazard levels are within identified acceptable levels (see **8.4.2**); and

e) other procedures required by the organization are implemented and effective.

The output of this planning shall be in a form suitable for the organization's method of operations.

Verification results shall be recorded and shall be communicated to the HPC product safety team. Verification results shall be provided to enable the analysis of the results of the verification activities (see **12.4.3**).

10 Traceability system

The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records.

The traceability system shall be able to identify incoming material from the direct suppliers and the initial distribution route of the end product.

Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product recall or withdrawal.

NOTE *Attention is also drawn to relevant statutory and regulatory requirements.*

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11 Control of non-conformity

11.1 Corrections

The organization shall ensure that when there is a loss of control of operational PRP(s) and CCPs, the products affected are identified and controlled with regard to their use and release.

A documented procedure shall be established and maintained defining:

a) the identification and assessment of affected end products to determine their proper handling (see **11.3**), and

b) a review of the corrections carried out.

Products manufactured under conditions where critical limits have been exceeded or PRPs have not been conformed with shall be handled in accordance with **11.3**. The evaluation shall be recorded.

All corrections shall be approved by the responsible person(s), and shall be recorded together with information on the nature of the non-conformity, its cause(s) and consequence(s), including information needed for traceability purposes related to the nonconforming lots.

11.2 Corrective actions

Data derived from the monitoring of operational PRPs and CCPs shall be evaluated by designated person(s) with sufficient knowledge (see **6.2**) and authority (see **5.4**) to initiate corrective actions.

Corrective actions shall be initiated when there is a lack of conformity with operational PRP(s).

The organization shall establish and maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected non-conformities, to prevent recurrence, and to bring the process or system back into control after non-conformity is encountered. These actions shall include:

a) reviewing non-conformities (including customer complaints);

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

c) determining the cause(s) of non-conformities;

d) evaluating the need for action to prevent future non-conformities;

e) determining and implementing the actions needed;

f) recording the corrective actions taken and their outcomes; and

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

Corrective actions shall be recorded.

11.3 Handling of non-conforming products

11.3.1 General

The organization shall handle non-conforming products by taking action(s) to prevent the non-conforming product from entering the supply chain unless it is possible to ensure that:

a) the product safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels;

b) the product safety hazard(s) of concern are to be reduced to identified acceptable levels (see **8.3.2**) prior to entering into the supply chain; or

c) the product still meets the defined acceptable level(s) of the product safety hazard(s) of concern despite the non-conformity.

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All products that may have been affected by a non-conforming situation shall be held under control of the organization until they have been evaluated.

If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant parties and initiate a withdrawal (see **11.4**).

NOTE *The term "withdrawal" includes recall.*

The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.

11.3.2 Evaluation for release

Each lot of product affected by the non-conformity shall only be released as safe when any of the following conditions apply:

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

b) evidence shows that the combined effect of the control measures for that particular product complies with the performance intended (i.e. identified acceptable levels as identified in accordance with **8.3.2**); or

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

11.3.3 Disposition of non-conforming products

Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities:

a) reprocessing or further processing within or outside the organization to ensure that the HPC product safety hazard is eliminated or reduced to acceptable levels; or

b) destruction and/or disposal as waste.

11.4 Withdrawals

To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as non-conforming:

a) top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal; and

b) the organization shall establish and maintain a documented procedure for:

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

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

   3) the sequence of actions to be taken.

Withdrawn products shall be:

i) secured or held under supervision until they are destroyed;

ii) determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe.

The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review (see **5.7.2**).

The organization shall verify and record the effectiveness of the withdrawal programme through the use of appropriate techniques (e.g. mock/dummy withdrawal or practice withdrawal).

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12 Validation, verification and improvement of the HPC product safety management system

12.1 General

The product safety team shall plan and implement the processes needed to validate control measures and/or control measure combinations, and to verify and improve the product safety management system.

12.2 Validation of control measure combinations

Prior to implementation of control measures and any changes to them, the organization shall validate that:

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

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

If the result of the validation shows that one or both of the above elements cannot be confirmed, the control measure and/or combinations thereof shall be modified and re-assessed (see **8.3.4**).

NOTE *Modifications may include changes in control measures (i.e. process parameters, rigorousness and/or their combination) and/or change(s) in the raw materials, manufacturing technologies, end product characteristics, methods of distribution and/or intended use of the end product.*

12.3 Control of monitoring and measuring

The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures.

Where necessary to ensure valid results, the measuring equipment and methods used shall be:

- calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- adjusted or re-adjusted as necessary at predetermined frequencies, based on risk assessment, adjustment shall be conducted by qualified staff or third parties;
- identified to enable the calibration status to be determined;
- safeguarded from adjustments that would invalidate the measurement results; and
- protected from damage and deterioration.

Records of the results of calibration and verification shall be maintained. In addition, the organization shall assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements. If the measuring equipment is non-conforming, the organization shall take appropriate action for the equipment and any product affected. Records of such assessments and resulting actions shall be maintained.

12.4 HPC product safety management system verification

12.4.1 Internal audit

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

a) conforms to the planned arrangements, to the product safety management system requirements established by the organization, and to the requirements of this PAS; and

b) is effectively implemented and updated.

An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits (see **12.5** and **5.7.2**). The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, shall be defined in a documented procedure.

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The management responsible for the area being audited shall take actions without undue delay to eliminate detected non-conformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.

12.4.2 Evaluation of individual verification results

The HPC product safety team shall systematically evaluate the individual results of planned verification (see Clause **9**).

If verification does not demonstrate conformity with the planned arrangements, the organization shall take action to achieve the required conformity. Such action shall include, but is not limited to, the review of:

a) existing procedures and communication channels (see **5.5**);
b) the conclusions of the risk assessment (see **8.3**);
c) the PRP(s) and CCPs (see **7.2**); and
d) the effectiveness of human resource management and of training activities (see **6.2**).

12.4.3 Analysis of results of verification activities

The HPC product safety team shall analyze the results of verification activities, including the results of the internal audits (see **12.4.1**) and external audits. The analysis shall be carried out in order:

a) to confirm that the overall performance of the system meets the planned arrangements and the product safety management system requirements established by the organization;
b) to identify the need for updating or improving the product safety management system;
c) to identify trends which indicate a higher incidence of potentially unsafe products;
d) to establish information for planning of the internal audit programme concerning the status and importance of areas to be audited; and
e) to provide evidence that any corrections and corrective actions that have been taken are effective.

The results of the analysis and the resulting activities shall be recorded and reported, in an appropriate manner, to top management as input to the management review (see **5.7.2**). It shall also be used as an input for updating the product safety management system (see **12.5**).

12.5 Continual improvement and updating of the HPC product safety management system

The organization shall continually improve the effectiveness of the product safety management system through the use of communication (see **5.5**), management review (see **5.7**), internal audit (see **12.4.1**), evaluation of individual verification results (see **12.4.2**), analysis of results of verification activities (see **12.4.3**), validation of control measure combinations (see **12.2**), corrective actions (see **11.2**) and product safety management system updating.

Top management shall ensure that the product safety management system is periodically reviewed and updated as required.

In order to achieve this, the product safety team shall evaluate the product safety management system at planned intervals. The team shall then consider whether it is necessary to review the hazard analysis (see **8.3**) and, the PRP(s) (see **7.2**).

The evaluation and updating activities shall be based on:

a) input from communication, external as well as internal, as stated in **5.5**;
b) input from other information concerning the suitability, adequacy and effectiveness of the product safety management system;
c) output from the analysis of results of verification activities (see **12.4.3**); and
d) output from management review (see **5.7.3**).

System updating activities shall be recorded and reported, in an appropriate manner, as input to the management review (see **5.7.2**).

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Annex A (normative)
Additional requirements for the manufacture of home and/or personal care products

A.1 Laboratory facilities

In-line and on-line test facilities shall be controlled to minimize the risk of product contamination.

Microbiology laboratories shall be designed, located and operated so as to prevent contamination of people, plants and products. They shall not open directly onto a production area.

Where the organization undertakes or subcontracts analyses which are critical to product safety or legality, the laboratory, or subcontractors, shall have recognized laboratory accreditation or operate in accordance with the requirements and principles of BS EN ISO/IEC 17025. Documented justification shall be available where accredited methods are not undertaken.

A.2 Containers for waste and hazardous substances

Containers for waste and hazardous substances shall be locked where the waste poses a risk to the product

A.3 Drains and drainage

Drains shall have capacity sufficient to remove expected flow loads. Drains shall not pass over processing lines

External and internal drains shall be properly protected to prevent entry of pests.

Drains shall be kept clean and should not allow back flow.

Drains shall be trapped and covered.

A.4 Temperature control and monitoring equipment

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

Equipment shall provide for the monitoring and control of the temperature.

A.5 Preventive and corrective maintenance

Maintenance personnel shall be trained in the product hazards associated with their activities.

A.6 Management of purchased materials

Purchasing of materials which impact HPC product safety shall be controlled to ensure that the suppliers used have the capability to meet the specified requirements.

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

A.7 Selection and management of suppliers

The handling of identify preserved materials shall be managed.

A.8 Incoming material requirements (raw/packaging)

The method of vehicle checking shall be documented.

A process shall be in place to ensure the offloading of bulk materials does not introduce contamination into the bulk storage facilities, i.e. cleaning and sanitization of tanker hoses and offloading points.

All raw and packaging materials shall have written specifications that detail critical parameters.

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Annex B (normative) Requirements for manufacture of personal care (PC) products

B.1 General

For personal care organizations, this Annex shall be used in conjunction with the main body of the PAS.

NOTE *This also applies to Home & Personal Care organizations.*

B.2 Internal structures and fittings

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

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

Ceilings and overhead fixtures shall be designed to minimize build-up of dirt and condensation and facilitate cleaning. Where suspended ceilings are used, adequate access to the void shall be provided to facilitate cleaning, maintenance of utilities and inspection for pest activity.

External opening windows, roof vents or fan, where present, shall be insect screened. Windows shall be of non-opening design where ventilation is adequate. If windows are opened to the outside environment, they shall be properly screened. External opening doors shall be cleanable and closed or screened when not in use.

B.3 Storage of PC products, raw and packaging materials

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.

Where outside space is used for storage, stored items shall be protected from weather.

B.4 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 to ensure that materials, product or equipment are not contaminated in the case of breakages.

B.5 Containers for waste and hazardous substances

Containers for waste and hazardous substances shall be closed when not in immediate use.

B.6 Microbiological cross contamination

Areas where potential for microbiological cross contamination exists (airborne or from traffic patterns) shall be identified and a segregation (zoning) plan implemented.

NOTE *Control measures suitable for these areas are as follows:*

a) structural segregation – physical barriers/walls/ separate buildings;

b) access controls with requirements to change into required work wear;

c) traffic patterns or equipment segregation – people, materials, equipment and tools (including use of dedicated tools);and

d) air pressure differentials.

B.7 Physical contamination

Where glass, blades, sharp objects and/or brittle material are part of the manufacturing environment, periodic inspection requirements and defined procedures in case of breakage shall be put in place. Records of breakage shall be maintained.

NOTE 1 *Glass, blades, sharp objects and/or brittle material (such as hard plastic components in equipment) should be avoided where possible.*

NOTE 2 *Examples of such measures include:*

a) adequate covers over equipment or containers for exposed materials or products;

b) use of screens, magnets, sieves or filters; or

c) use of detection/ rejection devices such as metal detectors or X-ray.

NOTE 3 *Sources of potential contamination include wooden pallets and tools, rubber seals, personal protective clothing, packaging materials and equipment, etc.*

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B.8 Personnel hygiene facilities and toilets

Personnel hygiene facilities shall be available to ensure that the degree of personal hygiene required by the organization is 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 hot and cold or temperature controlled water, soap and/or sanitizer, single use towels or tissues and air hand driers);

b) have sinks designated for hand washing, separate from sinks for product and equipment cleaning stations;

   NOTE *Taps at hand wash stations should not be hand operated.*

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; and

f) have changing facilities sited to enable PC product handling personnel to move to the production area in such a way that risk to the cleanliness of their work wear is minimized.

B.9 Cleaning and sanitization

B.9.1 General

Cleaning and/or sanitization programmes shall be established to ensure that the PC product processing equipment and environment are maintained in a hygienic condition. Programmes shall be monitored for continuing suitability and effectiveness.

B.9.2 Cleaning and sanitization agents and tools

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

Cleaning and sanitization agents and chemicals shall be clearly identified, 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 which does not present a potential source of extraneous matter.

B.9.3 Cleaning and sanitization programmes

Cleaning and sanitization programmes shall be established and validated by the organization so that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule, including the cleaning of cleaning equipment.

Cleaning and/or sanitization 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/sanitization method and frequency (including holding times, temperatures, chemical concentrations as necessary);

d) monitoring and verification arrangements;

e) post-clean inspections (including time limit before equipment shall be used); and

f) pre start-up inspections.

B.9.4 Cleaning in place (CIP) systems

CIP systems shall be separated from active product lines.

Parameters for CIP systems shall be defined and monitored (including type, concentration, contact time and temperature of any chemicals used).

B.9.5 Monitoring cleaning and sanitization effectiveness

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

B.10 Pest control

B.10.1 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.

Detectors and traps shall be of robust, tamper resistant construction. They shall be appropriate for the target pest and be securely located to prevent unauthorized removal.

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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.

Materials shall be stored off the floor and sufficiently far away from walls to enable inspection, pest control and prevent pest ingress.

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

B.10.2 Harbourage and infestations

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).

B.11 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).

Clothing mandated for PC product protection or hygiene purposes shall not be used for any other purpose.

Based on hazard assessment work wear shall not have buttons. Work wear shall not have outside pockets above waist level.

NOTE *Zips or press stud fastenings are acceptable.*

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

Work wear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.

Shoes for use in processing areas shall be fully enclosed, made from non-absorbent materials and have non-slip soles.

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

Where self-care laundry is permitted:

- Employees shall receive written instructions regarding the laundering process to be used. These instructions shall be reinforced as part of an induction or other in-house training programme.
- Employees shall be provided with suitable means to safely transport washed garments from home to the workplace.
- There shall be a defined process within the organization for monitoring the effectiveness of the system.
- There shall be a procedure and system for dealing with any case where employees are unable to perform self-laundry effectively, either through lack of diligence or facilities.

The wearing of gloves does not remove the need for regular hand washing and gloves shall be replaced regularly.

Based on hazard assessment hair, beards and moustaches shall be protected (i.e. completely enclosed) by hair covers. Where gloves are used for product contact, they shall be clean and in good condition.

B.12 Illness and injuries

Employees shall be required to report the following conditions to management for possible exclusion from PC product handling areas: jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected skin lesions (boils, cuts or sores) and discharges from the ear, eye or nose.

In product handling areas, personnel with wounds or burns shall be required to cover them with specified dressings. Any lost dressing shall be reported to supervision immediately.

NOTE *Dressings should be brightly coloured and metal detectable where appropriate.*

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B.13 Personal cleanliness

Personnel in PC product production areas shall be required to wash, dry and where appropriate, sanitize hands:

a) before starting any product handling activities and as required to prevent contamination; and
b) immediately after using the toilet or blowing nose/sneezing.

Personnel shall be required to refrain from sneezing or coughing over materials or products. Spitting (expectorating) shall be prohibited.

Fingernails shall be kept clean and trimmed.

B.14 Personal behaviour

A documented policy shall describe the behaviours required of personnel in processing, packing and storage areas. The policy shall at a minimum cover:

a) permissibility of smoking, eating, chewing in designated areas only;
b) control measures to minimize hazards presented by permitted jewellery;

   NOTE *Permitted jewellery includes specific types of jewellery which may be worn by the personnel in processing and storage areas, taking into account religious, ethnic, medical and cultural imperatives.*
c) permissibility of personal items, such as smoking materials and medicines, in designated areas only;
d) prohibition of the use of nail polish, false nails and false eyelashes;
e) prohibition of carrying of writing implements behind the ears;
f) maintenance of personal lockers so that they are kept free from rubbish and soiled clothing;
g) prohibition of storage of product contact tools and equipment in personal lockers.

B.15 Warehousing requirements

Gasoline or diesel powered fork lift trucks shall not be used in PC product ingredient or product storage areas.

B.16 Reworked products

Stored rework shall be protected from exposure from the environment to microbiological contamination and prevent microbiological growth.

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Annex C (normative)
Product characteristics

C.1 Raw materials, ingredients and product-contact materials

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis, including the following, as appropriate:

a) biological, chemical and physical characteristics;
b) composition of formulated ingredients, including additives and processing aids;
c) origin;
d) method of production;
e) packaging and delivery methods;
f) storage conditions and shelf life;
g) preparation and/or handling before use or processing;
h) HPC product safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses.

The descriptions shall be kept up-to-date including, when required, in accordance with **C.2**.

C.2 Characteristics of end products

The characteristics of end products shall be described in documents to the extent needed to conduct the hazard analysis (see **8.3.3**), including information on the following, as appropriate:

a) product name or similar identification;
b) composition;
c) biological, chemical and physical characteristics relevant for HPC product safety;
d) intended shelf life and storage conditions;
e) packaging;
f) labelling relating to HPC product safety and/or instructions for handling, preparation and usage;
g) method(s) of distribution.

C.3 Flow diagrams

Flow diagrams prepared for the products or process categories covered by the HPC product safety management system shall, as appropriate, include the following:

a) the sequence and interaction of all steps in the operation;
b) any outsourced processes and subcontracted work;
c) where raw materials and intermediate products enter the flow;
d) where reworking and recycling take place;
e) where end products, intermediate products, by-products and waste are released or removed.

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Annex D (normative)
Selection and categorization of control measures

An assessment of control measures shall consider, as a minimum:

a) its effect on identified HPC product safety hazards relative to the strictness applied;

b) its feasibility for monitoring (e.g. ability to be monitored in a timely manner to enable immediate corrections);

c) its place within the system relative to other control measures;

d) the likelihood of failure in the functioning of a control measure or significant processing variability;

e) the severity of the consequence(s) in the case of failure in its functioning;

f) whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s);

g) synergistic effects (i.e. interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects).

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