Global Safety and Quality Management System Certification Scheme for Home, Laundry & Personal Care Products

in compliance with PAS 420, ISO 17021 and additional requirements

Part 0
General provisions

Gorinchem, The Netherlands: 2016

Version Control	Version 1.0 September 2016

Global Safety and Quality Management System
Certification Scheme for Home, Laundry & Personal Care Products

in compliance with PAS 420, ISO 17021 and additional requirements

The Foundation HPC 420 retains the ownership of this Scheme.

Due to the dynamic content of this document the user of same must always verify if the correct version is held. Future revisions of this document will always be published under the same name.

In all cases the English version of this Scheme is valid.

Foundation HPC 420
P.O. Box 693
4200 AR Gorinchem, The Netherlands
t: +31-183 822995
website: www.hpc420.com
email: info@hpc420.com

Table of Contents

1 Introduction

Safety and quality of Home, Laundry and Personal Care Products (HPC) is a global concern. Globalization of HPC production and procurement makes supply chains longer and more complex, increases the risks of incidents and adds unnecessary costs to the supply chain. For this reason a number of large players, together with the British Standards Institution (BSI), developed the publicly available standard PAS 420 to provide a HPC product safety management system.

PAS 420, however, does not set requirements for quality management, nor contains provisions for auditing, certification and certification bodies (CBs) accreditation. Large players in the HPC supply chain have requested HPC 420 to add these components, which has been done in "HPC 420" ('the Scheme').

The HPC 420 Scheme consists of:

- Part 0: General provisions
- Part I: Requirements for HPC 420 certification
- Part II: Requirements for CBs providing HPC 420 audit and certification services

2 Scopes

The Scheme is intended for the auditing and certification of HPC safety and quality management systems, covering:

- Sector A; the manufacturing of Home Care products (e.g. detergents, fabric softener, dish washing tablets etc.)
- Sector B; the manufacturing of Personal Care products (e.g. shampoo, lipsticks, cotton pads, soap)
- Sector C; (bio)chemical manufacturing (HPC ingredients e.g. vitamins, additives and bio-extracts (but excluding technical and technological aids of the manufacturing process)
- Sector D; the manufacturing of HPC product packaging (e.g. direct, indirect contact with the HPC products).

Transport and storage on site and as part of an operation are included. The Scheme is applicable to all organizations in the HPC supply chain in these categories, regardless of size and complexity, whether profit-making or not and whether public or private.
For integrity reasons manufacturing processes using ingredients and or raw materials from not allowed rare natural resources cannot be certified.

3 Reference documents

The Scheme is based on the following documents and their future versions:

BSI 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.

ISO 9001:2015, Quality management systems – Requirements.

ISO/IEC 17000:2004, Conformity assessment – Vocabulary and general principles.

ISO/IEC 17021:2015, Conformity assessment – Requirements for bodies providing audit and certification of management systems.

ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories.

4 Ownership, governance and Integrity Program

The Scheme is owned, governed and managed by the Foundation HPC 420, based in Gorinchem, Stephensonweg 14, 4207 HB, the Netherlands, registered with the Chamber of Commerce in Gorinchem, the Netherlands.

4.1 The Foundation

4.1.1 The Foundation has as its objectives:

a) promoting the application of home and personal care safety and quality management systems;
b) developing, designing, managing and amending home and personal care safety and quality certification and inspection systems in the field of home and personal care;
c) promoting national and international recognition and general acceptance of systems it has developed for home and personal care safety and quality;
d) running information campaigns and providing information on home and personal care safety and quality;
e) providing support services for certification of home and personal care safety and quality systems in the field of home and personal care;
f) performing all other actions that are related in the broadest possible sense to the aforementioned or that could in any way be beneficial to same.

4.1.2 The Foundation endeavors to achieve these objectives by:

a) entering into agreements with certification bodies;
b) taking appropriate measures in the event of abuse or improper use of the certificates issued by accredited certification bodies;
c) taking appropriate measures in the event of abuse or improper use of the Foundation's logo;
d) supporting, supervising and financing of other foundations and organizations which strive to achieve similar or partially similar objectives as those mentioned in this Article.

4.2 The Management Board

4.2.1 The Foundation's management board, hereinafter referred to as “the Board”, consists of at least three members.

4.2.2 The Board may never consist of a majority of members who represent the interests of one of the stakeholder groups involved. Stakeholder groups in this context being stakeholders or certification bodies or certificate holders or organizations which are intended to be certificate holders.

4.2.3 The Board shall elect a chairman and a treasurer from among its members. The Board shall also appoint a secretary to carry out all necessary administrative activities.

4.3 Representation

4.3.1 The Foundation is represented by the Board or two Board members acting together.

4.3.2 The Board can grant a Board member or a third party a power of attorney to represent the Foundation within the confines of the power of attorney and the limitations from this Part of the Scheme and/or applicable law.

4.4 Board meetings

4.4.1 The Board shall meet at least once each year and, furthermore, as often as the chairman or at least two Board members consider necessary.

4.4.2 The secretary shall convene the meeting by sending a written summons to all Board members. At least seven days must pass between the day of the summons and that of the meeting. The summons shall contain the agenda of subjects to be dealt with and, where needed, further explanation. The secretary or another person than the chairman shall keep minutes of the subjects dealt with during the meeting. Each member of the Board has the right to a copy of the minutes signed by the secretary.

4.4.3 Board members are entitled to have another Board member represent them in a meeting after such written authorisation is given which the chairman of the meeting deems sufficient. A Board member may only act as proxy for one other Board member.

4.4.4 The Board is authorised to set conditions for the use of electronic means of communication. If the board exercises this authority, the conditions shall be published in the summons.

4.5 Board decision making

4.5.1 The Board can pass resolutions in and outside meetings. Unless these articles stipulate otherwise, a resolution can only be passed in a meeting at which a majority of current members is present. A decision taken outside a meeting requires a unanimous written vote of all current Board members.

4.5.2 Voting will be oral, unless a Board member requests a written vote.

4.5.3 Unless these articles state otherwise, the Board shall adopt motions by a simple majority of votes cast.

4.6 Stakeholders Committee

4.6.1 The Board appoints a Stakeholders Committee, hereinafter referred to as the "SC", of which it determines the number of members and shall appoint or reappoint its chairman. A Board member cannot be appointed as member of the SC, but the Foundation secretary can act as secretary of the SC, having an advisory role, not having any voting rights. The chairman leads the meetings of the SC and shall be independent. The SC consists of representatives of the categories covered by the HPC 420 scopes including, but not limited to relevant stakeholders like industry, standard setting bodies, ABs and CBs. The composition ensures a balance of interests.

4.6.2 The SC advices the Board on the design, development, changes and emendation of the Scheme, including interpretation of clauses, scopes, accreditations, work methods, methods and frequency with which certification bodies are inspected, complaints procedures and standards of expertise of auditors.

4.6.3 The Board shall adopt the advice referred to in this article 4.6.2, unless it is in conflict with any statutory provisions, or is in conflict with any requirement that the Foundation must meet in the context of accreditation, or if the Board is of the opinion that, taking into account all relevant interests of all stakeholders, the interests of the Foundation oppose the adoption of the advice. In such case the Foundation shall inform the SC in writing, the SC having the right to convene a meeting to discuss same.

4.7 Financial control and administration

4.7.1 The Foundation's financial year coincides with the calendar year.

4.7.2 The Board is required to keep records of the Foundation's financial position and of all that concerns the Foundation's operation so that the Foundation's rights and obligations can be known at all times; it is also required to archive these records conscientiously and in a way that makes all documents and other related data carriers accessible for consultation and verification.

4.7.3 The Board shall issue a financial annual report which gives evidence of the receipts and expenditures of the previous financial year and the Foundation's financial position at the end of that year.
The Board must adopt these annual accounts within five months of the end of the Foundation's financial year. The same applies to the budget for the current year, if it has not been adopted earlier.

4.8 HPC 420 Integrity Program

4.8.1 The HPC 420 Integrity program consists at least of the following elements:

a) a standard contract with HPC 420 contracted certification bodies,
b) a program of KPI driven desk reviews of full audit reports, as determined by the Board,
c) a program of KPI driven analysis of audit reports, as determined by the Board,
d) registration of all auditors qualified under the Scheme,
e) a program of office and witness audits as determined by the Board,
f) a program for obligatory unannounced audits by contracted certification bodies, as determined by the Board.

4.8.2 The Foundation shall appoint an independent expert assessing the results of the above mentioned programs, reporting same to the Board.

4.8.3 The Board shall maintain a sanction policy consisting of a system of written warnings, and yellow and red cards, based on major and minor findings in the programs.

4.8.4 Directly interested parties may appeal in writing against sanction decisions made by the Board.

4.8.5 The Board will make public the way on which any interested third party may file complaints against any of the aspects of the Scheme.

4.8.6 The Foundation shall maintain a public register for all certificates duly issued on basis of the Scheme, safeguarding all information on certified organizations which are to be treated as confidential.

4.8.7 The Foundation shall decide on specific provisions on accreditation of CBs and requirements for accreditation bodies.

4.8.8 The standard contract with certification bodies as referred to hereabove will contain provisions for the use of the HPC 420 logo.

4.9 Additional Governance Provision

4.9.1 The Foundation and the management of the Scheme are, additionally to all the above, governed by the By-Laws of the Foundation HPC 420.

5 Terms and definitions

For the purpose of the Scheme the terms and definitions given in the PAS 420 apply. Further, the following terms and definitions apply:

Audit

Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

Batch

A defined quantity of an ingredient, raw material, packaging or product manufactured in one operation or a series, such that it can be considered as uniform.

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.

Certification Scheme

A set of requirements for the process of certification to certify conformance with a performance standard which is included or referred to in the Scheme. Apart from the performance standard, the Scheme may contain normative documents for the certification body and the accreditation body which accredits the certification body.

Certification system

Rules of procedure and management for carrying out conformity assessment leading to the issuance of a certification/registration document and its subsequent maintenance.

Cleaning

Removal of soil, dirt, grease or other objectionable matter.

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.

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.

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.

Contamination
Introduction or unintended occurrence of a contaminant 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 HPC 420.

Expected use
Its intended use and how the product actually is used, e.g. a degreaser liquid used to wash fatty hands, cotton buds to clean ears etc.. Disclaimers for expected use are legally not valid.

Facility
A building or structure that provides a particular service or is used by a supplier.

Foundation
Also referred to as Foundation HPC 420: the Dutch legal entity owning the HPC 420 Scheme.

HPC Ingredient
A component of HPC product(s) or packaging that has undergone processing with the intended safe application in HPC products.

HPC Manufacturing, also called HPC processing
The set of methods and techniques used to make HPC products. HPC manufacturing typically uses physical processes like but not limited to heating, cooling, extraction, mixing, portioning and blending of specified HPC ingredients.

HPC product safety
Concept that a HPC product will not cause harm to the consumer when used according to its intended and/or expected use.

HPC product safety hazard
Biological, chemical or physical agent in HPC products, or condition of HPC products, with the potential to cause an adverse health effect to humans when applied and stored according intended and/or expected use.

HPC product safety policy
Overall intention and direction of an organization related to HPC product safety as formally expressed by top management.

First expired first out (FEFO)
Stock rotation based on the principle of dispatching earliest expiration dates first.

First in first out (FIFO)
Stock rotation based on the principle of dispatching earliest received products first.

Hazard analysis
First step in a process necessary to assess risk.

Ingredient
Component part in mixture of a product or half-product; as such no further processing is demanded.

Intended use
Consumers use the products in the way specified in the design and/or as advertised/labeled.

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: the package itself, printed multi packs which have an inner label on the individual product and matter attached to the package, or a sticker used for over-labeling; an outer combined label for the whole contents; label hand-outs, when the products are to small, etc.*

Major nonconformity
A nonconformity, as referred to in ISO 17021-1, clause 3.12, that represents failure to fulfil one or more requirements of the management system standard or

a situation that raises significant doubt about the clients system to achieve its intended outputs.
In particular when the client is not able to give evidence that all identified product safety risks are well managed and that the product is safe for its expected use.

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.

Materials
General term used to indicate raw materials, packaging materials, ingredients, process aids, tools, cleaning materials and lubricants.

Medical devices
A medical device is an instrument, apparatus, implant, *in vitro* reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body. Medical devices only for prevention of diseases or other conditions might be within the scope of this Scheme.

Minor nonconformity
Other nonconformities as indicated in ISO 17021-1, clause 3.13.

Organization in the HPC chain
The HPC organization that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based.

Periodically reviewed
Periodically reviewed includes minimum annually.

Product contact
All surfaces that are in contact with the product or the primary package during manufacturing.

Product defense
The process to ensure the security of HPC products and their supply chains from all forms of malicious attack, including ideologically motivated attack leading to contamination or supply failure.

Product recall
Removal of a nonconforming product from the market, including recovery from consumers, trade and warehouses, distribution centers and/or customer warehouses because it does not meet specified standards.

Product withdrawal
Removal of a nonconforming product from the supply chain because it does not meet specified standards.

QMS, Quality Management System
A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality (*including safety and legality as basic requirements*) policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

Quality
The ability to consistently provide a product that meets customer and applicable statutory and regulatory requirements. Product safety is as such an inseparable part of quality.

Raw material
A component of HPC products or packaging that has to be processed.

Realization
Activities that culminate in the delivery of safe HPC products.

Rework
The re-utilization of (semi-finished) HPC products, or (spoiled) ingredients or raw materials.

Risk
The probability of causing an adverse health effect caused by the likelihood of occurrence and by the possible severity of the adverse health effect of a particular hazard in HPC products when applied according to its intended and expected use.

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.

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.

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).

Scheme
HPC 420, Home, Laundry and Personal Care Safety and Quality Management System Certification Scheme, in compliance with PAS 420, ISO 17021 and additional requirements.

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.

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.*