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 II

Requirements for CBs providing HPC 420 audit and certification services

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1. INTRODUCTION

1.1 Purpose

Certification Bodies (CBs) and their personnel intending to provide audit and certification services in conformance with the Scheme will find in this Part II of the Scheme all the necessary requirements and rules that must be met. This includes how they can enter into a license agreement with the HPC Foundation (Owner of the HPC 420 Scheme and logo). Part II consists of:

- additional compliance rules and requirements for the CB to be used in the certification processes, e.g. the additional requirement of reporting according a fixed format.
- the regulations and rules for the assignment and authorization of the CB to offer certification against the criteria of the Scheme (contractual and accreditation requirements).

1.2 Standards and technical specifications

The normative requirements for the organization to gain certification are PAS 420 and additional Scheme requirements. Although PAS 420 is a complete product safety management system, in practise product safety management is usually an integrated part of organization's quality management system (QMS). In Part I, Appendix 1A the minimum requirements of a QMS are summarized.

The Scheme shall be used by CBs that provide management system certification in a competent, consistent and impartial manner in accordance with ISO 17021:2015 requirements.

1.3 Additional requirements

Specific additional requirements for certification are included in the Scheme. These additional requirements are included in section "Additional requirements" (Part I, Appendix IA) and in the mandatory checks of compliance in the Scheme checklist for auditors.

When additional explanation is needed for parts of the Scheme, the Foundation will publish guidance documents on the Scheme's website to be sure that these parts are understood in a uniform way.

2. REQUIREMENTS FOR CERTIFICATION

2.1 Requirements

- Evaluation of conformance:
  The CB shall evaluate conformance with the PAS 420 standard and fully comply with the additional requirements of the Scheme.
- Criteria for providing certification:
  The requirements for providing certification are specified in Part I, Appendix I B

2.2 Additional requirements

Additional requirements for the implementation of the certification system are specified in Appendix IIA of this Part II.

2.3 Accreditation

Most requirements in this addendum are in line with ISO/IEC 17021-1:2015 requirements; others are explicitly included in the Scheme and require attention to guarantee full accordance.

CBs intending to offer audit and certification services shall be accredited for ISO/IEC 17021-1:2015 by an approved AB and shall apply first for an agreement with the Foundation before they can start the Scheme certification processes.

The CB shall inform the Foundation Secretariat about the accreditation status and directly communicate suspensions or withdrawals of the relevant accreditations.

3. REGULATIONS FOR CBS

3.1 Application

When applying for a license contract with the Foundation, the CB shall specify the required category or categories related to its competence and experience (A, B, C and/or D). Also the contact details of its headquarter (or HPC 420 dedicated centre(s) of excellence) and, if any, of other offices managing HPC 420 certification will be specified. The applicant CB will agree to meet all applicable requirements of the Scheme. The CB will then be given written authorization by the Foundation enabling it to use the Scheme for certification.

3.2 Application fee

An application fee has to be paid before this authorization will be given.

3.3 Design of the certificate

The design of the certificate shall meet the Scheme requirements in compliance with Appendix II B4.

3.4 Certification logo

Organizations may not display the HPC 420 certification logo or mention possession of a HPC 420 certificate on their products. The logo (copyright) is allowed to be used on the issued certificates if the certification is conducted in accordance with all requirements of the Scheme.

Reference: Conditions for the use of the logo which can be found on the HPC 420 website, ISO/IEC 17021-1:2015, clause 8.3.

3.5 Implementation of new Scheme requirements published by the Foundation

These may be the following:

1) New requirements that will mainly effect the way the CB operates. The Foundation will give, after publishing, a two months period to the CBs for adding these requirements to the CBs QMS and implementing the new requirements.
2) Changes, concerning relevant documents of the Scheme being changed. In most cases this leads to new Scheme versions. The Foundation will give, after publishing, a two months period to the CBs for adding these requirements to the CBs QMS and implement the new requirements internally (impact assessment, document change, training, etc.) After this two months the CB has a 1 year time transition period to have all certified organizations of the Scheme adapted to the new Scheme version, unless legal regulations stipulate a different transition period. When compelling reasons exist that make this transition impossible to execute, the CB shall inform the HPC 420 Secretariat in due time.

3.6 Communication of Scheme changes

New information or changes with regards to the requirements in the Scheme shall be communicated by the CBs to those parties involved, such as, but not limited to Scheme certificate holders and auditors (auditors and experts), within a period of 2 months after the Scheme changes were published.

Reference: ISO/IEC 17021-1:2015, clause 8.5.2.

3.7 Appeals and complaints

The CB shall have arrangements for appeals and complaints.

Reference: ISO 17021, clauses 9.7 and 9.8.

3.8 Conflicts of interest

The CB shall require all staff involved in the certification process to sign a contract or agreement which clearly commits them to:

- comply with the rules of the organization, with particular reference to confidentiality and independence from commercial or personal interests.
- declare any issues in relation to personal conflicts of interests.
- sign (electronic signing is allowed) an impartiality declaration before every HPC 420 audit, when an audit is performed by subcontracted auditors.

3.9 ISO/IEC 17021-1,-3 :2015

The CB shall clearly document and make known to its employees all requirements in ISO 17021-1,-3 related to personnel and has training and/or verification-exams records.

3.10 Full application of the Scheme

The CBs are responsible for the full application of the Scheme and have to observe the regulations and directives issued by the Foundation. See also 3.6 and 3.18

3.11 Annual fee for CBs

CBs will be charged for an annual fee to the Foundation. The Foundation will decide annually on the amount of this fee. The CBs will be charged at least annually for the total amount of fees of all certificates they have under contract per 31 December of each year.

3.12 Duration of certification

The maximum validity of the certificate is three years after the CBs certification decision date. A surveillance assessment has to take place every year to ensure that recertification is granted. The re-certification assessment is planned timely (recommended at least 2 months) before the validity date of the certificate. By doing this, the organization has sufficient time to correct an eventual major non conformance.

3.13 Register of certified organizations

The Foundation will keep a register with the names and certification information of the certified organizations. This register will be made publicly available on the website of the Foundation. The CBs will submit the following information to the Foundation in a format as agreed in the contract between the Foundation and the CB:

- Name and location of the certified organization

- Category of the certification (A, B, C and/or D)
- Scope description
- Date of the initial certification
- Expiry date of the certificate
- In case of suspension or withdrawal: the date of suspension or withdrawal.

This information shall be submitted in the Foundations database by the CB within 4 weeks after the delivery of the certificate. The CB shall agree in the certification agreement with the certified organization that this information will be submitted by the CB to the Foundation and explain that this information will be made public.

3.14 Auditor registration system

The Foundation shall have in place an auditor registration system for every Scheme specific auditor employed or contracted by a CB. The details of the auditor's qualifications, training, experience and scope of activity in relation to the Scheme's product categorization shall be held and maintained within this register. The Foundation will register approved auditors and shall ensure that the CB has a system to update the auditors' details, where appropriate. The CB shall register qualified auditors in the Foundation database and maintain relevant data.

3.15 Distribution of audit reports

The CB shall provide a written report to the Foundation for each audit in English according to the format of Appendix IIB1. Ownership of the audit report shall be maintained by the CB. The content of audit reports is to be treated confidentially by the CB and by the Foundation.

3.16 Scheme operation information

The CB shall cooperate with regular requests from the Foundation to provide information regarding the operation of the Scheme.

3.17 Harmonization process

The CB is obliged to participate in consultations on the interpretation of the Scheme. At least once every year there will be a harmonization meeting. In principle a coordinating officer represents the CB during this meeting. Preferably, this officer is involved in the Scheme report verification or auditing and, as a minimum, has sufficient technical knowledge for understanding of the Scheme. Cases will be brought in for discussion. Each CB shall discuss the cases and the results with their auditors.

3.18 Implementation of CB regulations

The CBs are required to ensure that the regulations which are decided by the Foundation are included in their existing system documentation within a period of two months after publication by the Foundation. CBs are required to control these documents according to their own document control procedures of their MS.

3.19 Non conformance with the Scheme requirements

In cases where a CB fails to comply with the requirements set out in the Scheme documents, detailed information will be gathered for review by the Foundation. If the non-conformance is of such a serious nature that the integrity of the Scheme is at stake, the Board may request a special meeting with the CB to deal with the matter.

4. Appendix II A1 Additional requirements

Note: if an additional requirement refers to a subject that is also addressed in one or more of the standards mentioned in section 2.1 of Part II, the applicable clause(s) of these standard(s) is/are indicated in the reference at the end of the section with the additional requirement.

4.1 Auditor competence – category A, B and C

4.1.1 Work experience of auditors

All auditors have at least 2 years' working experience in industry in a research, process/product development, quality assurance, lab control, risk assessment or management training job where chemistry is applied at professional level.
Consultants in these sectors can comply by showing a log of work experience of 2 years time equivalence (+/- 400 days) in the sectors.
Or/and
Work experience as a registered ISO 9001 lead auditor with 2 years audit records of companies producing chemical product(s). Sector knowledge of category the auditor will be working in, may be linked to performed audits in category A, B and C.
OR/and
Work experience as a registered ISO 22000/FSSC 22000 lead auditor category K (Bio Chemicals) with 2 years audit records.

4.1.2 Auditor Education

The auditor has completed post-secondary education in chemistry or a closely related field such as but not limited to biology, biochemistry and pharmacy or can demonstrate equivalent knowledge. Basic chemical identification skills (IUPAC, INCI and or CAS names) are readily available.

4.1.3 Auditor Training

Contracted CBs shall assure that all their registered Scheme auditors are trained for the Scheme categories they are qualified for and that the CB training programs contain the required subjects (See Appendix II B3) at adequate level. (able to understand and verify organization's compliance with this standard).

A mandatory training program for each auditor will incorporate:

- a pass in the examination for HPC training Module (A, B and/or C). The required training subjects for the different modules will be published and updated by the Foundation and shall be used by contracted CBs to train and examine their

auditors (Auditor Competence Management system in place according ISO 17021 and ISO 19011). *Ref. 5.3 Appendix II B3 Training program elements for auditors.*

- for extension of the auditor scope for new categories, the auditor shall follow additional mandatory training for the new sector or submits evidence of work experience of 2 years in the required sector; Sector D is excluded. See below
- an ISO 22000 and/or ISO 9001 accredited Lead Auditor training. The training in audit techniques shall have a duration of at least 5 days.
- on-going additional training as part of continuous competence and skills development, the CB shall take care that the auditor will be updated by trainings or harmonisation events, regarding new identified, safety risks for the sectors regarding raw materials, processes, products, sector related legislation and GMP codes. A plan for continued training to keep the auditors up to date with the best practices and relevant regulatory and statutory developments in the sector(s) in which they perform audits.
- the requirement that auditors shall carry out a minimum of 5 risk based QMS audit's (only ISO 9001-2015, ISO/FSSC 22000, HPC 420 count) of which 2 HPC 420 on-site audits per calendar year.
- for new auditors, supervised training in the assessments of Scheme's safety and quality management systems, HACCP skills, CCPs, PRPs and applied Product Safety Risk Management system principles (PAS 420 Chapter 8) , specific audit techniques and specific category knowledge, shall include a successful completion of the Scheme through 5 audits or 10 audit days at a number of different organizations. Combination audits of ISO 22716 with ISO 9001 count as well. In this case the auditor has to conduct both audits where ISO 22716 and ISO 9001 are combined.
- a documented sign off of the satisfactory completion of the training program by the appointed supervisor.
- instructions for the auditor to maintain written records of all relevant training undertaken for the categories A, B and/or C.
- the competence of auditors, inclusive category knowledge shall be re-established every 3 years by the CB.

Reference: ISO 17021-1 and 3.

4.2 Auditor competence – category D: HPC 420 Packaging

4.2.1 Packaging auditor qualifications and requirements

Packaging auditors for HPC products have knowledge and awareness of the interaction between the packaging and substances that are intended to be packed and what safety risks are related to wrong packaging material choice or

unintentional exchange of packaging. Also quality characteristics like sizes, repeatability, tolerances and shapes could be of great influence on the safety of a product.

A plan for continued training shall exist to keep the auditors up to date and qualified with the best practices and relevant regulatory and statutory developments in the packaging sector in which they perform audits. In order to maintain category and scheme knowledge, auditors shall be required to carry out a minimum of 5 on-site audits per calendar year; Packaging certification audits for ISO 22000 or FSSC 22000 count as well. Auditors may qualify to audit packaging scopes by one of the 2 routes described below.

4.2.1.1 QMS auditor with a packaging certificate

A primary qualification in HPC technology, product safety hygiene or related science subject and a certificate in packaging technology. The CB needs to demonstrate that the certificate is delivered by a World Packaging Organization recognized training organization and includes the following minimum training requirements and post-training examination which have to be verified by the CBs:

- Basics of Packaging Principles & Concepts
- Packaging Legislation, Standards and Regulations
- Aerosol and child Safe closures safety legislation
- Interaction between packed products and the packaging. Migration but also solving processes
- Packaging Materials (Plastics, Paper & Board, Metal, Glass) Manufacturing
- Specifics to Packaging of HPC Products – HPC related Hazards
- Quality / HPC Safety Control and Testing
- Printing Processes and Printing Inks
- Packaging Recycling
- Design of Packaging Materials
- Basic understanding of chemical names used in the cat A, B and C
- Hygiene of packaging treatments (γ-radiation, fungicides, use of virgin versus reworked packaging materials etc.)
- In each case, training is required in the specific sub sectors of packaging manufacture to be audited: 1)plastics, 2)paper and board, 3)metal, 4)glass and ceramics and other sector relevant materials used for packaging (e.g. inks, glues, tape, winders etc).

4.2.1.2 Auditor with packaging certificate (certified training of a recognized packaging institute)

A primary qualification, a degree or higher certificate in packaging technology.

Has at least 2 years' experience in a category A, B, C and/or D industry in a packaging research, process/product development, quality assurance, lab control, risk assessment or process management job where chemistry is applied at professional level and packaging (specifications) were part of it.

Records shall be available showing that the training covers, for the applicable packaging material type, as minimum the knowledge and understanding of:

- characteristics of raw materials, intermediate and finished packaging materials;
- the intended use of packaging materials and related hazards and risks;
- packaging material production processes and supporting processes;
- applicable potential HPC product safety hazards, PRPs (see also HPC Packaging Auditor requirements) and CCPs.

The qualification shall at least cover basic knowledge in the packaging material type included in the scope.

4.3 General Requirements for the audit reports

4.3.1 General

The CB shall provide a printed or electronically readable report file for each audit in an obligatory format to the certified organization.

The Scheme audit report shall give confidence that the certified organization has all basic QMS conditions and PRPs well managed and fulfilled.

Additional to the items for the audit and certification reports as stipulated in ISO 17021, clause 9.4.8, the audit and certification report shall identify the following:

- name and description of the organization (name, legal entity, address of actually audited organization and aligned headquarters);
- date of previous audit and name of CB conducting the previous audit
- details of existing certificates;
- overview of relevant changes to documentation, requirements, processes and products since the last audit;
- registered complaints on the Scheme organization safety and reports to concerning government;
- list of key personnel present at the audit;
- evidence that the organization representative has accepted any nonconformities raised and provided an appropriate response;

- description of the assessment of the identification by the organization of the HPC hazards to be controlled and the selection of the appropriate (combinations of) control measures for relevant hazards;
- results and the conclusions of the audit per clause of the normative standard or technical specification and per additional requirement.
- overview of major nonconformities and minor nonconformities together with the corresponding clause number of the normative standard or technical specification or the number of the additional requirement expiry date of the certificate.

In the result section of the report, conformance of compliance or noncompliance shall be indicated. In case of non-conformance, details shall be provided. Non applicable clauses shall be motivated. In the summary section positive evidence of confirming compliance shall be provided.

4.3.2 Defining the scope of the certification

When defining the scope, the CB shall indicate for each location the name of the Scheme product categories (A, B, C and/or D) and the specific sector as specified below.

A: Formulated Home Care products

B: Formulated Personal Care products

C: Raw material/Ingredients for A, B and/or C

D: Packaging and Product contact materials for category A, B, and/or C products including raw materials for category D

For category C only the manufacturing for HPC ingredients is covered by the scope. This needs to be added in the scope name.

E.g. scope:

cat. A The manufacturing of sealers and adhesives for DIY home repairs

cat. B The manufacturing of shampoos, hand soaps and skin lotions

cat. C The manufacturing of lanoline products for cosmetic products

cat. D The production of PE bottles for detergents

4.3.3 Safety by Design and Development processes in the scope

If applicable, design and development processes have to be clearly described in the scope and detailed in the report. Safety by Design compliance is the main part of the development process. The auditor shall assess and report for all stages in the development process if QMS is implemented. Safety of the products is assured in the product design specifications (validation of safe design principles) and be

verified for samples as well as for the first production runs. Management of Change in input (composition and variation) shall be applied.

4.3.4 Duration of audit and audit reporting

The minimum audit time for a single site, *T*s, expressed in days, is calculated as follows:

$$Ts = (T\,D + T\,H + T\,QMS + T\,FTE)$$

where

T D is the basic on-site audit time, in days;

T H is the number of audit days for additional hazard analyses studies;

T QMS is the number of audit days, necessary to audit additional the quality part where safety is covered by the PAS 420 part of the MS.

T FTE is the number of audit days per number of employees.

The audit time for each site in addition to the main site, is calculated according to the table below with a minimum of 1 audit day per site. When properly documented and justified, a reduction can be made for a less complex organization measured by number of employees, size of the organization and/or product volume or within categories having a *T*s time of less than 1,5 audit days.

Table: Minimum initial certification audit time on site

Category	Basic on-site audit time, in audit days D	Number of audit days for each additional hazard analysis study H	Number of audit days for QMS	Number of audit days per nr. of employees FTE*	For each additional site visited*
A	1,5	0,5	1 day shall be added for the absence of a certified QMS	1 to 19 = 0 20 to 49 = 0,5 50 to 79 = 1,0 80 to 199 = 1,5 200 to 499 = 2,0 500 to 899 = 2,5 900 to 1299 = 3,0 1300 to1699= 3,5 1700 to2999 =4,0 3000 to5000 = 4,5 > 5 000 = 5,0	20% audit time reduc-tion may be applicable. HQ with no production on site does not has an own certificate
B	1,5	0,5			
C	1,5	0,5			
D	1	0,25			
Cat A = Home Care and Laundry Cat B = Personal care Cat C = Raw materials an half products for A, B, D Cat D = Packaging for A, B, C					

* Multi site certification is not possible, max 3 (incl. HQ) off site process parts, can be audited in addition of max 0,25 days per location

* *The number of employees involved in any aspect of product safety shall be expressed as the number of fulltime equivalent employees (FTE). When an organization deploys workers in shifts and the products and/or processes are similar, the FTE number will be calculated based on employees on the main shift (including seasonal workers) plus office workers.'*

Calculation of minimum surveillance and recertification audit time

The minimum surveillance audit time shall be half of the initial certification audit time, with a minimum of 1 audit day.

The minimum recertification audit time shall be two-thirds of the initial certification audit time, with a minimum of 1 audit day

Additional reporting time based on 1 FTE auditor days on site (*for initial , surveillance and recertification audit.*)

Sufficient time to write the report with a minimum of 0,5 day.

4.3.5 Requirements for audit of PRPs

The CB shall report the implemented and maintained PRPs, established by the organization, according to the requirements of PAS 420. These PRPs are part of the required GMP program or are identified by the organization as part of their risk assessment. The specific requirements for which the necessary PRP is not established or is not effective in controlling the introduction of HPC safety hazards shall be identified and classified as such. In order to verify if the PRPs are met, a site tour shall be part of the audit.

4.3.6 Criteria for nonconformities and certification decision

The CB is required to establish, maintain and communicate about criteria as a reference against which a minor nonconformity and a major nonconformity is determined, in accordance with the definitions in the Scheme.

Reference: ISO 17021, clauses 3.11-3.13.

Organizations can only qualify for granting certification on the basis of the Scheme if:

- the CB has not revealed any outstanding major conformities (closed within 28 days) and
- the CB has reviewed (within 1 month) and accepted the planned (within 6 month) corrections and corrective actions for minor nonconformities.

Reference: ISO 17021.

4.3.7 Requirements for initial certification

Stage 1 shall be performed at the organizations premises (on site). Main purpose of this Stage 1 audit is to evaluate the preparedness of the organization for Stage 2. However, all objectives of Stage 1 shall be met and reported for the Scheme.
Reference: ISO 17021-1, clause 9.3.1.2.
The auditor with her/his sector knowledge, validates organization's QMS including organization's safety risk assessment on completeness and if the safety risks the company identified as to be managed are relevant. The report shall include a list of these identified safety risks as well as how these risks are managed (CCPs and critical safety limits).

Areas of Concern are reported for potential NCs if these areas still exist when the Stage 2 audit is performed. The auditor shall use the outcome to plan together with the organization when the Stage 2 part will be executed.
During the initial certification audit (Stage 1 and 2) all requirements of the Scheme shall be evaluated. This includes PAS 420 and additional Scheme requirements (Part 1 Appendix I A).
Stage 2 has as main purpose to verify if organization's QMS (inclusive product safety management), is fully operational and effective. The assessment includes a site tour and shall cover all product lines covered by the scope. The site tour shall include the review of implementation of all CCPs and shall include a representative sampling of the PRPs. Important is, to find situations of CCPs out of control, PRPs not operational and investigate what has been done in practise to correct these situations.
The period between Stage 1 and Stage 2 shall be limited till a maximum time interval of 6 months. If the maximum time interval is exceeded, a new Stage 1audit has to be done.

The tour shall include all areas that might influence product safety. Where comparable activities / processes take place it is allowed to sample.
Reference: ISO 17021-1, clause 9.3.1.2, 9.3.1.

4.3.8 Requirements for the surveillance audits

In preparation for the surveillance audit, the CB will contact the organization to confirm the date for the surveillance audit and verifies if there were any significant changes since last on-site audit that influence product safety.

During the surveillance audit all Scheme requirements, PAS 420 and additional Scheme requirements, will be reviewed. Reference: ISO 17021-1, clause 9.6.2.

This includes the assessment of documentation, records and reports about changes of input.

If changes have been made, the audit shall include:

- Internal communication of changes in the production process or products
- Documentation requirements
- Establishment and implementation of the PRPs
- Additional or new risk assessment and the operational PRPs and CCPs involved.

The format of the surveillance report has the same obligatory format as the initial report but with updated information as a result of the review. Records of the CCPs are examined on absence of control and irregularities (sampling is allowed).

4.3.9 Notification of factors affecting the certification

The CB shall have arrangements in place with certified organizations for the timely notification in the event that the organization becomes aware of legal proceedings with respect to product safety or legality, or in the event of a product recall. The organization shall notify the CB about such an event within 3 working days after occurrence. The CB, in turn, shall take appropriate steps to assess the event and concludes if there are any implications for organization's certification, and shall take appropriate action to protect the integrity of the Scheme.

4.3.10 Withdrawal or suspension of the certificate

The CB shall withdraw, suspend or reduce the scope of certification in cases when, for example, the organizations certified management system has persistently or seriously failed to meet the Scheme requirements, including requirements for the effectiveness of the management system, immediate risk to the safety of the product impacting public health, the certified organization does not allow surveillance or recertification audits to be conducted at the required frequencies, or the certified organization has voluntarily requested a suspension.

The CB shall inform the organization in writing of the withdrawal or suspension decision within three days after the last day of the audit and confirm the decision.

In case of withdrawal or suspension, the organizations' management system certification is invalid. The CB shall immediately change the status of the certified organization in the HPC 420 database and shall take any other measures it deems appropriate to protect the integrity of the Scheme. If the suspended certificate is not restored within 6 months after the date of the suspension decision, the certificate shall be withdrawn.

4.3.11 Requirements for additional audits

The CB shall undertake additional (also unannounced) surveillance audits or take appropriate measures in the event that there is evidence or suspicion of nonconformity within the certified organization. Reference: ISO 17021-1, clause 9.6.4.2.

4.3.12 Requirements for recertification

All requirements given in ISO 17021, clause 9.6.3 apply. Recertification shall include a full assessment and reporting of all these requirements. Reference: ISO 17021-1, clause 9.6.

4.3.13 Risk based office audits and witness audits

The CB shall participate in a risk based program of office audits and announced, but unscheduled, witness audits of certified organizations.

5.0 Appendix II B Format of the audit report

For the requirements for general information in the audit report see ISO 17021, clause 8.2.2 and relevant items of Appendix II A, section 4.3 “Requirements for the audit reports”.

In the audit report of PRPs and annexes A, B, C, D reference can be made to corresponding information in the main audit report.

Reference: *ISO 17021, clauses 8.2.2, and 9.4.8.*

5.1 Appendix II B1 Main audit report format

HPC 420 Product Safety and Quality Management Systems, requirements for organizations throughout the HPC product chain. Guidance text in blue.

Organization profile	
Description of the certified organization.	
Name	
Address	
Country	

If applicable Head Office	
Description of the role of head office. Does the organization belong to a larger group with a central head office? Does the head office control certain functions pertinent to certification? Is the Head Office mentioned in the report overview?	
Name	
Address	
Country	

Number of sites	The Scheme does not allow the application of multi site certification. Each site requires a separate audit, report and certificate. There are exceptions: 1. Head office controlling certain function pertinent to certification; 20% audit time reduction may be applicable. HQ with no production on site does not has an own certificate 2. Organizations with a so called split process; Refer to the derogation granted by the Foundation secretariat 3. Off-site storage, warehousing, packing and distribution belonging to the same legal entity; A maximum of three off-site locations are allowed.

Details of other sites
See exceptions shown in no. 3.

Name	
Address	
County	

Audit team	
Auditor 1	
Auditor 2	
Auditor 3	

Audit details	
Audit objective	
Audit type	
Audit date	
Man-days	
Audit time reduction when the head office controls certain functions.	See exceptions shown in no. 3.
Additional audit time for off-site activities	See exceptions shown in no. 3.

Audit time calculation				
D	H	MS	FTE	HPC 420 addition

Audit details previous audit	
CAP and objective evidence of closure of findings of previous audits.	
Audit type	
Audit date	
CB conducting audit	

Details with regard to the audit	
Other standards	Mention the other standards that are audited together with the Scheme. Also show audit type and man-days allocated to these standards.
product chain category	HPC categories supporting the scope statement. Multiple HPC categories may be applicable.

Number of different HACCP/Risk assessment -studies	Cross check with audit time calculation.
Number of employees	Cross check with audit time calculation.
Shifts	Cross check with audit time calculation.
Employees per shift	Cross check with audit time calculation.
On-site sub-contractors	
Off-site sub-contractors	

Scope of Certification	
Special attention for the organizational units, functional units and/or processes audited.	
Scope statement	The organization shall take care that the scope of certification is fully covered by the MS. The scope shall specify the products or product categories, processes and off site production sites that are addressed by the QMS
Exclusions	Exclusions may not have a (negative) influence on the certified end products. Assess and describe the exclusions from the scope.
Non-applicable clauses	Only applicable for the PRP standards. Non-applicable clauses shall be clearly documented and justified
Outsourced activities	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 MS.

Certification audit	
Result of stage 1 audit	Clearly show the conclusion of the stage 1 audit.; The risk assessment is complete and validated by the auditor by using his sector knowledge. Summary of the Risks the organization wants to manage, related to List of CCPs, limits of compliance.

Summary of audit findings	
Evidence and conclusions, consistent with the requirements of the type of audit.	
Summary of MNCs	For each nonconformity, as referred to in ISO 17021, clause 9.1.15b, that: Represents failure to fulfil one or more requirements of the Quality and Safety Management System that raises doubt about the capability of the management system to achieve the expected product safety outcomes in the HPC chain or to effectively control the process for which it was intended.
Summary of mNCs	For each other nonconformities as indicated in ISO 17021, clause 9.1.15c.
Summary areas of concern	Stage 1 finding that may lead to a nonconformity during the stage 2 audit.
Opportunities of improvement	The audit team may identify opportunities for improvement, but shall not recommend specific solutions.
Unresolved issues	If applicable. Any unresolved issues if identified by the auditor. No classification but shall be discussed again by next audit

Audit conclusion	
Postponement or cancellation of stage 2 audit	Specify audit conclusion. Advice of the auditor to the body that takes the certification decision.
Proceed to stage 2 audit	
Certification	
Continue certification	
Re-certification	

Additional	
Complaints	Number of complaints since the previous audit.
Changes since the previous audit	Verify impact of the changes, additional risk assessments and verification, demand more verification time
Use of HPC 420 logo	Certification audit: Explain the correct use of the HPC 420 logo.

	Surveillance audit: Assess the use of the HPC 420 logo. Re-certification audit: Assess the use of the HPC 420 logo.

Risk assessment		
Conducting Risk Assessment	The basic part of every product safety system is the identification (or not) of CCPs as result of risk assessment done by the audited organization.	
CCPs should be reported and listed including the method of control related to the risks the organization wants to manage and how they are managed (critical limits and frequencies).		
CCP1	Risk to manage	Critical limits + frequencies
PRPs	PRPs should be reported according an obligatory report format, See Appendix II B2 Report if they are functional, effective and if they are subject of an annual review	
Change management	Special attention has to be paid to Management of Inputs and the effect of changes on the operational MS.	
Complaints management	Special attention has to be paid to complaints and the effect on the operational MS.	
Internal audits	Special attention has to be paid to the results of internal audits and the effect on the operational MS.	
Management review	Special attention has to be paid to the management review and the effect on the operational MS.	

Non-conformance sheet previous audit				
NC no.	Classification	Requirement	Description of non-conformity	Closed/date

Non-conformance sheet			
NC no.	Classification	Requirement	Description of nonconformity

5.2 Appendix II B2 Audit report formats PRPs

5.2.1 Scheme main checklist.

5.2.2 Annex A: Additional requirements for the manufacturing of Home and/or Personal Care products

5.2.3 Annex B: Additional requirements for the manufacturing of Personal Care products

5.2.4 Annex C: Product characteristics

5.2.5 Annex D: Selection and categorization of control measures

5.2.6 Scheme PRP standard checklist

5.2.1 Scheme main checklist

Organization name:		Organization address:		
Date:		Assessor:		
	Reference: PAS 420	Conformance Yes	Conformance No	Remarks
	Provide a summary for each PAS 420 requirement below			
3.15	*Material/Product safety data sheets and/or product safety and quality specs See also P1,App.1A, 1 MS,5*			
	Summary:			
4	*HPC Quality and Product Safety Management System*			
4.1	*General requirements*			
4.2	*Documentation requirements*			
4.2.1	*General*			
4.2.2	*Control of documentation See also P1,App.1A, 1 MS,2*			
4.2.3	*Control of records+ storage See also P1,App.1A, 1 MS,3&4*			
	Summary:			
5	*Leadership & Management responsibility*			
5.1	*Management commitment (Vision Mission + planning)*			
5.2	*HPC product quality and safety policy*			

5.3	*HPC Product quality and safety management system planning*			
5.4	*Responsibility and authority (summary responsible persons)*			
5.5	*Communication*			
5.6	*Emergency preparedness and response*			
5.7	*Management review (Once a year)P1,App.1A, 1 MS,8*			
	Summary:			
6	*Resource management*			
6.1	*Provision of resources*			
6.2	*Human resources*			
6.2.1	*General*			
6.2.2	*Organization structure chart*			
6.2.3	*Competence, awareness and training*			
	Summary:			
7	*Planning and realization of safe products with a constant and agreed quality*			
7.1	*General*			
7.2	*Prerequisite programmes (PRPs)*			
	Summary:			
8	*Risk assessment and ongoing risk management*			
8.1	*General*			
8.2	*Preparation for risk assessment*			
8.2.1	*HPC Product Safety team*			

8.2.2	*Product characteristics*			
8.2.2.1	*Raw materials, ingredients and product contact materials*			
8.2.2.2	*Intended use (+ expected use)*			
8.2.3	*Flow diagrams, process steps and control measures*			
8.2.3.1	*Flow diagrams*			
8.2.3.2	*Description of process steps and control measures*			
8.2.3.3	*Additional info for conducting risk assessment*			
8.3	*Risk assessment*			
8.3.1	*General*			
8.3.2	*Hazard Identification and determination of acceptable levels*			
8.3.3	*Conducting the risk assessment*			
8.3.4	*Selection and assessment of control measures*			
8.4	*Ongoing Risk assessment*			
8.4.1	*General*			
8.4.2	*Determination of critical limits for CCPs*			
8.4.3	*System for monitoring CCPs*			
8.4.4	*Actions when monitoring results exceed critical limits.*			
	Summary:			
9	*Verification planning*			
	Summary:			
10	*Traceability system*			

	Summary:			
11	*Control of non-conformity*			
11.1	*Corrections*			
11.2	*Corrective actions*			
11.3	*Handling of non-conforming products*			
11.3.1	*General*			
11.3.2	*Evaluation for release*			
11.3.3	*Disposition of non-conforming products*			
11.4	*Withdrawals*			
	Summary:			
12	*Validation, verification and improvement of the HPC product safety management*			
12.1	*General*			
12.2	*Validation of control measure combinations*			
12.3	*Control of monitoring and measuring*			
12.4	*HPC QMS verification*			
12.4.1	*Internal audit See also P1App.1A, 1 MS,6*			
12.4.2	*Evaluation of individual verification results*			
12.4.3	*Analyses of result of verification activities*			
12.5	*Continual improvement and updating of the HPC MS, Control of records See also P1,App.1A, 1 MS,6*			
	Summary:			
Part 1, App.1A, 3	*Process Control*			

Part 1, App.1A, 4	*Management of Inputs*			
Part 1, App.1A, 5	*Retention Samples*			
Part 1, App.1A, 6	*Management of Change*			
5.2.2 Annex A: Additional requirements for the manufacturing of Home and/or Personal Care products				
A1	*Laboratory facilities*			
	Summary:			
A2	*Containers for waste and hazardous substances*			
	Summary:			
A3	*Drains and drainage*			
	Summary:			
A4	*Temperature control and monitoring Equipment*			
	Summary:			
A5	*Preventive and corrective Maintenance*			
	Summary:			
A6	*Management of purchased materials*			
	Summary:			
A7	*Selection and management of Suppliers*			
	Summary:			
A8	*Incoming material requirements (raw/packaging)*			
	Summary:			
Part 1,App.1A, 7	*Safety Assessment of Home Care and Laundry products*			

5.2.3 Annex B: Additional requirements for the manufacturing of Personal Care products

B1	*General Application*			
	Summary:			
B2	*Internal structure and fittings*			
	Summary:			
B3	*Storage of PC products, raw and packaging materials*			
	Summary:			
B4	*Lighting*			
	Summary:			
B5	*Containers for waste and hazardous substances*			
	Summary:			
B6	*Microbiological cross contamination;*			
	Summary:			
B7	*Physical contamination*			
	Summary:			
B8	*Personnel Hygiene facilities and toilets*			
	Summary:			
B9	*Cleaning and sanitation*			
	Summary:			
B10	*Pest control*			
	Summary:			
B11	*Work wear and protective clothing*			
	Summary:			
B12	*Illness and injuries*			
	Summary:			
B13	*Personal cleanliness*			
	Summary:			
B14	*Personal behaviour*			
	Summary:			
B15	*Warehousing requirements*			
	Summary:			

Part 1, App.1A, 8	*Safety Assessment of Personal Care products*			
5.2.4 Annex C: Product characteristics				
C1	*Raw materials, ingredients and product-contact material*			
	Summary:			
C2	*Characteristics of end products*			
	Summary:			
C3	*Flowdiagrams*			
	Summary:			
5.2.5 Annex D: Selection and categorization of control measures				
D1	*Assessment of control Measures*			
	Summary:			

5.2.6 Scheme PRP standard checklist

Results and conclusion of the audit of PRPs

Information on assessment per item. The number of the items refer to the sections of PAS 420 for PRPs. For each item shall be referred to the requirements of technical specification for sector PRPs and to the requirements of applicable legislation, recognized sector codes and customer requirements.

+ = assessed; OK – = assessed; Indicate: MNC = major nonconformity mNC = minor nonconformity NA = not applicable	Result, Record evaluation	Identification of specific requirement which is not fulfilled	Details of MNC or mNC e.g. location

7.2.2 Construction and layout of buildings			
7.2.2.1 General requirements			
7.2.2.2 Environment			
7.2.2.3 Locations of establishments			
Summary Construction and layout of buildings:			

7.2.3 Layout of premises and workspace			
7.2.3.1 General requirements			
7.2.3.2 Internal design, layout and traffic patterns			
7.2.3.3 Internal structures and fittings			
Summary Layout of premises workspace:			

7.2.4 Location of Equipment			
7.2.4.1 Hygienic Design of equipment			
7.2.4.2 Equipment access for operation, cleaning and maintenance			
Summary Location of Equipment:			

7.2.5 Storage of HPC products, raw and packaging materials			
7.2.5.1General, Storage shall provide protection			
7.2.5.2 Storage shall be conditioned (dry and well ventilated) and monitored/controlled on temperature and humidity where specified.			
7.2.5.3 Designed or arranged to allow segregation.			
7.2.5.4 Designed to allow maintenance, cleaning, prevent contamination and minimize deterioration			
7.2.5.5 Cleaning materials, chemicals and other hazardous substances shall be stored in a manner that minimizes the risk of mix-ups and cross-contamination			
7.2.5.6 Storage methods and control of bulk			

materials are documented			
Summary Storage of HPC products, raw and packaging materials			

7.2.6 Utilities – air, water, lighting			
7.2.6.1 General requirements			
7.2.6.2 Water supply			
7.2.6.4 Air quality and ventilation			
7.2.6.4 Compressed air, steam and other gases			
7.2.6.5 Lighting			
Summary Utilities – air, water, lighting:			

7.2.7 Waste disposal			
7.2.7.1 General requirements			
7.2.7.2 Containers for waste and hazardous substances			
7.2.7.3 Waste management and removal			
7.2.7.4 Drains and drainage			
Summary Waste disposal:			

7.2.8 Equipment suitability, cleaning and maintenance			
7.2.8.1 General requirements			
7.2.8.2 Hygienic design			

7.2.8.3 Product contact surfaces			
7.2.8.4 Cleaning plant, utensils and equipment			
7.2.8.5 Preventive and corrective maintenance			
Summary Equipment suitability, cleaning and maintenance:			

7.2.9 Management of purchased materials, See also P1,App.1A, 1 MS,3&4			
7.2.9.1 Selection and management of suppliers			
7.2.9.2 Incoming material requirements (raw/ingredients/packaging)			
Summary Management of purchased materials:			

7.2.10 Measures for prevention of cross contamination			
7.2.10.1 General requirements			
7.2.10.2 Chemical cross contamination			
Summary Measures for prevention of cross contamination:			

7.2.11 Pest control			
7.2.11.1 General requirements			
7.2.11.2 Pest control programmes			
7.2.11.3 Preventing access			
7.2.11.4 Harbourage and			

infestations			
7.2.11.5 Eradication			
Summary Pest control:			

7.2.12 Personnel hygiene and employee facilities			
7.2.12.1 General requirements			
7.2.12.2 Staff canteens and designated eating areas			
7.212.3 Health status			
Summary Personnel hygiene and employee facilities:			

7.2.13. Reworked product			
7.2.13.1 General requirements			
7.2.13.2 Storage. identification and traceability			
7.2.13.3 Rework usage			
Summary Rework:			

7.2.14. Product recall procedures			
7.2.14.1 General requirements			
7.2.14.2 Product recall requirements			
Summary Product recall procedures:			

7.2.15 Warehousing			
7.2.15.1 General requirements			
7.2.15.2 Vehicles, conveyances and containers			
Summary Warehousing:			

7.2.16 Product information/consumer awareness
Summary Product information/consumer awareness:

7.2.17 HPC product defence, biovigilance and bioterrorism see Part I, Appendix 1A, 1, MS, 9			
7.2.17.1 General requirements			
7.2.17.2 Access controls			
Summary HPC product defense, bio-vigilance and bio-terrorism:			

5.3 Appendix II B3 Training program elements for auditors

5.3.1 Category A = Home and Laundry and/or Personal Care products

History of the home care products
1. Raw materials
Surfactants;
Abrasive products;
Optical brighteners;
Color Guards;
Bleed products (Ablaufmittel);
Washing and waxing;
Propellants;
HDD (heavy duty detergents);
Lubricants;
Preservatives
Oil components, waxes and resins;
UV filters
Propellants;
Nano components;
Natural products
Fragrances (perfumes);
Enzymes
Solvents;
Preservatives;
2. Packaging:
Materials; plastic, metal, glass (aluminium), paper, cardboard;
Press Packaging, propellants; bioplastics
3. Environmental issues.
4. Main Product categories:
Detergents, solid / liquid
Fabric softeners (softeners)
Window cleaner;
Products car wash;
Floor cleaners;
WC cleaners with chlorine, hydrogen peroxide, sodium hypochlorite;
5. Legislation:
REAch CLP Exemption for Consumer products.
6. Production
6.1Production methods:
Mixing;

Agitation;
Syringes;
Distillation;
Melting;
Cooling;
Emulsifying (Vacuum
Gelling
Mixing and stirring;
Cooling and heating;
Filling under pressure.
Spray drying
Powder mixing
7. Safety Assessments
Required background, qualification and training;
Perform audit in the production site;
Microbiology,
Reporting and accountability;
Responsibility for the created audit / assessment;
8. Additional education / training assessor / security officer.

5.3.2 Category B = Personal Care products

History of the use of cosmetics.

1. Introduction use of cosmetics; beautification, cover, masking, cleaning;
2. Raw Materials

Surface active agents (surfactants);
Emulsifiers;
Oil components, waxes and resins;
Sunscreens;
Propellants;
Nano components;
Natural products
Fragrances (perfumes);
Pharmaceuticals;
Solvents;
Preservatives;

3. Packaging:

Materials; plastic, metal, (aluminium), glass, paper, cardboard;
Press Packaging, propellants;
Environmental issues.
Labelling:
Ingredients declaration, INCI;
Shelf life;
EU agreements Symbols such as +/-, hand, durability;
Claims, claim support;
Eligibility advertising according Claim management:

4. Advertising cosmetics;
5. Interfacial pharmacy / cosmetics; definition pharmaceuticals versus cosmetics.
6. Legislation and standards

EU Cosmetic Regulation (2009/1223 / EU) in force as of July 11, 2013;
Commodities Act Regulation on general product safety;
Safety Ratings (PIP file);
Special requirements fragrances alongside MSDS / PDS: IFRA statement, SCCP statement;
European RAPEX notification system;
REAch; exemption cosmetics to provide a Safety Data Sheet (MSDS);
Animal testing;
GMP.EU,<->GMP VS
Enforcement legislation.
Safety, Occupational Health and Safety Act, storage of flammable materials.

7. Logistics

ADR transport of hazardous substances;(Recall leaking aerosols)

Storage;

Aerosol Directive;

8. Sustainability

9. Production

9.1Production methods

A, B, C phases

Mixing;

Agitation;

Syringes;

Distillation;

Melting;

Cooling;

emulsifying (Vacuum);

Gelling

9.2Machines:

Mixing and stirring;

Cooling and heating;

Filling under pressure;

filling under atmospheric conditions; single head / multihead;

10. Risk Assessments as part of QMS

Obligatory safety assessments for PIP files and CPNP (responsible person organization) microbiology

11. Auditing the Scheme

5.3.3 Category C = raw materials/ingredients

Assessor is an approved assessor for Cat A and/or B, and has knowledge of basic organic chemistry processing for producing of raw materials intended for category A, B applications. such as, but not limited to: 1 Preservatives and max. application levels and risks 2 Chemical processes - Hydrogenation - (Trans-) esterification - (De-) Hydration - saponification etc. 3 Recognition an characteristic function of - different type of surfactants (Kat-,an-, non-ionic and amphoteric) - fats, proteins, silicones, salts, -acid, alchols-,-amine, halogens, - etc 4 Known contaminants and free radicals that can interact with other ingredients and oppose a risk for the consumer. Nitrosamines, Nonoxinol, plastifiers, Dioxins and Dioxine like PCB,s etc from destillates or filtration techniques. 5 Microbiology risks 6 Risk Assessments as part of QMS 7 Obligatory safety assessments for PIP files and CPNP (responsible person organization) microbiology 8 Auditing the Scheme

5.4 Appendix II B4 Format certificate

Certificate of registration

The Safety and Quality Management System for Home, Laundry and Personal Care products of

Name of Company
at
Site Address

has been assessed and was found in compliance with the requirements of

HPC 420

Home and Personal Care (HPC) Safety and Quality Management System Certification Scheme, in compliance with
PAS 420:2014, ISO 17021:2015 and additional HPC 420 requirements.

This certificate is applicable for:
Scope(s)
Category A, B, C and/or D

This certificate is provided on the basis of the HPC 420 certification Scheme, version 1, published September 2016

The certification system consists of a minimum annual audit of the HPC Product safety and quality management systems and a minimum annual verification of the PRP elements and additional requirements as included in the Scheme.

Certificate of registration No: *Certificate number*

Date of the certification decision:
Initial certification date: Authorized by:
Reissuing date: Position of signatory:
Valid until:
Issued by:
Name and address of certification body