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

Non-Food Packaging Module (HPC 420)

Version: 1.0 | October 2020

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1. INTRODUCTION

FSSC 22000 has supported a project to develop a Non-Food Packaging Module (HPC 420). This project has been initiated on request of Procter & Gamble (P&G) and ALPLA.

The Non-Food Packaging Module (HPC 420) (hereafter: The Module) was drafted by a FSSC 22000-P&G working group based on a set of requirements supplied by iCompliance members and is intended to be used in combination with FSSC 22000-Quality:

1. To certify packaging manufacturers who manufacture food packaging and non-food packaging materials; and,
2. To certify the total Food Safety Management System of the manufacturing site.

By applying the Module both the food and non-food manufacturing processes are covered by certification.

The Module is an additional module that covers the HPC 420 (non-food) requirements that are not covered by FSSC 22000-Quality.

FSSC 22000-Quality including the Module could be used to audit a packaging manufacturing site that manufactures food and non-food packaging material. The Food Safety Management System (FSMS) of the site is audited against FSSC 22000-Quality including the Module.

2. HPC 420

FSSC 22000 participated in the project to develop the Module in order to serve the needs of packaging manufacturers to certify the total FSMS of the site. The scope of the Foundation FSSC 22000 is limited to food safety and quality management systems. Therefore, the Module will be owned and managed by the Foundation HPC 420. This Foundation will also retain the copyright and provide the Certification Bodies licenses for the use of the Module.

3. CERTIFICATION BODY

A Certification Body (CB) that wishes to offer certification services against the Module shall have:

1. A valid accreditation against FSSC 22000 (preferably FSSC 22000-Quality);
2. A valid accreditation against ISO 9001;
3. A license with the FSSC 22000 Foundation and the HPC 420 Foundation.

4. RELATIONSHIP WITH ICOMPLIANCE

The HPC Module is accepted by the new platform iCompliance. The Module audit report shall be accepted by all iCompliance members. The aim of the Module is to integrate the needs of all brand owners participating in the iCompliance initiative. The advantage is that the FSSC 22000-Quality audit including the Module (and audit report) replaces second party audits that are conducted by iCompliance members.

The iCompliance Initiative is intended to drive value in the supply chain through trust, collaboration, inclusion, continuous improvement and openness. It provides an efficient and collaborative way to ensure the quality of raw materials, components and products that will give consumers the positive product experience and safety they deserve.

5. AIM OF THE MODULE

The Module in association with FSSC 22000-Quality packaging is designed to:

- Reduce the need for multiple brand supplier audits;
- Demonstrate effective management of safety and quality throughout production;
- Demonstrate effective change management controls;
- Provide confidence to customers.

6. SCOPE OF THE MODULE

The use of the Module is voluntary but subject to customer mandate. It is applicable to organizations that manufacture packaging and packaging materials.

The Module shall not apply to packaging or materials that do not undergo any process at the site audited, nor to activities relating to traders/brokers, wholesale, importation, distribution or storage outside the direct control of the company.

Where the Module is requested, the scope statement shall include all of the applicable processes on site. It is not possible to select processes and/or products to exclude from the scope of certification.

7. FSSC 22000-QUALITY

This Module is an additional Module that is intended to be used in combination with FSSC 22000-Quality (Packaging).

Alternatively organizations that are FSSC 22000 (packaging) certified in combination with a separate ISO 9001 (packaging) certification, may also participate in the program provided that the organization has a valid FSSC 22000 certificate and valid ISO 9001 certificate, (both) issued by the same CB that will provide the certification services against the Module.

8. FOOD CHAIN CATEGORY

The use of the Module is limited to FSSC 22000-Quality certified organizations with food chain category I[1] (Production of packaging and packaging material) supporting the scope statement.

9. AUDITOR QUALIFICATION

The assessment against the requirements of the Module shall be conducted by FSSC 22000 qualified auditors who shall additionally meet the Module qualification requirements.

The CB shall have a system and documented procedures for selecting, training, evaluating, qualification and maintenance of qualification of the auditor.

[1] Food chain category according to ISO 22003:2013, Annex A.

9.1 MODULE QUALIFICATION AND COMPETENCE REQUIREMENTS

1. At least 5 years' working experience in the packaging industry:
   - in quality assurance, manufacturing, auditing, inspection: or,
   - enforcement EU or US FDA standards.
2. FSSC 22000-Quality packaging qualified auditor (Food Chain Category I); and,
3. Performed audits as an FSSC 22000 lead auditor category I (Packaging) with 5 years audit records; and,
4. Have demonstratable knowledge and awareness of the interaction between the packaging and substances that are intended to be packed and what safety and quality 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;
5. The qualification shall be based on additional training on the Module and at least cover basic knowledge in the packaging material type included in the scope of the qualification.

Records shall be available showing that the qualification 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 product safety hazards;
- Manufacturing processes with a focus on manufacturing excellence;
- Packaging product quality.

9.2 MAINTAINING AUDITOR QUALIFICATION

A mandatory qualification maintaining program for each auditor shall incorporate:

- That auditors shall conduct a minimum of 5 FSSC 22000 packaging on-site audits per calendar year of which at least one shall include the Module.
- That the competence of auditors shall be re- established every 3 years by the CB.

10. EXEMPTIONS ON THE BASIS OF RISK

The Module requirements have been written to reflect expectations typical of the particular product or process technology across a range of packaging formats (e.g. board, glass, metals, etc.). There may be occasions where a requirement may be deemed not applicable in a particular operation and excluded on the basis of risk. In such exceptional cases a requirement could be deemed not applicable. In each such case a documented risk assessment shall be provided for the auditor to evaluate and this shall be substantiated and justified in the audit report.

11. COMMUNICATION BY THE ORGANIZATION

The CB shall be notified in advance of the audit, of the intention to add the Module to the scope of the audit. This ensures that sufficient additional time could be scheduled and that an auditor with the appropriate qualifications for the additional the Module is selected.

The organization shall supply the CB with any additional background information requested prior to the audit day to ensure that the auditor is fully prepared to audit against the Module.

12. ADDITIONAL AUDIT TIME CALCULATION

In order for the Module to be included within the audit program, additional time will be needed for assessing the Module. It is expected that at least an additional half-day (0,5 man-day; 4 hours) will be required to complete the auditing against the requirements of the Module. The CB shall indicate the expected additional time requirements at the time of planning and/or confirming the on-site audit.

13. MULTI-SITE AUDITING

Where the CB offers multi-site sampling, a sampling program can be used to audit the Module in accordance with Annex 1. The ISO 22003 and IAF MD 1 requirements shall be applied for the use of the multi-site auditing of the Module.

Multi-site sampling is only allowed on the Module provided that:

1. The Module is audited annually at the central organization; and,
2. The annual internal audit program of the central organization, including the Module, shall include all sites of the organization.

14. THE ON-SITE AUDIT

14.1 GENERAL

Compliance with the requirements of the Module shall be assessed as integrated part of the audit against the requirements of FSSC 22000-Quality. The Module is expected to be integrated into the on-site audit program as appropriate.

14.2 REPORTING

The result of the audit against the requirements of the module shall be used as the basis for an addendum to the FSSC 22000-Quality audit report. The auditor(s) shall assess the nature and severity of any nonconformities.

For each nonconformity (NC), a clear concise statement of the requirement, the NC, grade of the NC and the objective evidence shall be written.

Nonconformities shall be managed in accordance FSSC 22000 scheme requirements.

The template for the addendum for the Module audit report is contained in Annex 2. In the “Remark” section, conformance of compliance or noncompliance shall be detailed. Non applicable clauses shall be motivated.

14.3 COMMUNICATION TO THE ORGANIZATION

At the closing meeting, the (lead) auditor shall present the findings and discuss all nonconformities that have been identified during the audit including the nonconformities against the Module.

A written summary of the nonconformities discussed at the closing meeting will be documented by the auditor, either at the closing meeting or within 2 working days after completion of the audit.

14.4 DECISION

The decision of compliance with the Module will be determined independently by the CB management, following a technical review of the module audit report and the 'closing out' of nonconformities within the appropriate timeframe. The organization will be informed of the certification decision following the review.

14.5 ADDENDUM DOCUMENT

An organization that complies shall receive an addendum to the FSSC 22000 certificate.

The CB shall issue an addendum in accordance with the template(s) set out by the Foundation (see Annex 3).

The HPC 420 logo shall be used by the CB on the addendum.

Dates shown on the addendum shall be as follows:

a) Decision date:

c) issue date:

d) valid until.

14.6 UNANNOUNCED AUDIT

Where the Module is audited as part of an unannounced audit, the requirements will be assessed as an integral part of the audit.

15. REQUIREMENTS

Compliance to the Module can only be achieved if the site is also fully compliant with the requirements of FSSC 22000-Quality packaging.

GUIDANCE TO THE REQUIREMENT

The organization shall have a valid FSSC 22000-Quality Packaging certificate and the audit against the Module is integrated with a scheduled FSSC 22000-Quality Packaging audit.

15.1 GENERAL REQUIREMENTS

1. The most senior production or operation manager on site shall participate in the opening and closing meetings of the audit.
2. The site shall have a genuine, current hard copy or electronic version of the FSSC 22000 scheme and the Module available.

15.2 DOCUMENTATION

Electronic files, records, data and systems shall be suitably protected and backed up. A test of the system shall be carried out at least once per year, or whenever any significant changes are made to the system.

GUIDANCE TO THE REQUIREMENT

As part of an effective management system the site shall have a system in place that is suitable to enable recovery of documents and documented information in a force majeure situation, such as power failure affecting electronic stock management systems. Back-up systems shall be suitably protected against any situation which may put data at risk.

The test of the system shall ensure that the backed-up data is complete and not corrupted. The site shall determine how far back into its archives it makes the test, bearing in mind that complaints from customer product recalls may occur when the packaging material is in use and on the market and applicable legal requirements with regard of storing of data and information.

15.3 PRODUCT AND PROCESS CONTROL

1. A documented procedure shall be in place to register customer specifications.
   This shall include (but is not limited to):
   - Validation of the accuracy of data and specifications;
   - How changes to customer specifications are updated and communicated;
   - How customer testing method requirements are met;
   - Evaluation of how changes made to the customer specification affect the technical product specification.

GUIDANCE TO THE REQUIREMENT

The procedure shall clearly describe who is responsible and/or accountable for the integrity of the specification(s) and information. Periodic validation of specification(s) is advised to ensure that the correct information is used. This may be integrated with periodic customer contract review.

2. New products or product changes shall be subject to suitable testing to ensure that the required customer and quality specifications can be achieved.

GUIDANCE TO THE REQUIREMENT

The site shall ensure that it can meet the product specification set by its customers, including the required quality parameters for products and/or new products.

In the case of changes of customer requirements, the customer shall be notified, and the change shall be agreed and documented.

The customer shall be informed about changes in performance and/or characteristics of raw materials.

3. The site shall determine what outputs and success criteria are required from a production trial, any changes and/or additions made to materials, and processing characteristics or equipment.

GUIDANCE TO THE REQUIREMENT

The site shall have a documented test procedure for managing changes including:

- *a description of the categories of typical changes;*
- *how such changes will be controlled;*
- *how and under what conditions a change will be tested;*
- *how they are to be assessed as being successful.*

This approach shall be applied to all changes that could be made, such as e.g. new automation or inventory control systems.

The test results produced shall be documented, clearly showing the conclusions and whether further testing is required.

4. Settings derived from successful production trials or equipment installations shall be transferred accurately to process control documentation.

GUIDANCE TO THE REQUIREMENT

Demonstrated successful (changed) settings or procedures (e.g. new equipment, material or processing modification) shall be managed by the site's process control systems. This ensures that the validated conditions are not changed and do not negatively influence of the quality control of the product.

5. Test procedures shall be validated to ensure their validity, sensitivity, repeatability and range.

GUIDANCE TO THE REQUIREMENT

Site-developed test methods (other than simple compendial methods or where measurement is purely dependent on effective calibration) shall give reliable and repeatable results that allow effective release (or otherwise) of in-process or finished goods.

6. The documented line clearance procedure shall include:
   - The roles of persons involved inline clearance;
   - Areas where materials can become trapped;
   - Validation of the line clearance;
   - sign-off or continuing production.

The line clearance procedure shall be fully implemented for each production run.

GUIDANCE TO THE REQUIREMENT

When each person involved in line clearance properly understands their role, then whether or not there is the potential for materials to be trapped, the associated risk is reduced. The key here may be to train the people involved in the potential ramifications of trapped materials to product safety and the quality of output.

7. Samples for checking in-process quality shall be selected either according to customer requirements or by industry-standard testing protocols.

GUIDANCE TO THE REQUIREMENT

Where the customer specifies a particular quality level, this shall be met. Where no customer requirement is in place, the site shall use industry standards to determine the appropriate frequency of checks. The applied tool will depend on process characteristics and the site might use a risk-based approach to determine what to use and when. The method and frequency shall be suitably justified.

8. The site shall define how samples used for checking in-process quality are disposed of.

GUIDANCE TO THE REQUIREMENT

Where samples are pulled from the production flow for testing, the site shall determine and document how the samples are disposed of and preventing the introduction of non-conforming product to the production flow, where the testing itself might compromise product quality. Product samples shall not be reintroduced to the product flow where this may cause a product safety or quality issue.

9. Test methods, analytical methods and customer-approved reference samples shall be available. They shall be kept up to date, either in the laboratory or where offline testing is conducted and shall be suitably stored to avoid degradation.

GUIDANCE TO THE REQUIREMENT

To ensure consistency of testing, the organization shall ensure that laboratory analysis services used for verification and/or validation, shall be conducted by a competent laboratory that has the capability to produce precise and repeatable test results using validated test methods and best practices (e.g. successful participation in proficiency testing programs, regulatory approved programs or accreditation to international standards such as ISO 17025).

10. Traceability of test data and samples to production lots shall be maintained.

GUIDANCE TO THE REQUIREMENT

The site shall be able to identify the production batches or lots from which the testing samples have originated. Results shall be linked to the correct batch and assists the site in validating its ongoing product quality results.

11. Where testing shows out-of-specification results, there shall be a documented procedure for how these are investigated to determine whether the cause is non-conforming product or a testing failure.

GUIDANCE TO THE REQUIREMENT

The translation of customer specification test methods to the site's own comparable methods shall demonstrate, through validation or otherwise, that the achieved results are identical.

12. Maintenance logs shall be maintained for all offline testing equipment.
    This shall include as a minimum:
    - Adjustments;
    - Recalibration;
    - Date of any interventions.

GUIDANCE TO THE REQUIREMENT

Records shall be kept of what adjustments, repairs or calibrations have been carried out, and by whom to ensure that errors or trends in measurements can be referenced to the equipment logs.

15.4 ENVIRONMENTAL MONITORING

1. The conditions required in production and storage areas shall be specified. There shall be a regular documented check that conditions match those required and corrective action taken where necessary.

GUIDANCE TO THE REQUIREMENT

The organization shall have in place:
1. *Risk-based environmental monitoring program;*
2. *Documented procedure for the evaluation of the effectiveness of all controls on preventing contamination from the manufacturing environment;*
3. *Data of the monitoring activities including regular trend analysis.*

2. The site shall evaluate the impact of typical local environmental conditions, such as temperature and humidity, on the quality and process characteristics (e.g. machine settings). Any hazards identified and the measures established to manage their impact shall be documented and validated.

GUIDANCE TO THE REQUIREMENT

The site shall be aware that the local temperature and humidity may have an impact on the process characteristics. The typical local atmospheric conditions shall be evaluated and documented to demonstrate that there are measures in place to manage their effects and maintain control of product quality and safety.

15.5 COMPLAINTS

All complaints regarding raw material defects identified by the site shall be recorded and investigated (including root cause analysis) and the results of the investigation documented.

GUIDANCE TO THE REQUIREMENT

Customers complaints relating to product safety, quality or hygiene shall be recorded, with complaint data contributing to analysis to identify improvements.

15.6 PREREQUISITES

15.6.1.1 GENERAL

The site shall use a documented risk and ongoing assessment to determine whether there shall be double sets of doors between external and internal areas.

The site shall conduct ongoing assessments to determine whether the closing systems are effective, where implemented.

GUIDANCE TO THE REQUIREMENT

Additional specific measures may be required to mitigate the risk of contamination from external to internal areas. The site is obliged to use a risk assessment to determine whether double sets of doors might be necessary. Part of this risk assessment will be the nature of the environment (e.g. dusty or tarmacked) immediately outside the door and the activity (or its sensitivity to cross-contamination) that is carried out inside.

This risk assessment may be part of the site's hazard and risk analysis.

15.6.1.2 STORAGE

1. Where production and storage areas are surrounded by grassed or planted areas, there shall be a vegetation-free zone around the buildings.

GUIDANCE TO THE REQUIREMENT

A clear area without grass or other plants around the site's buildings shall ensure that exterior walls are clear and any potential points for pest ingress (e.g. gaps or holes) that may cause product quality concerns are clearly visible.

2. The conditions required in production and storage areas shall be specified. There shall be a regular documented check that conditions match those required and corrective action taken where necessary.

GUIDANCE TO THE REQUIREMENT

The site shall determine how its housekeeping and cleaning plan shall operate. Where multiple languages may be in use, alternatives such as photographs or pictograms shall be considered for improved understanding.

3. The handling and management of intermediate and finished products shall ensure that their quality is maintained.

GUIDANCE TO THE REQUIREMENT

The handling of intermediate or finished products by personnel or automated equipment shall not subject products to unacceptable hazards.

4. Packaging used for storage or dispatch of intermediate or finished products, such as pallets, shall be appropriately covered if it is stored outside and inspected for signs of damage or contamination before use.

GUIDANCE TO THE REQUIREMENT

To ensure that the materials used to transport and protect manufactured products do not themselves cause a product safety or quality hazard, any type of packaging material for finished products shall be stored so that it remains dry and in good condition.

It is not allowed to store pallets outside in the open air.

5. Unloading areas for bulk deliveries shall be clearly identified and designed to prevent product mix-ups.

GUIDANCE TO THE REQUIREMENT

Identification of materials shall be simple and easy to prevent product mix-ups.

6. Finished product storage shall meet customer requirements with regards to first-in first-out (FIFO), where applicable, with dispatch after quality release.

GUIDANCE TO THE REQUIREMENT

It is essential that any specific requirements are understood and communicated throughout the organization. Personnel in charge of dispatch of finished product shall be particularly aware of product release procedures that might be specific to one customer but not another and shall be able to demonstrate that these are followed.

15.6.1.3 EQUIPMENT

The lubrication points and application methods of any lubricant shall not be able to contaminate the product.

GUIDANCE TO THE REQUIREMENT

Neither the lubrication point nor the lubricant itself shall cause a product quality hazard, such as visual or physical contamination or suitable mitigation procedures shall be put in place to prevent potential product contamination.

Example: Where lubrication points are located directly above the product flow, for example, excess lubrication could drip onto the material.

15.6.1.4 CROSS CONTAMINATION

The site shall ensure that equipment, in-process and finished articles are subject to sufficient segregation to reduce the risk of mixing.

GUIDANCE TO THE REQUIREMENT

Employees shall be aware of the potential risks arising from microbiological, physical or chemical contamination, as well as potential risks of mixing from materials at different stages of production that are placed adjacent to each other.

15.6.1.5 PEST CONTROL

1. The site shall assess the suitability of its pest control program to address variations in pest activity through different seasons and consider any additional preventive activity that may be required.

The site shall document and implement this additional activity.

GUIDANCE TO THE REQUIREMENT

The site shall take typical seasonal variations in temperature and humidity into account and ensure that its pest control program addresses them at the right time in the season.

2. Risk assessment and ongoing data shall be used to determine whether the type or positioning of lighting is adversely attracting insects, and/or to highlight any mitigation where required.

   Internal and external lighting for production and storage buildings shall be designed and constructed so as to avoid attracting insects through windows or other openings.

GUIDANCE TO THE REQUIREMENT

The intention is to reduce the risk of pest entry via light attraction.

The site shall use a risk assessment approach to select the location for the installation of lighting and to determine whether ingress of pests by this route is likely to cause a problem.

15.6.1.6 RAW MATERIALS

1. All incoming raw materials shall be appropriately validated or tested before use.

All raw materials awaiting results of in-house testing or validation of data shall be held until released for use.

GUIDANCE TO THE REQUIREMENT

The data within a certificate of analysis (CoA) shall be checked to ensure that it is valid, meets the requirements of the supplier's own specification and matches the packaging supplier's own tests. Either supplier data or in-house testing may be used to determine whether the product meets specific requirements (e.g. for moisture content), which will ensure that only fit materials are used in production. This process ensures effective process control of the characteristics of incoming goods.

Each batch of incoming materials shall either have a CoA or there shall be evidence that the requirements of the process and the customer specification are met by the incoming goods. It may be that the site is able to validate its processes to accept the potential variation in parameters of incoming goods, working within tolerances acceptable to meet customer specifications.

Risk assessment may be used to determine the most appropriate way to assess the validity of incoming goods (e.g. in-process validation of incoming goods for fiber-based products, or CoA for inks and adhesives).

2. All raw materials shall have a defined and documented expiry date and a procedure defining how they shall be handled where they exceed this date.

   Where raw materials have no reasonable expiry date (e.g. cullet for glass manufacture), this shall be documented.

GUIDANCE TO THE REQUIREMENT

Raw materials will typically have a useful lifetime which may relate to the conditions they are stored under and the properties of the materials themselves. Some materials are higher risk than others; for example, paper is hygroscopic and once its relative humidity (RH) exceeds acceptable tolerances, the paper becomes unusable through warp and dimensional changes. Managing raw material usage within these defined parameters will support the performance and manufacturing characteristics of the finished goods.

However, it is recognized that some raw materials will not have an expiry date or will have a very extended shelf life. These will typically be raw materials further up the conversion process (such as resins, cullet, aluminum, steel and cellulose-based pulp), where further processing alters the characteristics of the materials to a product with a different shelf life, such as paperboard.

3. The site shall have a system in place to validate all raw materials and intermediate products before they are introduced to the process.

GUIDANCE TO THE REQUIREMENT

A check shall be made to confirm that the new material or lot meets the product schedule and specification, and this shall be documented.

15.6.1.7 LABELLING

1. Labelling or any other type of identification shall be applied at the line of manufacture upon completion.

GUIDANCE TO THE REQUIREMENT

The site shall have processes in place to ensure that identification is applied at the right point to prevent mix-ups or wrong allocation of product.

2. The site shall have a documented procedure in place controlling label reprints and pallet labelling.

GUIDANCE TO THE REQUIREMENT

All original labels that have been replaced by reprints shall be made unusable.

15.7 GRAPHIC DESIGN AND ARTWORK

1. The site shall have a documented artwork management procedure covering the activities for which the site has responsibility.

GUIDANCE TO THE REQUIREMENT

The site is required to have a documented procedure which outlines all artwork activities. Where the activity is carried out at another site belonging to the same company, the site shall have visibility of those processes and procedures and is accountable.

Final artwork is to be verified and approved by the customer; this is referring to the artwork itself and not the final product. This may be in the form of digital or wet proofing, depending on customer requirements. The purpose here is to ensure that the customer has seen the artwork in its assembled form once the site has carried out any of its processes in order to prepare the image for print.

2. A process shall be in place to seek formal acceptance and approval of final product concepts and artworks by the specifier. The outcome shall be documented.

GUIDANCE TO THE REQUIREMENT

A process of approval shall be in place to gain documented approval such as a signature from a customer. The results shall be documented and retained.

3. Where appropriate, print trials shall be carried out and testing shall validate that the agreed product quality and print standards can be consistently achieved.

GUIDANCE TO THE REQUIREMENT

The site is required to determine when a production trial is required, and this applies also to printed and decorated packaging materials in order to ascertain that the desired appearance is achievable on a consistent basis.

Sites that are decorating packaging without the use of a print process, such as glass bottles with embossed shaller decorations, will not be able to produce full trials until molds are available. On the basis of risk, so-called 'first-offs' are used as the production trial and full production will only be continued on the basis of acceptance of those first-off pieces.

4. Printing equipment such as plates, silk screens, anilox rollers, cylinders and blankets shall be verified as being correct to specification and artwork version or agreed master prior to use, and fully traceable to the customer's approved origination material.

GUIDANCE TO THE REQUIREMENT

Traceability of all materials and media associated with a piece of packaging shall be possible. This requirement may be met through job codes that do not form part of the final packaging but are clearly visible on the plates and traceable to the approved artwork.

5. Customer-approved reference material, including artwork masters and color standards used during print runs, shall be controlled to ensure minimization of degradation and shall be returned to appropriate storage after use. The site shall have a policy to address requirements for renewal of approved masters, as necessary.

GUIDANCE TO THE REQUIREMENT

When decorating packaging materials, it is good practice to have an approved master or set of standards against which production is assessed for accuracy. As an example, if a color standard is exposed to long periods of light, it may degrade through fading and subsequent print runs may then suffer from color differentiation and fail to meet the customer's quality requirements.

6. The site shall have a documented procedure for managing changes to artwork and print specifications to manage obsolete artwork and printing materials.

GUIDANCE TO THE REQUIREMENT

This requirement applies to all print media (including cutting dies, print blankets, etc. that have an impact on the final printed image), so sites that carry out only digital print may still find that this is applicable to them.

7. Where artwork files and approved masters are in electronic form, these shall be suitably protected to prevent loss or malicious intervention.

GUIDANCE TO THE REQUIREMENT

The integrity of the artwork and subsequent printed image shall be protected from any sort of damage, whether through digital file corruption, malicious intervention or the impact of damage to digital networks.

15.8 PRINT CONTROL

1. An assessment shall be carried out of the pre-press activity, print process and handling of printed packaging (product). Controls shall be established and implemented to reduce the risks identified.

GUIDANCE TO THE REQUIREMENT

All print activity shall be included in the hazard and risk analysis.

Of particular concern in this requirement is the risk of the packaging either not containing information that is essential (such as allergen or legal information) or being mixed up with other similar packaging that is printed with different information (such as packaging for a product that contains an allergen with one that does not). The implications of such scenarios may have serious repercussions for consumers.

Where risk is identified, the company shall put in place procedures to eliminate or reduce the risk to an acceptable level.

Where changes are made to artworks or processes, this shall be reflected in the hazard and risk analysis study. A change to artwork, may result in additional hazards where safety, legal or allergen information is displayed. Such changes may already be part of the quality management system, but the auditor will need to see that the site has considered, and continues to consider, any risks associated with the points in this requirement.

2. Printing plates, cylinders, cutting dies, print blankets and any other printing equipment shall be appropriately stored to minimize damage.

GUIDANCE TO THE REQUIREMENT

Damage to the printing equipment that may either render it unusable or remove part of the information on the plate shall be prevented to ensure that steps are taken to minimize the potential for malicious contamination or damage. Traceability shall be maintained.

3. Each print run shall be approved against the agreed standard (or master sample). This shall be recorded.

GUIDANCE TO THE REQUIREMENT

To ensure consistency of print and that the consistency and legality of product are maintained, the site shall ensure that a procedure for approval of print runs against the master sample is in place. The master sample may be pre-supplied or be an approved sample from the first print run. It is essential that this approved sample is maintained in conditions that prevent its degradation, so as to ensure the supplied packaging is to specification and customer requirements.

4. A system shall be in place to detect and identify printing errors during the run and to sort these errors from the acceptable printed material.

GUIDANCE TO THE REQUIREMENT

The company shall have a method by which to identify these materials so that they may immediately (or later) remove the non-conforming product for disposal.

5. Where composite print is used (a mixture of different designs printed together), a process shall be in place to ensure effective segregation of differing print variants.

GUIDANCE TO THE REQUIREMENT

Composite print is often used on smaller items of printed materials, such as labels, where the print run length justifies mixing variants of smaller numbers to fully use the printing equipment and minimize 'set-up' and down times.

Where composite print is used, the company needs to ensure that the potential for variants to be mixed up once they have been separated (e.g. through slitting for material that is on a reel) is eliminated or minimized to an acceptable level.

6. Samples of printed packaging shall be retained together with production records for a period of time to be agreed with the customer/specifier/brand owner.

GUIDANCE TO THE REQUIREMENT

Any sort of retention of printed product samples shall be agreed with its customers.

7. Any unused printed product shall be accounted for and either disposed of or identified and appropriately stored.

GUIDANCE TO THE REQUIREMENT

The site shall have a process to handle excess material to minimize the risk of genuine printed packaging being used for counterfeit products. The way that excess material is handled will vary between customers and between jobs, depending on the nature of the packaging material and its application.

Where the packaging material is disposed of, the site shall take care to ensure that it is rendered unusable.

8. Lighting in print inspection cabinets and other means of print/color checking shall be agreed with the customer or conform to accepted industry standards.

GUIDANCE TO THE REQUIREMENT

Light cabinets used for print checking shall be calibrated, where required, and the specific lighting conditions agreed with customers.

This shall either be to customer requirement (e.g. where a Pantone reference has been supplied) or to industry standard color properties regarding hue, brightness and saturation, depending on the print or decoration process used.

15.9 PERSONNEL

1. The effectiveness of trainers shall be monitored and verified.

GUIDANCE TO THE REQUIREMENT

This requirement is applicable to both internal and external training. Are trainers able to convey information and achieve results from delegates? The site might consider training the trainers themselves (via professional courses or otherwise) to improve their effectiveness.

2. The site shall ensure that the competency of personnel responsible for laboratory testing and assessment is defined, maintained and developed.

GUIDANCE TO THE REQUIREMENT

Maintaining accuracy of analysis requires frequent comparison of results – checking for variability both in the method/ instrument of measurement and in or between the operator(s) performing the measurements (e.g. by using gauge repeatability and reproducibility or gauge R&R) – so that any differences can be corrected.

ANNEX 1

MULTI-SITE REQUIREMENTS

A multi-site organization is an organization having an identified central function.

The following conditions apply:

1. all sites are operating under one centrally controlled and administered FSMS; and,
2. an internal audit has been conducted on each site within one year prior to the annual audit cycle; and,
3. audit findings of the individual sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

Where the CB offers multi-site sampling, the CB shall utilize a sampling program, to ensure an effective audit of the module where the following shall apply.

a) For organizations with 20 sites or less, all sites shall be audited.
b) The sampling for more than 20 sites shall be at the ratio of 1 site per 5 sites. Sites shall be randomly selected.
c) At least annually, audits shall be performed by the CB on the required number of sampled sites.

EXAMPLE 1

An organization has a total of 100 sites (including the central function).

The sampling calculation method is applied on 80 sites (100 minus 20 sites). 80 divided by 5 is 16.

Based on the sampling calculation method, annually in 36 sites (20 plus 16), the Module is audited annually by the CB.

The organization shall audit the full Module at all sites annually (internal audit).

The results of the internal audits shall be available to auditor prior to the start of the scheduled annual audit cycle.

During the annual audit cycle, FSSC 22000-Quality Packaging is audited at all sites and at a sample of sites Module is also audited.

EXAMPLE 2

An organization has a total of 18 sites (including the central function).

Multi-site sampling cannot be offered because the organization has less than 20 sites. In this case the Module is audited all sites annually.

ANNEX 2

SUMMARY OF REQUIREMENTS

ADDENDUM TO FSSC 22000-QUALITY AUDIT REPORT

Summary Non-Food Packaging Module (HPC 420) requirements		Conform			Grading	Remark
Clause	**Requirement**	**Yes**	**No**	**N/A**		Detail 1. conformance of compliance 2. noncompliance 3. non applicable
	13.1 General					
13.1	Compliance to this Module can only be achieved if the site is also fully compliant with the requirements of FSSC 22000-Quality packaging.					
	13.2 Documentation					
13.2	Electronic files, records, data and systems shall be suitably protected and backed up. A test of the system shall be carried out at least once per year, or whenever any significant changes are made to the system.					
	13.3 Product and process control					
13.3-1	A documented procedure shall be in place to register customer specifications. This shall include (but is not limited to): • Validation of the accuracy of data and specifications; • How changes to customer specifications are updated and communicated; • How customer testing method requirements are met; • Evaluation of how changes made to the customer specification affect the technical product specification.					
13.3-2	New products or product changes shall be subject to suitable testing to ensure that the required customer and quality specifications can be achieved.					
13.3-3	The site shall determine what outputs and success criteria are required from a					

	production trial, any changes and/or additions made to materials, and processing characteristics or equipment.					
13.3-4	Settings derived from successful production trials or equipment installations shall be transferred accurately to process control documentation.					
13.3-5	Test procedures shall be validated to ensure their validity, sensitivity, repeatability and range.					
13.3-6	The documented line clearance procedure shall include: • The roles of persons involved inline clearance; • Areas where materials can become trapped; • Validation of the line clearance; • sign-off or continuing production. The line clearance procedure shall be fully implemented for each production run.					
13.3-7	Samples for checking in-process quality shall be selected either according to customer requirements or by industry-standard testing protocols.					
13.3-8	The site shall define how samples used for checking in-process quality are disposed of.					
13.3-9	Test methods, analytical methods and customer-approved reference samples shall be available. They shall be kept up to date, either in the laboratory or where offline testing is conducted and shall be suitably stored to avoid degradation.					
13.3-10	Traceability of test data and samples to production lots shall be maintained.					
13.3-11	Where testing shows out-of-specification results, there shall be a documented procedure for how these are investigated to determine whether the cause is non-conforming product or a testing failure.					
13.3-12	Maintenance logs shall be maintained for all offline testing equipment. This shall include as a minimum: • Adjustments; • Recalibration; • Date of any interventions.					

	13.4 Environmental monitoring					
13.4-1	The conditions required in production and storage areas shall be specified. There shall be a regular documented check that conditions match those required and corrective action taken where necessary.					
13.4-2	The site shall evaluate the impact of typical local environmental conditions, such as temperature and humidity, on the quality and process characteristics (e.g. machine settings). Any hazards identified and the measures established to manage their impact shall be documented and validated.					
	13.5 Complaints					
13.5	All complaints regarding raw material defects identified by the site shall be recorded and investigated (including root cause analysis) and the results of the investigation documented.					
	13.6 Prerequisites					
	13.6.1 General					
13.6-1	The site shall use a documented risk and ongoing assessment to determine whether there shall be double sets of doors between external and internal areas. The site shall conduct ongoing assessments to determine whether the closing systems are effective, where implemented.					
	13.6.2 Storage					
13.6.2-1	Where production and storage areas are surrounded by grassed or planted areas, there shall be a vegetation-free zone around the buildings.					
13.6.2-2	The conditions required in production and storage areas shall be specified. There shall be a regular documented check that conditions match those required and corrective action taken where necessary.					
13.6.2-3	The handling and management of intermediate and finished products shall ensure that their quality is maintained.					
13.6.2-4	Packaging used for storage or dispatch of intermediate or finished products, such as					

	pallets, shall be appropriately covered if it is stored outside and inspected for signs of damage or contamination before use.					
13.6.2-5	Unloading areas for bulk deliveries shall be clearly identified and designed to prevent product mix-ups.					
13.6.2-6	Finished product storage shall meet customer requirements with regards to first-in first-out (FIFO), where applicable, with dispatch after quality release.					
	13.6.3 Equipment					
13.6.3	The lubrication points and application methods of any lubricant shall not be able to contaminate the product.					
	13.6.4 Cross contamination					
13.6.4	The site shall ensure that equipment, in-process and finished articles are subject to sufficient segregation to reduce the risk of mixing.					
	13.6.5 Pest control					
13.6.5-1	The site shall assess the suitability of its pest control program to address variations in pest activity through different seasons and consider any additional preventive activity that may be required. The site shall document and implement this additional activity.					
13.6.5-2	Risk assessment and ongoing data shall be used to determine whether the type or positioning of lighting is adversely attracting insects, and/or to highlight any mitigation where required. Internal and external lighting for production and storage buildings shall be designed and constructed so as to avoid attracting insects through windows or other openings.					
	13.6.6 Raw materials					
13.6.6-1	All incoming raw materials shall be appropriately validated or tested before use.					

	All raw materials awaiting results of in-house testing or validation of data shall be held until released for use.					
13.6.6-2	All raw materials shall have a defined and documented expiry date and a procedure defining how they shall be handled where they exceed this date. Where raw materials have no reasonable expiry date (e.g. cullet for glass manufacture), this shall be documented.					
13.6.6-3	The site shall have a system in place to validate all raw materials and intermediate products before they are introduced to the process.					
	13.6.7 Labelling					
13.6.7-1	Labelling or any other type of identification shall be applied at the line of manufacture upon completion.					
13.6.7-2	The site shall have a documented procedure in place controlling label reprints and pallet labelling.					
	13.7 Graphic design and artwork					
13.7-1	The site shall have a documented artwork management procedure covering the activities for which the site has responsibility.					
13.7-2	A process shall be in place to seek formal acceptance and approval of final product concepts and artworks by the specifier. The outcome shall be documented.					
13.7-3	Where appropriate, print trials shall be carried out and testing shall validate that the agreed product quality and print standards can be consistently achieved.					
13.7-4	Printing equipment such as plates, silk screens, anilox rollers, cylinders and blankets shall be verified as being correct to specification and artwork version or agreed master prior to use, and fully traceable to the customer's approved origination material.					
13.7-5	Customer-approved reference material, including artwork masters and color standards used during print runs, shall be controlled to ensure minimization of degradation and shall be returned to appropriate storage after use. The site shall have a policy to address requirements for renewal of approved masters, as necessary.					
13.7-6	The site shall have a documented procedure for managing changes to artwork and print specifications to manage obsolete artwork and printing materials.					

13.7-7	Where artwork files and approved masters are in electronic form, these shall be suitably protected to prevent loss or malicious intervention.					
	13.8 Print control					
13.8-1	An assessment shall be carried out of the pre-press activity, print process and handling of printed packaging (product). Controls shall be established and implemented to reduce the risks identified.					
13.8-2	Printing plates, cylinders, cutting dies, print blankets and any other printing equipment shall be appropriately stored to minimize damage.					
13.8-3	Each print run shall be approved against the agreed standard (or master sample). This shall be recorded.					
13.8-4	A system shall be in place to detect and identify printing errors during the run and to sort these errors from the acceptable printed material.					
13.8-5	Where composite print is used (a mixture of different designs printed together), a process shall be in place to ensure effective segregation of differing print variants.					
13.8-6	Samples of printed packaging shall be retained together with production records for a period of time to be agreed with the customer/specifier/brand owner.					
13.8-7	Any unused printed product shall be accounted for and either disposed of or identified and appropriately stored.					
13.8-8	Lighting in print inspection cabinets and other means of print/color checking shall be agreed with the customer or conform to accepted industry standards.					
	12.9 Personnel					
13.9-1	The effectiveness of trainers shall be monitored and verified.					
13.9-2	The site shall ensure that the competency of personnel responsible for laboratory testing and assessment is maintained and developed.					

ANNEX 3

ADDENDUM TEMPLATE

ADDENDUM

Addendum to the FSSC 22000 certificate

FSSC certificate registration number: Valid until:

Non-Food Packaging Module (HPC 420)

version 1, published October 2020

Name of Company

at

Site Address

has been assessed and was found in compliance with the requirements of the **Non-Food Packaging Module (HPC 420)**

This module is applicable for HPC 420 category: D (Packaging)

Scope Statement: [process/activities, product and/or service description]

Addendum registration No:

Name and address of Certification Body

Authorized by:

Position of signatory:

Date of the conformity decision:

Issuing date:

Valid until:

Issued by: