FSSC 22000 ADDENDUM

HAVI tms GLOBAL QUALITY AND SAFETY REQUIREMENTS

Version 3 | February 2024

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TRANSLATIONS

Please note that in case of translations of this Addendum, the English version is the valid and binding version.

REVISION HISTORY

Date Published	Issue	Changes
November 2022	1	First publication
April 2023	2	Updated Section 5.12 (Disposal of customer branded materials) due to HAVI tms GQSR version update from V1.14 to V1.15

February 2024	3	Updated in line with Version 6 of the FSSC 22000 Scheme, including but not limited to:
		• Replaced HAVI with HAVI tms
		• Minor updates made to Section 3, 3.3, 3.9 and 4.1
		• Updated Section 5 and Annex A:
		  ○ Removed clause 3.5, 3.5.2, 4.3; and
		  ○ Updated clause 4.1, 4.2.1, 5.3.1
		• Added COID into Annex A

CONTENTS

1. PURPOSE

This document describes the additional requirements for organizations certified to FSSC 22000 to meet those specified in HAVI tms Global Quality and Safety Requirements (GQSR), as well as the process for Certification Bodies to follow when conducting audits to this Addendum. The HAVI tms GQSR Addendum can only be delivered when combined with an FSSC 22000 audit against Category I - *Production of food packaging and packaging materials.* It is necessary for the supplier to fully meet the requirements of both FSSC 22000 and the specific requirements within this document.

2. SCOPE

This addendum is a mandatory document for all HAVI tms supplier partners who need to meet the requirements of HAVI tms Global Quality and Safety Requirements.

This addendum is applicable to:

1. Suppliers manufacturing or supplying packaging and packaging materials to HAVI tms and within the scope of FSSC 22000.
2. Production of materials to be used further in manufacturing packaging materials.
3. Where additional processing to stored packaging materials takes place (coating, repacking).
4. Disposable plastic or paper plates and cups, aluminum foil, cling film, disposable cutlery when sold together with the food product.

Scope exclusion – there is no exclusion allowed to HAVI tms products/processes from the scope of certification.

In terms of exclusion of specific HAVI tms requirements, risk mitigation and justification of lack of applicability of particular requirements need to be documented and submitted to HAVI tms for approval by the organization. This approval needs to be referenced in the audit report. The organization must obtain documented evidence of the approval from HAVI tms to exclude HAVI tms-specific requirement(s), for the requirement to be indicated as not applicable in the Addendum report. If the evidence of the exclusion is not available, then the organization shall be audited on the requirement, and if the organization does not meet the requirement, a non-conformity shall be raised.

The additional requirements as specified in this document are based on a GAP analysis between FSSC 22000 and the HAVI tms Global Quality and Safety Requirements (GQSR). Meeting the additional requirements in this Addendum, in addition to the FSSC 22000 requirements, results in compliance with HAVI tms GQSR. This Addendum must be read in conjunction with the full HAVI tms Global Quality and Safety Requirements document in order to fully understand the context of the Addendum.

This document also sets out the auditing and certification process requirements for FSSC 22000 licensed Certification Bodies (CBs) wanting to audit to this Addendum.

Note: In relation to the content of this addendum, the term “Supplier Partner” and the term “Organization” are interchangeable. Both refer to the HAVI tms supplier who is being audited.

3. REQUIREMENTS FOR THE CERTIFICATION PROCESS

This section sets out the requirements for the certification process and applies to both organizations and FSSC 22000 licensed CBs as relevant.

The CB shall have procedures for including the Addendum in the FSSC 22000 audit process and apply the Addendum under the same principles as FSSC 22000.

This addendum may only be delivered by certification bodies that are licensed with the Foundation to deliver FSSC 22000 audits; no additional license with the Foundation is needed. HAVI tms supplier partners must notify their certification body that they need to undertake this Addendum audit going forward.

This Addendum may only be carried out together with an FSSC 22000 packaging audit with a corresponding scope and may not be delivered as a stand-alone addendum. The Supplier Partner must notify the certification body in advance that they want to undertake this addendum, so that additional audit duration may be determined prior to the commencement of the audit.

The scope of certification must include all HAVI tms products and production facilities. The Supplier Partner and certification body must agree to the scope of certification prior to the audit.

3.1 CONTRACT AND APPLICATION PROCESS

The organization shall inform the CB that they wish to include the Addendum as part of their FSSC 22000 audit, prior to the start of the audit. The CB determines how much notice is required from the organization to request a HAVI tms Addendum to be delivered with the FSSC 22000 audit. The CBs application system shall allow for this information to be captured, including the scope, and the contract with the organization shall be updated to include the Addendum.

3.2 AUDIT DURATION

The CB shall determine the additional audit duration needed to assess the Addendum requirements based on the size and complexity of the organization.

The minimum audit duration shall not be less than 0.5 man-days (4 hours) in all cases and does not include planning, reporting, or travel activities and only relates to effective time spent auditing the Addendum.

3.3 ALLOCATION OF THE AUDIT TEAM

The audit to the Addendum shall be conducted by an FSSC 22000 qualified auditor for category I, in accordance with the Scheme, Part 4, Section 3.5, and additionally, the auditor shall meet the requirements as defined under section 4 below.

3.4 AUDIT PROCESS

The Addendum audit is always a full audit covering all the requirements listed in Part 5 of this document and is to be assessed as an integrated part of the FSSC 22000 audit.

The audit program and audit plan shall clearly reference and include the Addendum requirements.

The combined audit shall be conducted annually as part of the FSSC 22000 audit. The first audit to the Addendum can take place at any full FSSC 22000 audit during the cycle (initial, surveillance, or recertification).

The audit delivery method (on-site, ICT Audit approach or full remote) shall be aligned to that of the FSSC 22000 audit and follow the same requirements.

3.5 UNANNOUNCED AUDITS

Where the FSSC 22000 audit is conducted as an unannounced audit, the Addendum shall also be assessed as unannounced.

3.6 AUDIT REPORT

The CB shall provide a written report for each audit to the Addendum. The report may be customized by the CB but shall include sufficient objective evidence to confirm that all the requirements in the Addendum have been assessed, including a summary of the nonconformities raised (where relevant) and meeting the requirements of Annex A of this document. It shall be referenced in the "Audit Details" section of the FSSC 22000 audit report that the HAVI tms GQSR Addendum was combined with the FSSC 22000 audit.

It is the responsibility of the organization to supply a copy of the full FSSC 22000 audit report and a copy of the HAVI tms Addendum Annex A report to their HAVI tms representative. The CB and Foundation FSSC do not supply this to HAVI tms directly.

3.7 NONCONFORMITY MANAGEMENT

The same criteria as defined in the FSSC 22000 Scheme applies to any nonconformities identified against the specific requirements of the HAVI tms Addendum, including grading, timelines, and follow-up actions. With the exception that:

- For minor and major nonconformities if the timelines are not met, then conformance to the Addendum will not be recommended.
- For critical nonconformities then conformance to the Addendum will not be recommended, as suspension does not apply to the Addendum.

The organization shall immediately notify their HAVI tms Representative, at the end of the audit, if any critical non-conformity is raised during their FSSC 22000 audit.

For nonconformities that also relate to a requirement of the Scheme, it shall also be raised and managed in accordance with the Scheme requirements for nonconformity management, Part 3, Section 6.2.

Where a systemic failure to meet the customer requirements of this Addendum is identified, a nonconformity shall also be raised against the relevant clause of ISO 22000 within the FSSC 22000 certification audit.

3.8 CERTIFICATION DECISION PROCESS

The CB shall conduct a technical review and undertake a certification decision for all audits against the Addendum, in conjunction with the review of the FSSC 22000 audit, to agree with the audit report content and outcome, NCs (objective evidence and grading), and effectiveness of corrections and corrective action plans. A positive certification decision for the FSSC 22000 audit is a prerequisite for achieving conformance to this Addendum.

It remains the responsibility of the CB to ensure a proper and robust audit and certification process.

3.9 ASSURANCE PLATFORM DATA AND DOCUMENTATION

The Addendum report shall be uploaded to the Assurance Platform, together with the FSSC 22000 related audit within 2 months of the last day of the audit. In addition, the CB shall indicate in the Assurance Platform, under the Addendum section of the relevant audit, that this Addendum was included as part of the FSSC 22000 audit. The same requirements relating to Data Quality, as set out in FSSC 22000, apply.

4. REQUIREMENTS FOR CERTIFICATION BODIES

4.1 COMPETENCE

The CB shall follow the same requirements described in Annex C of ISO 22003-1:2022 for defining the competencies required to conduct the audit and certification activities.

In addition, Technical Reviewers and Certification Decision Makers, are required to undertake the same specific training as the auditors as per 4.1.1 below.

Records of training shall be maintained by the CB.

4.1.1 AUDITOR REQUIREMENTS

Only FSSC 22000 auditors with the relevant category I approval may conduct audits to the Addendum. The auditor shall receive training on the following, by the CB, prior to conducting any audits:

- FSSC 22000: HAVI tms GQSR Addendum, and
- HAVI tms Global Quality & Safety Requirements document

Records of the training shall be maintained and uploaded in the Auditor database, under the maintenance tab, prior to commencing with Addendum audits.

The CB may define additional competency requirements in line with their procedures or accreditation requirements.

A specific witness audit to the Addendum is not required for approval to audit against the Addendum. Where an auditor does have approval to audit to the Addendum, it would be preferred if the CB can assign a 3-yearly witness audit which includes the Addendum, however, it is not mandatory.

The CB shall include the HAVI tms Addendum as a specific element in the 3-yearly auditor performance review during requalification of the FSSC 22000 auditor.

5. SPECIFIC AUDIT REQUIREMENTS

This section of the document sets out the specific requirements for organizations in addition to those defined in FSSC 22000 packaging. This includes requirements that have not been specifically defined in ISO 22000 or ISO/TS 22002-4, are partially addressed or have been addressed in a more general way. The organization shall comply with the FSSC 22000 requirements as well as these additional requirements to demonstrate compliance to the Addendum.

Related GQSR Clause	HAVI tms Addendum Requirement
1	**General**
1.1	**Scope**
1.1.2	Supplier Partners shall acknowledge that they have received, reviewed, and understood the contents of the HAVI tms Global Quality and Safety Requirements document as set forth and agree to abide by the requirements by annually signing a statement of agreement.
2	**Management Commitment**
2.5	**Management Review**
	The Supplier Partner's management shall implement a plan to meet the needs of the customer. The plan shall be reviewed for effectiveness and relevancy. Periodic reviews shall be scheduled and led by management at least once per year.
3	**Hazard and Risk Management**
3.2	**Food Safety (HACCP)**
3.2.2	The organization shall formally review the plan (HACCP Plan and Flow Chart) at least annually.
3.2.3	A copy of the plan shall be forwarded to HAVI tms.
3.4	**Food Packaging Defense Plan**
3.4.3	A formal annual audit of the food packaging defense plan shall be conducted to review the plan's effectiveness. The plan shall be revised and updated as needed or as changes dictate. All changes and results shall be documented.
3.9	**Chemical Control**
3.9.5	Identification of all chemicals with Safety Data Sheets (SDS) that are readily available to all employees. SDS sheets shall be maintained on-file for all chemicals in the appropriate language. SDS is the same as a MSDS (Material safety data sheet).
3.10	**Regulatory and Legislative Compliance**
	HAVI tms shall be notified of all visits and findings resulting from audits by governmental agencies.

Related GQSR Clause	HAVI tms Addendum Requirement
3.11	**Material Compliance**
3.11.4	The organization shall issue to HAVI tms CoC and CoA in keeping with HAVI tms and market regulatory and legislative requirements upon request - CoC and CoA - Where applicable, by country. *Note: This requirement is for those suppliers that are required to provide a CoC or CoA to the government of the country they are supplying, such as, but not limited to Japan and Korea. If this is not applicable to the country of sale, then please indicate not applicable.*
3.11.5	CoC shall be issued at least every two years or more frequently as requested/required by HAVI tms or the market.
3.11.6	CoC shall be issued in English and the official local government language where the packaging item shall be used.
3.11.10	The organization shall provide full product transparency to the CAS number for all packaging products, as HAVI tms requires and specifies.
4	**Quality Management**
4.1	**General** • Provide and maintain the map of the production process quality flowchart and quality matrix documents required by HAVI tms.
4.2	**Documentation**
4.2.1 a - e	The organizations quality system shall include at a minimum: a. Documented quality manual, b. Written work instructions, procedures, and protocols that drive planning, manufacturing, and control of their respective processes, including documented process maps and control plans, and c. Records associated with the quality systems, manuals, and products produced.
4.2.2	The organization shall establish, document, implement, train against, and maintain a quality manual that includes: The scope of the quality systems, The documented procedures established for the quality system, or reference to them, and a description of the interaction between the processes of the food safety, compliance, and quality system. The organization can define what its QMS Manual is.
4.2.4 d	Documents, records, and data which are part of the quality management system shall be retained for a minimum of 3-years or as specified by HAVI tms and/or regulatory and legislative requirements.
4.2.4 e	All records shall be retrievable within 24 hours.
4.3.5 a - c	**Quality Improvement Plan** The organization shall develop, implement, and provide a quality improvement plan to proactively identify potential and real quality improvement opportunities to drive the efficiency and effectiveness of the quality system. This plan shall be reviewed at least annually for effectiveness. The organization shall review this plan with HAVI tms.

Related GQSR Clause	HAVI tms Addendum Requirement
4.3.6 a - b	**Probationary Improvement Plan** An improvement plan may be required in order to improve unsatisfactory performance as determined by HAVI tms. The organization shall develop, implement, monitor, and report results of their probationary improvement plan upon request by HAVI tms. Failure to do so may result in loss of business, up to and including termination of the contract. The Probationary Improvement Plan must be approved by HAVI tms.
5	**Product and Process Control**
5.2	**Specifications** The organization shall collaborate with HAVI tms on the latest specification/revision for the packaging items the organization has been awarded to supply through the GSM System. The questionnaire contains the critical-to-quality characteristics of the product. The supplier agrees to produce to specification by signing off the acknowledgment of compliance for each specification. The approval process, including the agreed-upon qualification process, shall be completed before the organization is approved to supply the corresponding packaging item into the HAVI tms system unless authorization is provided in writing by HAVI tms. *Note: The GSM (Global Specification Management) is an Oracle-based specification management system employed by HAVI tms for controlling and managing specifications. A copy of the specification for each item manufactured by the organization must be available from the GSM system. The excel spreadsheet is the draft specification to outline the criteria of the specification before this information is entered into a GSM specification.*
5.2.2	Specifications shall contain technical and performance requirements for the following areas, at a minimum: Raw materials, Environmental information, Finished goods performance characteristics, Shipping container, Unit load, Graphics, and Engineered part drawing of the product.
5.3	**Product Traceability**
5.3.1	The organization shall be able to provide complete traceability of product, both forward and backward, within 3 hours of receiving item and lot code information during business hours and within 5 hours during off and holiday hours.
5.3.6	The organization shall test the traceability upstream and downstream (trace forward and trace backwards) through a timed and documented mock recall exercise at least once per year, to be successfully completed within 3 hours or less.
5.3.7	The organization shall objectively demonstrate the capability to implement a recovery scenario outside of regular office hours.
5.4.1 - 4	**Manufacturing Data Collection/Submission** The organization shall have a system in place to monitor and control compliance of properties for the product(s) they are responsible for manufacturing and demonstrate the ability to control their processes.

Related GQSR Clause	HAVI tms Addendum Requirement
	The organization shall have the capability to collect and report manufacturing data on performance criteria. Manufacturing data shall be reported to HAVI tms QA at a frequency and in a format agreed upon with HAVI tms. For processes with high variability and/or as required by HAVI tms: • Suppliers shall demonstrate statistical methods for maintaining control • Where required by HAVI tms, CTQ properties with Cpk values shall be greater than 1.33 • Product attributes shall meet product functionality requirements *Note: For those suppliers that have SPC or electronic data collection capability, CTQ characteristics should be electronically documented for variable attributes.*
5.7	**Notification of Formula, Material, Facility, or Process Change**
5.7.1 - 2	HAVI tms shall be notified in writing of all product-related changes prior to the changes taking effect. This includes, but is not limited to changes in: Formula, Process, Tooling, Equipment and Facility. Written notification of proposed changes to HAVI tms shall be provided as follows to give HAVI tms adequate time to assess and determine approvals and qualification requirements: • 30-days: Changes in process or raw materials, new inserts • 60-days: Changes in existing tooling, equipment relocation to another qualified facility • 90-days: new facility, new tooling, new equipment *Note: Tooling is generally classified as "forming" tools to form plastic lids or plastic or paper cups. Printing plates or die changes are not classified as tools that need to be notified via change management.*
5.8	**Product & Line Qualification Process** HAVI tms utilizes the "Commissioning, Qualification and Verification" (CQV) process to establish the process capability of a tool. The CQV process provides a total quality approach so that packaging produced at the start of production will fall within acceptable tolerances for all critical variable dimensions, attributes, and functional requirements. The CQV process is defined as: • Commissioning – The commissioning phase aims to ensure that lead/cavity production tooling can produce the packaging in agreement with component specifications and part drawing(s). Packaging will be examined on a cavity-to-cavity basis. • Qualification – The qualification phase aims to understand process capability once variation identified in the commissioning phase has been eliminated. Demonstrates over time that, using a larger sample base, packaging established during the commissioning stage could be maintained. This also defines how the tooling will perform in production. • Verification – The verification phase aims to ensure that production tooling has long–term capability. This is to understand how components from production are impacted by changes in raw material (lot-to-lot), shift (operators), and production facility environment (seasonal & within the plant).

Related GQSR Clause	HAVI tms Addendum Requirement
	The qualification of Extreme and High-Risk products, such as hot and cold beverage packaging, may require the completion and submission of a Production Part Approval Process (PPAP). A PPAP is used to anticipate and prevent problems, reduce costs, shorten product development time, and achieve safe and reliable products and processes.
5.8.1	The organization shall provide all relevant information necessary to successfully complete the qualification process.
5.8.1.a	The organization shall ensure that all materials used in the production of packaging products are compliant and meets all regulatory, legislative, and HAVI tms requirements. Objective evidence shall be provided. *Note: Organizations will have different KPIs and metrics that are specific to the facility.*
5.8.1.b	The organization shall verify that the packaging produced meets all food safety requirements, validating that the processes can consistently produce products to satisfy HAVI tms expectations. Objective evidence shall be provided.
5.8.2	The product shall not be introduced into the HAVI tms system without approval from HAVI tms Quality Assurance.
5.9	**Shipping Containers, Print Specifications and Other Tertiary Packaging Requirements**
5.9.1 – 2	Graphics, artwork, printing, and labels shall be in accordance with HAVI tms guidelines and approved by HAVI tms prior to the start of production. Used corrugated material shall be approved for its intended purpose. **Load Containment Specifications (Stretch wraps and others):** • All unit loads shall be stretch wrapped, the material of which is to be compatible with polyethylene as scrap. • Supplier Partners shall not use PVC. • Corrugated cartons shall be secured by glue or tape.
5.10	**Control of Nonconforming Product**
5.10.1	The nonconforming product shall not be used without written authorization from HAVI tms Quality Assurance. Disposition by HAVI tms is provided in writing or via e-mail.
5.11	**Product Holds and Recoveries**
5.11.4	The organization shall not send replacement products to the market or distribution centers without HAVI tms authorization. Any rework or replacement product is not released and remains on hold until HAVI tms provides approval/disposition.

Related GQSR Clause	HAVI tms Addendum Requirement
5.12	**Disposal of Customer Branded Materials** Supplier Partners shall establish, document, implement, train against, and maintain procedures that require the clear identification, containment and handling of customer branded bulk materials that have been designated as waste. This excludes routinely generated production line waste such as samples discarded after testing or inspection.
5.12.2	No customer branded waste material shall be shipped outside of the country of origin prior to pre-processing as outlined in 5.12.5 to 5.12.8. • 5.12.2.1. Supplier Partners shall receive written verification that the branded material was pre-processed within 48 hours following pre-processing. • 5.12.2.2. The written verification shall reference the notification outlined in 5.12.3, including the weight and or volume of the material disposed of. This record shall be retained for a minimum of 3 years.
5.12.3	A process shall be in place to formally notify the 3rd party waste management organization through documentation that branded waste materials are contained in a waste shipment. Objective evidence of this notification, including photographs prior to pre-processing, as well as the weight and or volume of the branded waste included in the shipment, shall be retained for a minimum of 3 years. *Note: Obsolete printing plates, dies, etc., are also classified as branded waste materials.*
5.12.4	Supplier Partners shall receive written certificates of destruction within 48 hours following the destruction of customer branded waste materials, where 3rd party waste management organizations are utilized. • 5.12.4.1. Certificates of destruction shall include photographs before and after pre-processing. • 5.12.4.2. The certificates of destruction shall reference the notification outlined in 5.12.3, including the weight of the material disposed of. • 5.12.4.3. This record shall be retained for a minimum of 3 years.
5.12.5	Branded wastepaper materials, including work-in-process materials, shall at a minimum be hogged or shredded to safeguard against unintended use prior to final disposition to safeguard against unintended use and must be processed at the first, primary waste handler. Note: Rolls of printed material can be over printed in place of hogging or shredding before sending the final waste handler, all branded names, trademarks, and images must be 100% obscured throughout the entire roll.
5.12.6	Branded waste plastic materials, including work-in-process materials, shall at a minimum be ground or chipped prior to final disposition to safeguard against unintended use and must be processed at the first, primary waste handler.
5.12.7	Branded waste metal materials, including work-in-process materials, shall at a minimum be cut, or ground prior to final disposition to safeguard against unintended use and must be processed at the first, primary waste handler.

Related GQSR Clause	HAVI tms Addendum Requirement
5.12.8	Branded waste wooden or other materials made of heavy gauge fibrous substrates, including work-in-process materials, shall at a minimum be cut or chipped prior to final disposition to safeguard against unintended use and must be processed at the first, primary waste handler.
5.12.9	Supplier Partners may, at their discretion, dispose of branded waste materials by means of waste-to-energy and thereby avoid hogging/shredding/chipping costs. Certificates of destruction shall be issued in accordance with 5.12.4.
5.12.10	Supplier Partners shall annually perform an unannounced audit of their 3rd party waste management organization to verify compliance. • 5.12.10.1. Supplier Partners shall audit the physical movement from loading through final disposition and ensure all elements of this section are adhered to for 3rd party waste management partners.
7.2	**Competence, Awareness, and Training**
7.2.8	The training program shall be reviewed for effectiveness at least annually and after changes in customer expectations, food safety, compliance, and quality policies and/or procedures.
7.3	**Medical screening / Hygiene**
7.3.5	The organization shall require the use of hairnets and beard nets in the manufacturing environment where primary or secondary packaging is being produced.

6. DEFINITIONS

The definitions in the HAVI tms GQSR document apply to the relevant terminology in Part 5 of this document, including but not limited to the following, extracted from the HAVI tms GQSR document:

- **Restricted Substances List** – A list of substances prohibited for use in packaging or raw materials used in producing packaging for HAVI tms.
- **Customer** – The customer is HAVI tms, who is responsible for understanding and communicating the expectations of its customers to the Supplier Partners.
- **CTQ (Critical-to-Quality)** – Specification properties identified as critical for ensuring consistent quality during manufacturing.
- **CoC (Certificate of Compliance)** – Document certifying that the product provided is compliant with the regulatory, legislative and HAVI tms requirements for the markets it will be used in.
- **SPC (Statistical Process Control)** – Methodology for measuring and controlling quality during the manufacturing process through the use of statistics.
- **Cpk (Process Capability Index)** – Statistical measurement of the capability of process.
- **COA (Certificate of Analysis)** – Document certifying that the product provided meets specification.
- **GSM (Global Specification Management)** – Oracle based specification management system employed by HAVI tms for controlling and managing specifications.
- **Quality** – Those product features that meet the needs of the customer. It is the degree to which a set of inherent characteristics fulfills the customer's requirements.
- **Quality Flowchart** – Flowchart describing each step of the manufacturing process and the test procedures associated with it.
- **Quality Matrix** – Matrix describing actions around each manufacturing process step.
- **Quality Management System** – A management system that directs and controls an organization with regard to food safety, quality and compliance, including the establishment of quality policies and objectives, planning, control and continuous improvement. A management system approach encourages an organization to analyze customer requirements, define the processes that contribute to the achievement of a product that is acceptable to the customer, and keep these processes under control.
- **Re-usable** – An item which is specifically designed to be used more than once.
- **HSS –** Hygiene, Safety and Sanitation (HSS) includes single-use and reusable face coverings, sanitizing chemicals and gloves.

The definitions in FSSC 22000 Appendix 1 apply to the remainder of the document unless otherwise specified.

7. REFERENCES

HAVI tms GLOBAL QUALITY & SAFETY REQUIREMENTS Version 1.15

ANNEX A: ADDENDUM REPORT TEMPLATE

The Addendum only addresses areas not specifically covered or not covered to the same extent as in FSSC 22000. The Report Addendum should always be read in conjunction with the FSSC 22000 Audit Report. The same general principles as set out in Annex 2 of the FSSC 22000 Scheme also apply to the completion of the Addendum report.

AUDIT DETAILS

Registered legal name	Name of organization to be certified.
Location/Address	Full address (or other unique identification of site location i.e., GPS, GLN etc. where a postal address is not available).
COID	
Contact person	Name and function – if different to the FSSC 22000 audit
General description of activities	
Scope of certification	Specific to the Addendum, but in line with the FSSC 22000 scope
FSSC 22000 report reference	Record the date and type of FSSC audit delivered in order for the Addendum report to be linked to the FSSC 22000 report.
Addendum Audit duration	Time spent auditing the Addendum in hours

AUDIT TEAM

Name	Function	Audit delivery	Date(s)	Time
Auditor name	Includes lead auditor, auditor, translators, TE, witnessor, trainees, observers	i.e., remote/onsite	DD/MM/YYYY	08h00-17h00

SUMMARY OF AUDIT FINDINGS

# Critical nonconformities	
# Major nonconformities	
# Minor nonconformities	

ADDENDUM AUDIT RECOMMENDATION

Recommended	☐
Not recommended	☐

NON-CONFORMITIES

#	Non-conformity Grading (Minor, Major, Critical)	Requirement Reference (std., clause)	NC statement (incl objective evidence)	Root Cause Analysis (determine why it arose)	Corrective Action Plan (action to prevent repeat; person responsible; due date for completion)	Correction (to address the immediate issue)	Objective Evidence Reviewed (relating to the correction)	Acceptance of correction and CAP (auditor and date)
1	For example: Minor	For example: HAVI tms GQSR §5.2	Provide a clear statement of the deviation from the requirement. Provide detailed objective evidence.	Completed by client	Completed by client	Completed by client	Indicate evidence reviewed for the correction i.e., document name and number	Auditor name and date of acceptance of Root cause analysis, CAP, correction, and objective evidence
2								
3								
4								

HAVI TMS GQSR ADDENDUM CHECKLIST

HAVI tms GQSR V1.15		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/ Major/ Critical**		
1	**General**						
1.1	**Scope**						
1.1.2	Supplier Partners shall acknowledge that they have received, reviewed, and understood the contents of the HAVI tms Global Quality and Safety Requirements document as set forth and agree to abide by the requirements by annually signing a statement of agreement.	☐	☐	☐			
Summary on General: Scope:							
2	**Management Commitment**						
2.5	**Management Review**						
	The Supplier Partner's management shall implement a plan to meet the needs of the customer. The plan shall be reviewed for effectiveness and relevancy. Periodic reviews shall be scheduled and led by management at least once per year.	☐	☐	☐			
Summary on Management Commitment: Management Review:							

HAVI tms GQSR V1.15		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/ Major/ Critical**		
3	**Hazard and Risk Management**						
3.2	**Food Safety (HACCP)**						
3.2.2	The organization shall formally review the plan (HACCP Plan and Flow Chart) at least annually.	☐	☐	☐			
3.2.3	A copy of the plan shall be forwarded to HAVI tms.	☐	☐	☐			
3.4	**Food Packaging Defense Plan**						
3.4.3	A formal annual audit of the food packaging defense plan shall be conducted to review the plan's effectiveness. The plan shall be revised and updated as needed or as changes dictate. All changes and results shall be documented.	☐	☐	☐			
3.9	**Chemical Control**						
3.9.5	Identification of all chemicals with Safety Data Sheets (SDS) that are readily available to all employees. SDS sheets shall be maintained on-file for all chemicals in the appropriate language. SDS is the same as a MSDS (Material safety data sheet).	☐	☐	☐			
3.10	**Regulatory and Legislative Compliance**						
	HAVI tms shall be notified of all visits and findings resulting from audits by governmental agencies.	☐	☐	☐			
3.11	**Material Compliance**						
3.11.4	The organization shall issue to HAVI tms CoC and CoA in keeping with HAVI tms and market regulatory and legislative requirements upon request - CoC and CoA - Where applicable, by country. *Note: This requirement is for those suppliers that are required to provide a CoC or CoA to the government of the country they are supplying, such as, but not limited to*	☐	☐	☐			

	Japan and Korea. If this is not applicable to the country of sale, then please indicate not applicable.						
3.11.5	CoC shall be issued at least every two years or more frequently as requested/required by HAVI tms or the market.	☐	☐	☐			
3.11.6	CoC shall be issued in English and the official local government language where the packaging item shall be used.	☐	☐	☐			
3.11.10	The organization shall provide full product transparency to the CAS number for all packaging products, as HAVI tms requires and specifies.	☐	☐	☐			
Summary on Hazard and Risk Management: Food Safety (HACCP): Food Packaging Defense Plan: Chemical Control: Regulatory and Legislative Compliance: Material Compliance:							
4	**Quality Management**						
4.1	**General** • Provide and maintain the map of the production process quality flowchart and quality matrix documents required by HAVI tms.	☐	☐	☐			
4.2	**Documentation**						
4.2.1 a - e	The organizations quality system shall include at a minimum: a. Documented quality manual,	☐	☐	☐			

	b. Written work instructions, procedures, and protocols that drive planning, manufacturing, and control of their respective processes, including documented process maps and control plans, and c. Records associated with the quality systems, manuals, and products produced.						
4.2.2	The organization shall establish, document, implement, train against, and maintain a quality manual that includes: The scope of the quality systems, The documented procedures established for the quality system, or reference to them, and a description of the interaction between the processes of the food safety, compliance, and quality system. The organization can define what its QMS Manual is.	☐	☐	☐			
4.2.4 d	Documents, records, and data which are part of the quality management system shall be retained for a minimum of 3-years or as specified by HAVI tms and/or regulatory and legislative requirements.	☐	☐	☐			
4.2.4 e	All records shall be retrievable within 24 hours.	☐	☐	☐			
4.3.5 a - c	**Quality Improvement Plan** The organization shall develop, implement, and provide a quality improvement plan to proactively identify potential and real quality improvement opportunities to drive the efficiency and effectiveness of the quality system. This plan shall be reviewed at least annually for effectiveness. The organization shall review this plan with HAVI tms.	☐	☐	☐			
4.3.6 a - b	**Probationary Improvement Plan** An improvement plan may be required in order to improve unsatisfactory performance as determined by HAVI tms. The organization shall develop, implement, monitor, and report results of their probationary improvement plan upon request by HAVI tms. Failure to do so may result in loss of business, up to and including termination of the contract. The Probationary Improvement Plan must be approved by HAVI tms.	☐	☐	☐			

Summary on Quality Management:

General:

Documentation:

Quality Improvement Plan:

Probationary Improvement Plan:

HAVI tms GQSR V1.15		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	Requirement	Yes	No	N/A	Minor/ Major/ Critical		
5	**Product and Process Control**						
5.2	**Specifications** The organization shall collaborate with HAVI tms on the latest specification/revision for the packaging items the organization has been awarded to supply through the GSM System. The questionnaire contains the critical-to-quality characteristics of the product. The supplier agrees to produce to specification by signing off the acknowledgment of compliance for each specification. The approval process, including the agreed-upon qualification process, shall be completed before the organization is approved to supply the corresponding packaging item into the HAVI tms system unless authorization is provided in writing by HAVI tms. *Note: The GSM (Global Specification Management) is an Oracle-based specification management system employed by HAVI tms for controlling and managing specifications. A copy of the specification for each item manufactured by the organization must be available from the GSM system. The excel spreadsheet is the draft specification to outline the criteria of the specification before this information is entered into a GSM specification.*	☐	☐	☐			
5.2.2	Specifications shall contain technical and performance requirements for the following areas, at a minimum: Raw materials, Environmental information, Finished goods performance characteristics, Shipping container, Unit load, Graphics, and Engineered part drawing of the product.	☐	☐	☐			
5.3	**Product Traceability**						
5.3.1	The organization shall be able to provide complete traceability of product, both forward and backward, within 3 hours of receiving item and lot code information during business hours and within 5 hours during off and holiday hours.	☐	☐	☐			

5.3.6	The organization shall test the traceability upstream and downstream (trace forward and trace backward) through a timed and documented mock recall exercise at least once per year, to be successfully completed within 3 hours or less.	☐	☐	☐			
5.3.7	The organization shall objectively demonstrate the capability to implement a recovery scenario outside of regular office hours.	☐	☐	☐			
5.4.1 - 4	**Manufacturing Data Collection/Submission** The organization shall have a system in place to monitor and control compliance of properties for the product(s) they are responsible for manufacturing and demonstrate the ability to control their processes. The organization shall have the capability to collect and report manufacturing data on performance criteria. Manufacturing data shall be reported to HAVI tms QA at a frequency and in a format agreed upon with HAVI tms. For processes with high variability and/or as required by HAVI tms: • Suppliers shall demonstrate statistical methods for maintaining control • Where required by HAVI tms, CTQ properties with Cpk values shall be greater than 1.33 • Product attributes shall meet product functionality requirements *Note: For those suppliers that have SPC or electronic data collection capability, CTQ characteristics should be electronically documented for variable attributes.*	☐	☐	☐			
5.7	**Notification of Formula, Material, Facility, or Process Change**						
5.7.1 - 2	HAVI tms shall be notified in writing of all product-related changes prior to the changes taking effect. This includes, but is not limited to changes in: Formula, Process, Tooling, Equipment and Facility. Written notification of proposed changes to HAVI tms shall be provided as follows to give HAVI tms adequate time to assess and determine approvals and qualification requirements: • 30-days: Changes in process or raw materials, new inserts • 60-days: Changes in existing tooling, equipment relocation to another qualified facility • 90-days: new facility, new tooling, new equipment	☐	☐	☐			

	Note: Tooling is generally classified as "forming" tools to form plastic lids or plastic or paper cups. Printing plates or die changes are not classified as tools that need to be notified via change management.						
5.8	**Product & Line Qualification Process** *(Refer to section 5 above for further details on 5.8)*						
5.8.1	The organization shall provide all relevant information necessary to successfully complete the qualification process.	☐	☐	☐			
5.8.1.a	The organization shall ensure that all materials used in the production of packaging products are compliant and meets all regulatory, legislative, and HAVI tms requirements. Objective evidence shall be provided. *Note: Organizations will have different KPIs and metrics, which are specific to the facility.*	☐	☐	☐			
5.8.1.b	The organization shall verify that the packaging produced meets all food safety requirements, validating that the processes can consistently produce products to satisfy HAVI tms expectations. Objective evidence shall be provided.	☐	☐	☐			
5.8.2	The product shall not be introduced into the HAVI tms system without approval from HAVI tms Quality Assurance.	☐	☐	☐			
5.9	**Shipping Containers, Print Specifications and Other Tertiary Packaging Requirements**						
5.9.1 – 2	Graphics, artwork, printing, and labels shall be in accordance with HAVI tms guidelines and approved by HAVI tms prior to the start of production. Used corrugated material shall be approved for its intended purpose. **Load Containment Specifications (Stretch wraps and others):** • All unit loads shall be stretch wrapped, the material of which is to be compatible with polyethylene as scrap. • Supplier Partners shall not use PVC. • Corrugated cartons shall be secured by glue or tape.	☐	☐	☐			
5.10	**Control of Nonconforming Product**						

5.10.1	The nonconforming product shall not be used without written authorization from HAVI tms Quality Assurance. Disposition by HAVI tms is provided in writing or via e-mail.	☐	☐	☐			
5.11	**Product Holds and Recoveries**						
5.11.4	The organization shall not send replacement products to the market or distribution centers without HAVI tms authorization. Any rework or replacement product is not released and remains on hold until HAVI tms provides approval/disposition.	☐	☐	☐			
5.12	**Disposal of Customer Branded Materials**						
	Supplier Partners shall establish, document, implement, train against, and maintain procedures that require the clear identification, containment and handling of customer branded bulk materials that have been designated as waste. This excludes routinely generated production line waste such as samples discarded after testing or inspection.	☐	☐	☐			
5.12.2	No customer branded waste material shall be shipped outside of the country of origin prior to pre-processing as outlined in 5.12.5 to 5.12.8. • 5.12.2.1. Supplier Partners shall receive written verification that the branded material was pre-processed within 48 hours following pre-processing. • 5.12.2.2. The written verification shall reference the notification outlined in 5.12.3, including the weight and or volume of the material disposed of. This record shall be retained for a minimum of 3 years.	☐	☐	☐			
5.12.3	A process shall be in place to formally notify the 3rd party waste management organization through documentation that branded waste materials are contained in a waste shipment. Objective evidence of this notification, including photographs prior to pre-processing, as well as the weight and or volume of the branded waste included in the shipment, shall be retained for a minimum of 3 years.	☐	☐	☐			

	Note: Obsolete printing plates, dies, etc., are also classified as branded waste materials.						
5.12.4	Supplier Partners shall receive written certificates of destruction within 48 hours following the destruction of customer branded waste materials, where 3rd party waste management organizations are utilized. • 5.12.4.1. Certificates of destruction shall include photographs before and after pre-processing. • 5.12.4.2. The certificates of destruction shall reference the notification outlined in 5.12.3, including the weight of the material disposed of. • 5.12.4.3. This record shall be retained for a minimum of 3 years.	☐	☐	☐			
5.12.5	Branded wastepaper materials, including work-in-process materials, shall at a minimum be hogged or shredded to safeguard against unintended use prior to final disposition to safeguard against unintended use and must be processed at the first, primary waste handler. Note: Rolls of printed material can be over printed in place of hogging or shredding before sending the final waste handler, all branded names, trademarks, and images must be 100% obscured throughout the entire roll.	☐	☐	☐			
5.12.6	Branded waste plastic materials, including work-in-process materials, shall at a minimum be ground or chipped prior to final disposition to safeguard against unintended use and must be processed at the first, primary waste handler.	☐	☐	☐			
5.12.7	Branded waste metal materials, including work-in-process materials, shall at a minimum be cut, or ground prior to final disposition to safeguard against unintended use and must be processed at the first, primary waste handler.	☐	☐	☐			
5.12.8	Branded waste wooden or other materials made of heavy gauge fibrous substrates, including work-in-process materials, shall at a minimum be cut or chipped prior to final disposition to safeguard against unintended use and must be processed at the first, primary waste handler.	☐	☐	☐			

5.12.9	Supplier Partners may, at their discretion, dispose of branded waste materials by means of waste-to-energy and thereby avoid hogging/shredding/chipping costs. Certificates of destruction shall be issued in accordance with 5.12.4.	☐	☐	☐			
5.12.10	Supplier Partners shall annually perform an unannounced audit of their 3rd party waste management organization to verify compliance. • 5.12.10.1. Supplier Partners shall audit the physical movement from loading through final disposition and ensure all elements of this section are adhered to for 3rd party waste management partners.	☐	☐	☐			

Summary on Product and Process Control:

Specifications:

Product Traceability:

Manufacturing Data Collection/Submission:

Notification of Formula, Material, Facility, or Process Change:

Product & Line Qualification Process:

Shipping Containers, Print Specifications and Other Tertiary Packaging Requirements:

Load Containment Specifications (Stretch wraps and others):

Control of Nonconforming Product:

Product Holds and Recoveries:

Disposal of Customer Branded Materials:

HAVI tms GQSR V1.15		Conform			Grade	If No – detail NC If N/A – provide justification	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	**Minor/ Major/ Critical**		
7	**Personnel**						
7.2	**Competence, Awareness, and Training**						
7.2.8	The training program shall be reviewed for effectiveness at least annually and after changes in customer expectations, food safety, compliance, and quality policies and/or procedures.	☐	☐	☐			
7.3	**Medical screening / Hygiene**						
7.3.5	The organization shall require the use of hairnets and beard nets in the manufacturing environment where primary or secondary packaging is being produced.	☐	☐	☐			
Summary on Personnel: Competence, Awareness, and Training: Medical screening / Hygiene:							