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Focus Visit, Surveillance 4, Unannounced Planning, Unannounced Visit

Report for:

PT Molindo Raya Industrial

LR reference:	JKT6018099 / 3065142
Assessment dates:	23-July-2019 - 26-July-2019
Reporting date:	18-November-2019
Client address:	Jl. Sumber Waras No. 255, Lawang, Malang , ID
Assessment criteria:	FSSC 22000 Food Safety v4.1
Assessment team:	Iqbal, Mochamad
LR Client Facing Office:	JKT Indonesia OU

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Attachments:

JKT6018099_APP__FSSC_Un SV-FV_Mlx.doc

This report was presented to and accepted by:

Name: Mrs Erliess sartini

Job title: QA Manager



01. Executive report

Assessment outcome:

This visit was to assess the compliance of the management system of PT Molindo Raya Industrial against FSSC 22000 Food Safety v4.1 as defined in the audit planning documentation. The outcome of the visit is recorded below.

Continual improvement:

Not Applicable



Areas for senior management attention:

Not Applicable

02. Assessment findings

Where scheme requirement differs to the standard definition below, the scheme definition will take preference

Major Nonconformity

The absence of, or the failure to implement and maintain, one or more management system elements, or a situation which would, on the basis of the available objective evidence, raise significant doubt of the management to achieve: The policy, objectives or public commitments of the organisation, compliance with the applicable regulatory requirements, conformance to applicable customer requirements, conformance with the audit criteria deliverables.

Minor Nonconformity

A finding indicative of a weakness in the implemented and maintained system, which has not significantly impacted on the capability of the management system or put at risk the system deliverables, but needs to be addressed to assure the future capability of the system.

Reference number	3065142_JKAMIX01	Assessment Criteria (Clause)	FSSC 22000 Food Safety v4.1 (22002-1-5.3)
Grade	Minor NC	Issue Date	25-July-2019
Status	New	Process / Aspect	warehouse
Location(s)	Jl. Sumber Waras No. 255,Malang,ID		
Statement of Non Conformity	walls in warehouse found dirty		
Requirement	ISO TS22002-1 clause 5.3		
Evidence	Found the wall in drum cleaning are were not smooth that made water trap inside where the mould growth which resulted several black spot on the wall		
Proposed correction, corrective action and timescales	correction : clean the mould corrective action : improve walls condition Time scale a week after audit		
Correction			
Root Cause analysis			
Corrective action			
LR has reviewed and verified the implementation of actions taken.	Date of closure		

Reference number	3065142_JKAMIX02	Assessment Criteria (Clause)	FSSC 22000 Food Safety v4.1 (22000-7.3.3.1)
Grade	Minor NC	Issue Date	25-July-2019
Status	New	Process / Aspect	incoming material
Location(s)	Jl. Sumber Waras No. 255,Malang,ID		
Statement of Non Conformity	raw material not equipped with food safety acceptance criteria		
Requirement	ISO 22000:2005 clause 7.3.3.1		
Evidence	It was found raw alcohol supplied from PT Enero was not equipped wot COA in 2019, the last was attached during 2018 delivery. It needs also to communicate the specification to the supplier. Batch not available yet		
Proposed correction, corrective action and timescales	Correction : ask the supplier for COA Corrective action : review hazard analysis Time scale A week after audit		
Correction			
Root Cause analysis			
Corrective action			
LR has reviewed and verified the implementation of actions taken.	Date of closure		

Reference number	3065142_JKAMIX03	Assessment Criteria (Clause)	FSSC 22000 Food Safety v4.1 (22000-7.4.2.2)
Grade	Minor NC	Issue Date	25-July-2019
Status	New	Process / Aspect	Hazard analysis
Location(s)	Jl. Sumber Waras No. 255,Malang,ID		
Statement of Non Conformity	miss hazard analysis from the equipment		
Requirement	ISO 22000:2005 clause 7.4.2.2.		
Evidence	It was found that inside fermentation tank was fix due to peeled of the coating inside, however this issue for peeled the coating was not updated in hazard analysis yet.(7.4.2.2)		
Proposed correction, corrective action and timescales	correction : update Hazard analysis Corrective action : review all process for Hazard analysis Time scale: a week after audit		
Correction			
Root Cause analysis			
Corrective action			
LR has reviewed and verified the implementation of actions taken.	Date of closure		

03. Assessment summary

Visit generic objective:

This was a Focus Visit, Surveillance 4, Unannounced Planning, Unannounced Visit visit, conducted against objectives previously notified to the client. The objectives of the next visit, including any applicable visit specific objective (theme / focus), are confirmed in the audit plan attached to this report.

Client attendees at the opening and closing meeting:

Not Applicable

Visit specific objective:

Not Applicable

Introduction:

Not Applicable



04. Next visit details

Standard(s) / Scheme(s)	FSSC 22000 Food Safety v4.	Visit type	Certificate Renewal
Audit days	4.25 DAY	Due date	March, 2020
Team			
Site		Audit days	Activity codes
Jl. Sumber Waras No. 255,Malang,ID		4.25 DAY	096531,096202

Standard(s) / Scheme(s)	FSSC 22000 Food Safety v4.	Visit type	Follow up
Audit days	0.50 DAY	Due date	January, 2020
Team			
Site		Audit days	Activity codes
Jl. Sumber Waras No. 255,Malang,ID		0.5 DAY	096531,096202

05. Appendix



FSSC 22000 Food Choose an item. Choose an item.

Index:

Executive summary	Audit recommendation, Audit Statement, General Findings
Summary of findings	Non conformities, Areas of concern (Stage 1 only)
ISO 22000 Food Safety Management Systems	Summary per chapter
Pre requisite program	Summary per chapter
Additional FSSC requirements	Summary per item
Organization profile	Certified organization, local manufacturer, Food chain category, Off-site activities
Audit details	Audit team, Organization representatives Attendance sheet at opening and closing meeting, Audit specifications.
Checklist ISO 22000	Conformance of requirements throughout the food chain
Checklist Pre requisite program	Checklist
Checklist Additional FSSC requirements	Checklist
Audit details previous audit	No NC's from previous audit
Audit Programme/Plan	Audit program, Audit scope, Verification scope statement
Audit report considerations	Checklist
Client info note FSSC	Assessment process – FSSC22000

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Executive summary	
Summary of audit findings	
Audit recommendation	
Conclusion	Continue certification 4.1 version
Certification meets	Yes for this surveillance
The purpose of this Surveillance audit has been met. The organization has shown continuing conformity meet food safety management system based on FSSC 22000 version 4.1 requirements. No Major, nor critical non-conformity found in this audit however 3 minor NC have been noted The organization is still recommended for transition to FSSC22000 version 4.1 requirements	
Audit Statement	
Statement on the conformity and the effectiveness of the management system	
Is statement approved:	Based on sampling taken in this surveillance, an effective implementation food safety management system based FSSC 4.1 version is in place and comply with the standard requirements which resulted no complaint received regarding food safety.
Yes	
Evidence of the capability of the management system to meet applicable requirements and expected outcomes;	
Food safety and quality Policy have been established to show the commitment and it was supported with food safety objectives which have been met the target. There is no issue from government and customer for the product produce since initial audit. Management was found committed in maintaining the food safety system of the company.	
Evidence to the effectiveness of internal audit and management review process;	
Internal audit and management review were done on periodic basis to verify the effectiveness of food safety management system based on FSSC 4.1 requirement and other standard applied. Management review was done on end of Feb 2019. It has covered all the required agenda including review of food safety policy, objectives, internal audit, CCPs and OPRPs, complaints, resources needs and improvement. The latest Internal audit carried out based on schedule for specific function in specific month within a year. Corrective actions taken for non-conformities identified were presented during audit and found to be effective to close the root cause	
General Findings	
Policies and objectives	
The policy specifying not only for food safety it also covering quality, health and safety, environment which have been used to established objectives for every function within organization. It is defined clearly in the management system documentation	

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Conformation that audit objectives have been fulfilled		
Yes		
Unresolved issues: Record any unresolved resulting from the audit findings		
None.		
Legal compliance: Summarize the status, any governmental inspection findings, etc		
The company is certified by LRQA for QMS since 9 years ago also for FSSC since 6 years ago. An Inspection of product and water were conducted by local Ministry of Health. No serious deviation from the record shows. Product specification were following the beverages and local regulation		
Change management: Summarize findings related to changes (e.g. compared to previous audit, to FSMS, etc.) and the effect on the operational FSMS		
There is no change on the management organization. The production line was found maintained. No new process or CCP's. The only CCP is still in distillation process with critical set for temperature.		
Complaints management: Summarize the food safety related complaints (including customer feedback) and the effect on the operational FSMS.		
There is no complaint received related to food safety or food quality from the customer.		
Recalls and withdrawals: Summarize the recalls/withdrawals, actual notification to the CB and the effect on the operational FSMS.		
No recalls for year 2018 until June 2019		
Proper use of FSSC 22000 logo (mark) and LRQA logo and correct use of logo and certification documents		
Yes	If no, explain:	Click here to enter text.
Focus visit (only in case of Surveillance 2):		
Review:		
trends information on (food safety) complaints and other performance indicators, system documentation improvement, lessons learned from audits, trends in LRQA findings		
The customer is mostly for beverages most of feedback are related to quantity due to customer increase the demand. No food safety complaint received since 2016, so the trend is still remaining constant from previous year.		

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Preview:

Longer term expectations of the company related to strategy and objectives, business and operational risks on food safety issues, review of use of their FSMS

Longer expectation is still maintain to beverages/alcoholic drinks market in future, the product is low risk so limited issue will be coming. Other customer segment is for pharmaceutical however it is very limited.

Planning:

Specific topics or objectives for the coming certification cycle

Necessity to perform extra stage 1?

Exact planning: see Audit Program Plan

Next visit will be upgrade to FSSC 5th version

Summary of findings

Non conformities

Critical nonconformities (CR NC)

Choose an item.

Click here to enter text.
CR NC open

NA.

Click here to enter text.
CR NC new

NA.

Major nonconformities (Major NC)

Choose an item.

Click here to enter text.
Major NC open

NA.

Click here to enter text.
Major NC new

NA.

Minor nonconformities (Minor NC)

Choose an item.

Click here to enter text.
Minor NC open

NA.

Click here to enter text.
Minor NC new

3 minor NC

Stage 1 only.

Areas of concern that may lead to nonconformity during the stage 2 audit.

Choose an item.

Click here to enter text.
Areas of concern

NA.

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ISO 22000 Food Safety Management Systems

Summary per chapter related to all paragraphs including reference to non-conformities in the findings log

4. Food Safety Management System

Document control using the hard copy system and distributed through internal by FSMS team. The main original documents were kept by Quality system champion and HACCP team. The documentation system covers version control, process ownership, authorization and release functionality until corporate function where necessary. Document published in English and Bahasa which could be assess for any one authorized

5. Management commitment

Food Safety Policy was established by the top management and cascade from director function. It was supported with measurable Food safety objectives. Management review is schedule yearly and last was done on early Feb 2019 which reviewed all agenda as standard required. Quality Assurance Manager has been appointed as Food Safety Team Leader.

Frequent meeting was done to review the food safety issues.

Procedure on Emergency Preparedness and response was found established which tested in annual as mock recall program.

6. Resource management

Plant infrastructure and physical resources that covering Process, utilities and storage facilities were properly maintained.

Annual food safety training was held as refreshment for all internal employees and subcontractors that conducted by internal team. Reviewed the program for 2019 and its record. Qualification operators based on Competencies matrix defined in HR function. The competencies also required FSSC knowledge.

7. Planning and realization of safe products

PRP program available for all facilities within manufacture scope. It is documented in every function related.

Member for food safety team are defined and includes evidence of knowledge and experience. Validation team members are independent from FSMS/HACCP team member.

Reviewed risk assessments related to Ethanol product were done properly.

Reviewed product and raw material specification were conducted and approved by Internal Team. Flow diagrams properly documented

CCP 1 (Distillation process) specified: the critical limit and Monitoring control that are checked at every hour and end of every shift.

O-PRP's identified related to filter during Filling process,

Control non-conforming product based on pallet labelling and identification on site ;

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Periodic meetings HACCP-team and annual verification of the FSMS combined with management review has been done and found no changes anything yet until July 2019

[Click here to enter text.](#)

8. Validation, verification and improvement of the FSMS

Validation on the CCPs identified has been done since initial assessment. With chemical hazard such as methanol are absent in the finish product also no microbiological and physical hard found. For OPRP validation have been done also with resulting no physical contamination present in the product. Equipment for measuring the process is send to external party for calibration. Part of system verification is Internal audit which carried out yearly basis for specific function. Last internal audit was done in 22 – 29 May 2019 . Corrective actions are taken for non- conformities rose. No complaint on the foreign matter and other food safety issue.

9. Food Fraud Mitigation

No changes for critical supplier such as for raw material.

Vulnerability assessment documented in the checklist and found the identification of fraud was detailed. There is no significant issue to be highlighted

[Click here to enter text.](#)

10. Food defence

Food defense risk assessment setup with analysis covering all activity within the manufacturing scope that include data security. Risk assessment incorporates entrance of the site and sealing of the trucks during transport. Sufficient control measures in place related to the risk outcome. Training on food defense was also sighted done for the staff. The company were guiding from the consultant that already expert in food defense and food fraud mitigation.

PRP ISO/ TS 22002-1 (FSSC food)

Summary per chapter related to all paragraphs including reference to non-conformities in the findings log

4. Construction and layout of buildings

Site located on an industrial area. Facilities properly maintained. No food safety risk from environment identified. No waste and pollutant also contaminating the environment. Site area fully paved. Good controlled for access to facilities.

5. Layout of premises and workspace

Epoxy coated flooring were observed in the filling / packing room for products. Ceilings are smooth. Vents

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are screened. Material flow is adequate. Location of equipment were good for assessing and cleaning, Product are mostly in closed circuit(piping), however from filling/warehouse area found walls are molding that detail in finding log section.

6. Utilities – air, water, energy

Water from deep well were used through water treatment process and found all parameter were tested as required by local regulation PERMENKES 492 year 2010, compressor for air pressure were maintain in good condition even the air is not contacted to the food directly or primary packaging

7. Waste disposal

Waste disposal procedure has been established. Product waste sold to external party was controlled well to avoid miss used. No accumulation of waste. Mostly waste or scrap is from maintenance activity.

8. Equipment suitability, cleaning and maintenance

Application of materials to be expected in this sector that contact product directly mainly is stainless steel. Systematic of maintenance program were supported by schedule in periodic basis. Reviewed maintenance of production line. Daily evaluation of maintenance issues is reported. Limited lubricant used in production and when there is potentially contact product the food lubricant was mandatory

9. Management of purchased materials

All purchase of raw materials by company was conducted by logistics function that has to be approved by the board of managers. All material suppliers were included in food fraud assessment. All suppliers were approved and register in the internal system. Annual supplier performance evaluation was reviewed to assess, quality performance and service into account. Material storage in the facility were in good manner with stock were controlled by the system. Temperature were monitored in warehousing area.

10. Measures for prevention of cross contamination

Annual Microbiological, Heavy Metal & Chemical Testing schedule was reviewed. Result for selected product was also sampled for end 2018 until June 2019. Frequency for laboratory testing on finished goods is done according to inspection plan i.e. quarterly and yearly.
Testing parameter includes but not limited to microbial, heavy metal (arsenic, lead, ferrous and mercury) also methanol.
Besides laboratory testing, incoming raw materials are checked for moisture content as well as sensory. Allergen control procedure was found adequate.
Procedure handling the glass, brittle and sharp tools has been established.

11. Cleaning and sanitizing

Daily cleaning & sanitation and GMP inspection report was maintained. The cleaning program has Specify the areas/items to clean, frequency, chemical used if required, monitoring, etc. Overall production cleanliness was maintained.

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12. Pest control

Pest control subcontracted to external party that have been approved by internal team. Contract in place for mice/rats, insects and flies. Records reviewed of months December 2018 – June 2019. Corrective actions are in place in case to notify the pest controller. No poison used inside the building.

13. Personnel hygiene and employee facilities

The procedure for personal hygiene was in placed. Staff hygiene was checked on site and found in order. Regular medical check-up for the healthiness of employee was conducted. Staff and visitor entering the production compliance to the procedure. Staff changing room was available before entering the filling room and locker for staff were Available and found clean.

14. Rework

Rework processing were limited identified and recorded well as part of recycle within process, it is trace from software system used. Good implementation was sighted during the audit

15. Product recall

Recall and withdrawal procedure were available and included in emergency and preparedness program. Annual recall test was held In 6 December 2018. No actual recalls / withdrawals since Initial stage

16. Warehousing

FIFO system were used for raw materials that can be verified effectively implemented by the local software system
Finished goods are adequately identified with the batch number, production date and pasted with QC Release sticker. Finished goods are kept at designated warehouse/tank storage system. Finished goods are stacked in the pallet and racking system were used for product with plastic drum packaging.

17. Product information and consumer awareness

The products information established are noted and comply with food requirements, due the product is not directly consumed the information available that produce direct to customer is COA and MSDS. Procedure in place to ensure the product labelling is correct specially for lot identification. The product is intermediate which need more processing to the next food chain

18. Food defence, bio-vigilance and bio-terrorism

See for summary: summary on chapter 10 of ISO22000 above

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Additional FSSC requirements

Summary per item including reference to non-conformities in the findings log

1. Management of services

Documented specification on the food safety requirements was in place for the services providers that having impact on product safety such as pest control. Control measures have been determined

2. Product labelling

Product labelling was found being reviewed following the customer requirement and local regulation. The regulation was in place.

3. Food defence

See for summary: summary on chapter 10 of ISO22000 above

4. Food fraud prevention

See for summary: summary on chapter 9 of ISO22000 above

5. Use of Logo

See for summary: Executive summary part above

6. Management of allergens (only for FSSC food and FSSC packaging)

Allergen control procedure was found adequate even there is no allergen present along the process.

7. Environmental monitoring (only for FSSC food and FSSC packaging)

Air monitoring analysis was done yearly on the microbiological analysis. Records reviewed and found the result was acceptable meet the requirements

8. Formulation of products (only for FSSC food – pet food for dogs and cats only)

No specific formulation of product controlled by QA as required by specific customer.

Organization profile

Description of the certified organization

Registration	1018050
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General description of audited organization	Manufacturer of ethanol with raw material from molasses.				
Seasonal activities	No				
Head Office	NA		Description of the role of the head office		
Does the company belong to a larger group with a central head office					No
If Yes*, list functions of Head office involved for certification				None.	
Registered legal name	Click here to enter text.				
Trading name (s)	Click here to enter text.				
Registration	Click here to enter text.				
Location	Click here to enter text.				
Contact	Click here to enter text.				
Food chain category					
Food chain category	CIV	Choose an item.	Choose an item.	Choose an item.	Click here to enter text.
Category: E, G: If yes:				Y/N	Remarks
Multi-site certification? If yes:				No	Click here to enter text.
	number of sites			No	Click here to enter text.
	on certificate, head quarter is mentioned			No	Click here to enter text.
	on schedule, head quarter is added with all sub sites			No	Click here to enter text.
Category: C, D, I and K? If yes:				Y/N	Remarks
Does head office control certain functions pertinent to certification, like purchasing, quality assurance, product development? *				No	.
Is the head office shown on the certificate?				No	Click here to enter text.
Off-site activities				No	Click here to enter text.
	Does organization have off-site activities as mentioned in part IV, paragraph 7.2.5.			No	Click here to enter text.
	Are these off-site activities part of the certification?			No	Click here to enter text.
	Number of off-site production and / or storage locations			No	Click here to enter text.
Description of the off-site activities					
Click here to enter text.					

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Registered legal name	Click here to enter text.
Trading name (s)	Click here to enter text.
Registration	Click here to enter text.
Location	Click here to enter text.
	Click here to enter text.
Registered legal name	Click here to enter text.
Trading name (s)	Click here to enter text.
Registration	Click here to enter text.
Location	Click here to enter text.

Audit details

LRQA Certificate number	JKT6018099
Audit language	English and Bahasa as mutually agreed during audit

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Audit team, role and attendance sheet			
Name	Role in audit team	Opening meeting	Closing meeting
Mochamad Iqbal	Team Leader	Yes	Yes.
Click here to enter text.	Choose an item.	Choose an item.	Choose an item.

Organization representatives, function and attendance sheet			
Name	Function, Representative of	Opening meeting	Closing meeting
Mrs Erlies S.	Top Management	Yes	Yes
Mr. Indrayanto	Production Manager	Yes	Yes
Ms Kartika	Quality Manager	Yes	Yes
Mr. Umar	Engineering Manager	Yes	Yes
Mr. Bambang	Quality Supervisor	Yes	Yes
Mr. Yudi	Logistic Manager	Yes	Yes

Audit specifications		
Audit objective(s)	As defined in Client Information Note at the end of this report	
Audit criteria	Client policies, procedures and requirements of customers and FSSC 4.1 version	Yes
Audit date 1e day/ time	23 July 2019	08.30 – 10.30
Audit date 2e day / time	24 July 2019	08.30 - 1700
Audit date 3e day/ time	25 July 2019	08.30 - 1700
Audit date 4e day/ time	26 July 2019	08.30 - 1700
Audit date 5e day/ time	NA	
....		
Audit duration calculation	3.25 Man day's total.	
Head office (if applicable)	NA. Man day's	
Audit time reduction	NA. Man day's	
Additional audit time for off- site activities	NA. Man day's	
Other standards audited together with FSSC 22000	NA.	

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	NA.	Click here to enter text. Man day's
HACCP Studies		1 Studies
Employees	100 FTE's total	
	3 Shifts	
	100. FTE's / shift + FTE's office	

Checklist ISO 22000				
ISO 22000 Food Safety Management Systems, requirements for organizations throughout the food chain				
Ref: ISO 22000:2005		Conformance		Remarks if N/A
4	Food Safety Management System	Yes/No/NA	If NO, select NC below	Remarks if N/A
4.1	General requirements	Yes		
4.2	Documentation requirements	Yes		Documents control procedure was established. Document change notice has recorded the approvals for amendments of documents. Document is in hard copy and maintained. Retention period is adequate by considering of product self-life. Records are legible and retrievable.
5	Management responsibility	Yes/No/NA	If NO, select NC below	Remarks if N/A
5.1	Management commitment	Yes		
5.2	Food safety policy	Yes		
5.3	Food safety management system planning	Yes		
5.4	Responsibility and authority	Yes		
5.5	Food safety team leader	Yes		
5.6	Communication	Yes		
5.7	Emergency preparedness and response	Yes		
5.8	Management review	Yes		

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6	Resource management	Yes/No/NA	If NO, select NC below	Remarks if N/A
6.1	Provision of resources	Yes		
6.2	Human resources	Yes		
6.3	Infrastructure	Yes		
6.4	Work environment	Yes		
7	Planning and realization of safe products	Yes/No/NA	If NO, select NC below	Remarks if N/A
7.1	General	Yes		
7.2	Prerequisite programmes (PRPs)	Yes		
7.3	Preliminary steps to enable hazard analysis	NO	Minor NC jkamix02	
7.4	Hazard analysis	NO	Minor NC jkamix03	
7.5	Establishing the operational PRPs	Yes		
7.6	Establishing the HACCP plan	Yes		
7.7	Updating of preliminary information and documents specifying the PRPs and the HACCP Plan	Yes		
7.8	Verification planning	Yes		
7.9	Traceability system	Yes		
7.10	Control of nonconformity	Yes		
8	Validation, verification and improvement of the FSMS	Yes/No/NA	If NO, select NC below	Remarks if N/A
8.1	General	Yes		
8.2	Validation of control measure combinations	Yes		
8.3	Control of monitoring and measuring	Yes		
8.4	Food safety management system verification	Yes		
8.5	Improvement	Yes		

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PRP checklist ISO/TS 22002-1 (FSSC food)				
Ref: ISO/TS 22002-1:2009 p 22-26		Conformance		Remarks if N/A
4	Construction and layout of buildings	Yes/No/NA	If NO, select NC below	Remarks if N/A
4.1	General requirements	Yes		
4.2	Environment	Yes		
4.3	Locations of establishments	Yes		
5	Layout of premises workspace	Yes/No/NA	If NO, select NC below	Remarks if N/A
5.1	General requirements	Yes		
5.2	Internal design, layout and traffic patterns	Yes		
5.3	Internal structures and fittings	No	Minor NC jkamix01	
5.4	Location of equipment	Yes		
5.5	Laboratory facilities	Yes		
5.6	Temporary/mobile premises and vending machines	Yes		
5.7	Storage of food, packaging materials, ingredients and non food chemicals	Yes		
6	Utilities – air, water, energy	Yes/No/NA	If NO, select NC below	Remarks if N/A
6.1	General requirements	Yes		
6.2	Water supply	Yes		
6.3	Boiler chemicals	Yes		
6.4	Air quality and ventilation	Yes		
6.5	Compressed air and other gases	Yes		
6.6	Lighting	Yes		
7	Waste disposal	Yes/No/NA	If NO, select NC below	Remarks if N/A
7.1	General requirements	Yes		
7.2	Containers for waste and inedible or hazardous substances	Yes		
7.3	Waste management and removal	Yes		

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7.4	Drains and drainage	Yes		
8	Equipment suitability, cleaning and maintenance	Yes/No/NA	If NO, select NC below	Remarks if N/A
8.1	General requirements	Yes		
8.2	Hygienic design	Yes		
8.3	Product contact surfaces	Yes		
8.4	Temperature control and monitoring equipment	Yes		
8.5	Cleaning plant, utensils and equipment	Yes		
8.6	Preventive and corrective maintenance	Yes		
9	Management of purchased materials	Yes/No/NA	If NO, select NC below	Remarks if N/A
9.1	General requirements	Yes		
9.2	Selection and management of suppliers	Yes		
9.3	Incoming material requirements (raw/ingredients /packaging)	Yes		
10	Measures for prevention of cross contamination	Yes/No/NA	If NO, select NC below	Remarks if N/A
10.1	General requirements	Yes		
10.2	Microbiological cross contamination	Yes		
10.3	Allergen management	Yes		
10.4	Physical contamination	Yes		
11	Cleaning and sanitizing	Yes/No/NA	If NO, select NC below	Remarks if N/A
11.1	General requirements	Yes		
11.2	Cleaning and sanitizing agents and tools	Yes		
11.3	cleaning and sanitizing programmes	Yes		
11.4	Cleaning in place (CIP) systems	Yes		
11.5	Monitoring sanitation effectiveness	Yes		
12	Pest control	Yes	If NO, select NC below	Remarks if N/A
12.1	General requirements	Yes		
12.2	Pest control programmes	Yes		
12.3	Preventing access	Yes		
12.4	Harbourage and infestations	Yes		

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12.5	Monitoring and detection	Yes		
12.6	Eradication	Yes		
13	Personnel hygiene and employee facilities	Yes/No/NA	If NO, select NC below	Remarks if N/A
13.1	General requirements	Yes		
13.2	Personnel hygiene facilities and toilets	Yes		
13.3	Staff canteens and designated eating areas	Yes		
13.4	Workwear and protective clothing	Yes		
13.5	Health status	Yes		
13.6	Illness and injuries	Yes		
13.7	Personal cleanliness	Yes		
13.8	Personal behaviour	Yes		
14	Rework	Yes/No/NA	If NO, select NC below	Remarks if N/A
14.1	General requirements	Yes		
14.2	Storage, identification and traceability	Yes		
14.3	Rework usage	Yes		
15	Product recall procedures	Yes/No/NA	If NO, select NC below	Remarks if N/A
15.1	General requirements	Yes		
15.2	Product recall requirements	Yes		
16	Warehousing	Yes/No/NA	If NO, select NC below	Remarks if N/A
16.1	General requirements	Yes		
16.2	Warehousing requirements	Yes		
16.3	Vehicles, conveyances and containers	Yes		
17	Product information/consumer awareness	Yes/No/NA	If NO, select NC below	Remarks if N/A
17	Product information/consumer awareness	Yes		
18	Food defence, bio vigilance and bioterrorism	Yes/No/NA	If NO, select NC below	Remarks if N/A
18.1	General requirements	Yes		

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18.2	Access controls	Yes		
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Additional FSSC requirements checklist				
Reference: FSSC v4.1 : July 2017, part II p 5 -7		Conformance		Remarks if N/A
1	Management of services	Yes/No/NA	If NO, select NC below	Remarks if N/A
1	Management of services	Yes		
2	Product labelling	Yes/No/NA	If NO, select NC below	Remarks if N/A
2	Product labelling	Yes		
3	Food defence	Yes/No/NA	If NO, select NC below	Remarks if N/A
3.1	Threat assessment	Yes		
3.2	Control measures	Yes		
3.3	Plan	Yes		
4	Food fraud prevention	Yes/No/NA	If NO, select NC below	Remarks if N/A
4.1	Vulnerability assessment	Yes		
4.2	Control measures	Yes		
4.3	Plan	Yes		
5	Logo use	Yes/No/NA	If NO, select NC below	Remarks if N/A
5	Logo use	Yes		
6	Management of allergens	Yes/No/NA	If NO, select NC below	Remarks if N/A
6	Management of allergens (only for FSSC food and FSSC packaging)	Yes		
7	Environmental monitoring	Yes/No/NA	If NO, select NC below	Remarks if N/A
7	Environmental monitoring (only for FSSC food and FSSC packaging)	Yes		
8	Formulation of products	Yes/No/NA	If NO, select NC below	Remarks if N/A

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8	Formulation of products (only for FSSC food – pet food for dogs and cats only)	Yes		
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Audit details previous audit

Previous audit type	Surveillance 3			
Previous on-site audit dates	13 - 14 November 2019			
Certification body	Lloyd's Register			
NC's from previous audit Details of findings, see findings log				
All previous NC closed?	Yes			

Audit Programme/Plan (LRQA)

Both the audit plan and the programme are dynamic and must be in line with the client's developments. Any (last minute) changes are possible with valid reasons like e.g. changes with the client, processes, management review results etc. Prior to the closing meeting the audit team should (re)confirm the programme and identify any changes concerning e.g. changes to the management system, extent, time or dates of the audit, competences etc.

Visit Type	CR Visit	SV1	SV2 + Transition	SV3	SV45		CR	
Start Date	2 May 2018	TBA	28/6/18	13/11/18	23/7/19		TBA	
End Date	4 May 2018	TBA	2/7/18	14/11/18	26/7/19		TBA	
Audit Days	3	1	3	2	3.25		2	
Separate assessment plan?	N	N	N	N	N		N	
Any change in workforce numbers That may impact visit duration (if yes add new number)	N	N	N	N	N		N	

The generic audit objectives and team responsibilities are included in the Client Information Note 'Assessment Process'. The assessment standard and roles of the audit team are defined in the assessment visit confirmation to the client by LRQA. Any revised scope will be as agreed in formal correspondence between LRQA and the client or defined in this section of the previous LRQA visit report. Where identified above see separate assessment plan (latest issue) for further detail. Any additional observers will be as formally communicated to the client in writing. The audit criteria consist of the assessment standard and the client's management system processes and documentation.

Process / aspect / theme / location

Final selection will be determined after review of management elements and actual performance

Opening meeting	✓	✓	✓	✓	✓		✓	
Closing meeting	✓	✓	✓	✓	✓		✓	
Changes to organizational context ⁽²⁾	✓	✓	✓	✓	✓		✓	
Management Review	✓	✓	✓	✓	✓		✓	
Internal Audits	✓	✓	✓	✓	✓		✓	
Continual Improvement	✓	✓	✓	✓	✓		✓	

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Management of change	✓	✓	✓	✓	✓		✓	
Corrective action	✓	✓	✓	✓	✓		✓	
Preventive Action ⁽³⁾	✓	✓	✓	✓	✓		✓	
Complaint Management	✓	✓	✓	✓	✓		✓	
Use of Logo (LRQA & Accreditation Marks)	✓	✓	✓	✓	✓		✓	
Performance against the client management system objective	✓	✓	✓	✓	✓		✓	
Product characteristics and intense use, flow diagram ; process steps and control measures, Hazard Analysis ,HACCP Plan & Operational PRPs plan, Validation & Verification	✓	✓	✓	✓	✓		✓	
Emergency preparedness and response include Withdrawal /recall /Mock test Documentation for FSSC 4.1 version include Food fraud and Food defense	✓	✓		✓			✓	
Production Ethanol and filling process	✓	✓	✓	✓	✓		✓	
Warehouse Raw material, Finish good and supporting material include delivery	✓		✓		✓		✓	
PRPs: Infrastructure and work environment, Waste disposal control, Pest control, Water control, Glass control ,Personal Hygiene and health control, Cleaning & sanitation program,	✓	✓	✓	✓	✓		✓	
QA/ Laboratory	✓	✓	✓	✓	✓		✓	
Maintenance / Calibration	✓		✓		✓			
Control of document and record	✓	✓	✓	✓	✓		✓	
Purchasing including management outsources	✓	✓	✓	✓	✓			

* Complete the list of organisation (parts), departments and/or processes of the different locations

Audit scope

Audit scope: . Manufacture Of Ethanol

Scope Exclusions (when appropriate) Describe the exclusions from the scope (exclusions may not have an (negative) influence on the certified end products).

None

Verification scope statement

Does the scope of certification continue to be appropriate to the activities / products / services of organization:

Yes

If no then document the actions necessary in relation to the scope in the executive summary of the report and amend the APP as required.

Note: if the visit involves more than one team member and/or is more than one day duration, an additional

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plan detailing the activities of each member of the team on each day will be required.

Confidentiality

We will treat the contents of this report, together with any notes made during the visit, in the strictest confidence and will not disclose them to any third party without written client consent, except as required by the accreditation authorities.

Sampling

The assessment process relies on taking a sample of the activities of the business. This is not statistically based but uses representative examples. Not all of the detailed nature of a business may be sampled so, if no issues are raised in a particular process, it does not necessarily mean that there are no issues, and if issues are raised, it does not necessarily mean that these are the only issues.

Legal entity

The accredited legal entity and client facing office that has provided the assessment service in this report is referenced in the applicable agreement for this service.

Generic audit objectives and team responsibilities

The generic audit objectives and team responsibilities are included in the Client Information Note 'Assessment Process'. Any visit specific objectives for the next visit will be recorded in the report of the previous visit and will be addressed through the visit plan for that visit. The assessment standard and roles of the audit team are defined in the assessment visit confirmation sent to the client.

Audit report considerations			
LRQA Report considerations	Y/N/na	Reference made if Yes	Ref:
Have there been any deviation from the original assessment plan:	No	If yes detail these in the Audit Statement section of the report along with the reasons for the deviations	
Have there been any significant issues impacting on the audit programme:	No	If yes detail these in the Audit Statement of the report and amend the APP	
Have there been any significant changes that affect the management system of the client since the last audit took place:	No.	If yes detail these within the Audit Statement section of the report.	
If applicable has the organization effective corrective action regarding previously identified nonconformities:	Yes	Record outcome in the findings log against the relevant findings.	

Client information note

Assessment process – FSSC22000

Overview

This Client Information Note explains the key stage of the LRQA's process for assessment and certification to FSSC22000.

FSSC 22000 certification is the assessment of your Food Safety Management System.

The FSSC 22000 certification scheme is owned by the non profit Foundation for Food Safety Certification and it covers the international standard ISO 22000 and sector specific Technical Specifications for Prerequisite Programmes (PRPs) with the additional FSSC requirements. These additional FSSC requirements can be found in the FSSC scheme documents Part II paragraph 2.1.4. These scheme documents and other information can be found on the FSSC website: www.fssc22000.com.

The Technical Specifications for pre-requisite programmes (PRP's) which are used within the FSSC certification are:

FSSC Food: ISO/TS 22002-1

FSSC Packaging: ISO/TS 22002-4

FSSC Feed: ISO/TS 22002-6*

FSSC Catering: ISO/TS 22002-2

FSSC Transport & Storage: NEN/ NTA 8059

(*: in this document requirements are specified on food, for FSSC feed, this shall be replaced by feed)

FSSC 22000 certification is recognized by the Global Food Safety initiative (GFSI), but standalone ISO 22000 and Technical Specification for PRPs certificates are not. You have a choice of the kind of certification you need depending on your own needs or the needs of your clients.

We can offer you a gap analysis before starting the assessment process to see if your system is ready. After any gap analysis, the assessment process typically includes two assessment visits to your site before we can recommend approval. We call these two visits:

- Stage 1 (document review and planning visit), and
- Stage 2 (initial assessment).

Once we have issued your certificate of approval, we will carry out announced and unannounced surveillance visits to maintain your approval. At each visit, our assessors will be open and helpful and will follow a practical approach.

Before we visit, we will discuss and agree with you the visit dates (except for the unannounced audit), start and finish times, the assessment team members, how long the visit will last, and which parts of your business we will visit. The processes covered by the assessment have to meet the FSSC scope.

We will carry out the audit in your local language or mutual agreed language. The FSSC foundation requires us to do the basic reporting in the English language. The checklists and the completed NC forms can be reported in the local language

Conducting the assessment

For all assessment undertaken by LRQA the objectives of these audits are:

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- the determination of the conformity of the client's management system, or parts of it, with audit criteria;
- the determination of the ability of the management system to ensure the client meets applicable statutory, regulatory and contractual requirements; *NOTE: management system certification audit is not a legal compliance audit.*
- the determination of the effectiveness of the management system to ensure the client can reasonably expect to achieve its specified objectives;
- as applicable, identification of areas for potential improvement of the management system.

The details of the objectives for each type of visit are contained in the section related to the visit types below.

Where applicable to an assessment visit, the roles of the personnel involved will be as follows:

- the Team Leader is responsible for the whole assessment process and the production of the visit plan. They are responsible for managing the members of the team, including allocating activities to the team members to ensure that the visit plan can be completed, the compilation of the visit report and visit findings and making the recommendations in relation to your certification;
- the Team members undertake the assessment process under the direction of the Team Leader; they undertake the detailed assessment work in accordance with the visits plan producing a report of the work they have undertaken, including any findings, for inclusion within the overall visit report;
- a Technical Expert will be used on an assessment where the specialist knowledge is required to supplement that of the assessment team. Whilst they will act as advisors to the assessment team they will not undertake any assessment work;
- an Assessor under training (AUT) may be included within the audit team, they will perform the duties of either a team member or team leader under the direction of the Team leader;
- the Team Leader will ask that you appoint personnel from your organization who will act as guides for the assessment team during each of the visits and who will assist the audit team;
- from time to time the audit Team may be accompanied by an observer. An observer is not a part of the audit team and will not influence or interfere with the conduct of the audit. An observer can be from LRQA, an accreditation body or regulator, or from another interested party who wishes to witness the audit.

The planning department of your LRQA office will inform you of the makeup of any assessment team in advance of the visit, including where applicable any Technical experts, and if they will be accompanied by any observers.

The accreditation requirements define that there are four elements to the assessment process:

- assessment of the system design and definition;
- assessment of the client's system self-governance;
- planning of the implementation visit;
- assessment of system implementation.

We combine these elements to meet market requirements. However, any combination of visits must allow you, time to correct any major non-conformity before the next visit.

We normally conduct the initial certification assessment of a management system in two stages - Stage 1 and Stage 2.

Visit structure

In a Stage 1 visit we address the following elements:

- an assessment of the design and definition of the system to confirm conformity with certification requirements such as the assessment standard(s) and certification scope;
- an assessment of the self-governance undertaken by you, the essential indicators, including internal audits and management review and the process for the assessment of risk;
- a confirmation of the contractual arrangements, including definition of approval scope, and identifying the planning, logistics, sampling etc. that will be used during the Stage 2 visit.

A Stage 2 visit consists of:

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- an assessment of the implementation of the management system to confirm conformity with certification requirements such as the assessment standard(s) and certification scope.

Interval between Stage1 and Stage 2 visits

We recommend that the interval between Stage 1 and Stage 2 visits is a minimum of six weeks and no longer than three months. In planning the two visits for the assessment, we will consider:

- your needs to resolve, before the Stage 2 visit, any areas of concern that may be identified during the Stage 1 visit, and
- the continued relevance of our work undertaken at the Stage 1 visit.

If an interval longer than three months is planned, we may need to revisit some of the areas assessed at the Stage 1 visit. An interval less than six weeks may not provide you with adequate time to address any concerns from the Stage 1 visit.

Stage 1 visits

Our assessment team perform the Stage 1 visit of a client's management system on-site.

The Objective of the Stage 1 Visit

This will be communicated to you within the Client Information Note (CIN) sent to you in advance of Stage 1 visit. The assessor shall review the system to determine that it fulfils the requirements of the assessment criteria and covers the activities detailed within the assessment scope.

The objective of the stage 1 are to provide a focus for planning the stage 2 audit by gaining an understanding of the organization's food safety management system (FSMS) and the organization's state of preparedness for stage 2 by reviewing the extent to which:

- The design and definition of the FSMS is in conformance with certification requirements such as the assessment standards (including sector specific technical specifications for PRP's, and the extra FSSC requirements) and certification scope.
- The organization has identified PRP that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements).
- The FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures
- Relevant food safety legislation implemented.
- The FSMS is designed to achieve the organization's food safety policy.
- The validation of control measures, verification of activities and improvement programmes conform to the requirements of the FSMS standard.
- An assessment is undertaken for the self-governance of the essential indicators, including internal audits and management review - and that the level of implementation of the management system substantiates that your organization is ready for the Stage 2 visit.
- The FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties.
- There is any additional documentation which needs to be reviewed and/ or information which needs to be obtained in advance.

In addition, the assessor shall review and confirm the contractual arrangements. This includes any changes required as a result of the outcome of the Stage 1 visit (including changes to the scope of assessment, duration of the Stage 2 visit, and duration of subsequent surveillance visits). The assessor shall also determine the planning, logistics, sampling, etc. that will be used during the Stage 2 visit.

During the stage 1 visit

Our assessor will undertake the following:

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- a) evaluate your location and site-specific conditions and carry out discussions with your personnel to determine your preparedness for the Stage 2 visit;
- b) review your status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance indicators or significant aspects, processes, objectives and operation of the management system;
- c) collect the information we need regarding the scope of your management system, processes and location(s) of your organization, and related statutory, regulatory aspects and compliance, for example, legal aspects of your operation, associated risks, etc.;
- d) confirm that you have procedures in place to identify legal requirements and to ensure that you comply with your commitment to legal compliance through monitoring of legal and regulatory compliance;
- e) review the allocation of resources for Stage 2 and agree with you the details of the Stage 2 visit;
- f) provide a focus for planning the Stage 2 visit by gaining sufficient understanding of your management system and site operations in the context of possible significant aspects;
- g) confirm that your management system documentation is in place with clear links to any related management systems in operation.

Closing the visit

Our assessor will:

- document and communicate the Stage 1 visit results to you, including identifying any areas of concern that would result in nonconformity if not corrected before the end of the Stage 2 visit;
- consider the interval between Stage 1 and Stage 2 visits including:
- your needs and ability to resolve areas of concern identified during the Stage 1 visit, and
- whether our work completed during the Stage 1 visit will still be relevant at the time of the Stage 2 visit.

If you determine that you can take any required corrective action within the planned interval, the assessor will consider whether extra duration is required at the Stage 2 visit to verify the corrective action taken.

If the interval between visits is extended to:

- between three and six months, we will need to:
- identify the changes that you need to make to your system, including the need for records
- review the changes to determine the need for a further visit, or to extend the Stage 2 visit, to verify that the design, definition and operation of the system now conforms with certification requirements such as the assessment standard(s) and certification scope.
- greater than six months, a second Stage 1 visit is required. We may also need to revise our arrangements, duration and / or timing, for the Stage 2 visit.

The Objective of the Stage 2 Visit

The objective of this visit is to confirm conformity of your FSMS with certification requirements, such as the assessment criteria and certification scope, any applicable statutory, regulatory and contractual requirements and to ensure that the system is meeting its specified objectives. The assessor will also address all issues outstanding from previous visits and any changes to your organization or system that impacts on the potential approval.

Stage 2 visit

Parts of the management system that were assessed during the Stage 1 visit and were determined to be fully implemented, effective, and in conformity with requirements, may not need to be re-assessed during the Stage 2 visit. However, our assessor must confirm that those parts of the management system already assessed continue to conform to certification requirements. If so, our assessor will include a statement to this effect in the Stage 2 visit report. Our assessor will state that conformity was established during the Stage 1 visit.

Stage 2 visits must have a visit plan. The plan follows the requirements in ISO/IEC 17021-1 and takes into account the information obtained during the Stage 1 visit.

The Stage 2 visit:

- takes place at the site(s) of your organization;

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- evaluates the implementation and effectiveness of your management system.

Our assessment team:

- conducts the Stage 2 visit to gather objective evidence that your FSMS conforms to the assessment standard and other certification requirements;
- assesses a sufficient number of examples of your activities in relation to the FSMS to get a sound appraisal of the implementation, including effectiveness, of the management system;
- addresses a sufficient number of your staff, including senior management and operational personnel, of the assessed facility, to provide assurance of the implementation and understanding of the system throughout your organization, including food safety policies and objectives;
- analyses all information and objective evidence gathered during the Stage 1 and Stage 2 visits to determine the extent of fulfilment with all certification requirements and decide on any nonconformity.

The Stage 2 visit includes an examination of your management system including at least the following:

- a) information and evidence about conformity to all requirements of the applicable normative documents;
- b) performance monitoring, measuring, reporting and reviewing against food safety objectives and targets;
- c) your management system and performance as regards legal compliance;
- d) operational control related to food safety;
- e) internal auditing and management review;
- f) management responsibility for your policies;
- g) links between the normative requirements, policy, performance objectives and targets, any applicable legal requirements, responsibilities, personnel competence, operations, procedures, performance data, and internal audit results.

During the Stage 2, our assessor will plan a relevant random assessment of the Critical Control Points (CCPs) and Operational Prerequisite Programs (O-PRPs) to verify the thoroughness of your operational FSMS. The random test should be representative of your product groups and processes, and of your chemical, physical and microbiological hazards;

Our assessor will also:

- review the involvement and training of your employees directly related to the operational FSMS;
- observe and follow up potential hazards and critical points (audit trails);
- depending on the observations, follow the audit trails through to non-production related areas, for example, maintenance, sales, human resources, etc.;
- provide feedback of potential hazards and critical points to the hazard and risk analysis;
- review results of the verification and maintenance of the FSMS and its evaluation.
- Ensure that the PRP's form the technical specifications for PRP's are covered

Action undertaken after the completion of a Stage 2 visit includes at least the following:

- leave a record of any identified and agreed non-conformities with you before leaving;
- establish the assessment report.

Surveillance

The objective of surveillance is to determine:

- if the client's management system meets the assessment criteria and certification scope,
- and that any applicable statutory regulatory and contractual requirements are being achieved
- and to ensure that the system is meeting its specified objectives.
- To address all issues outstanding from previous visits and any changes to your organisation or system that impact on the approval.

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LRQA will carry out a surveillance visit on at least an annual basis and will assess the continued compliance and effectiveness of your system in line with the ISO22000, the PRP technical specification and additional FSSC requirements.

Themes for surveillance visits will normally have been agreed with you at your previous visit. We will confirm the details with you at an opening meeting.

Themes chosen will allow us to review:

- internal audit, food safety system verification and management review processes;
- progress in meeting food safety objectives and improvement targets;
- corrective and preventive action processes including food safety complaints, external audits, and follow up of any remarks and nonconformities from external parties;
- changes to your system and the effectiveness of their implementation, and
- how you manage changes relating to responsibilities and the authority of main staff.

Review of logos

During the visit, our assessor will review your use of the permitted LRQA, FSSC22000 and accreditation logos against the relevant LRQA, FSSC22000 and accreditation rules. Failure to comply constitutes a breach of the approval contract.

Certificate renewal

The Objective of the Certificate renewal planning visit

To review the system and the performance of your company during the previous certification cycle, to see how you plan to move forward in the future and to plan the Certificate renewal visit while confirming continued compliance with the assessment criteria and certification scope, any applicable statutory, regulatory and contractual requirements and to ensure that the system is meeting its specified objectives. To address all issues outstanding from previous visits and any changes to your organization or system that impact on the approval.

Planning for the Certificate renewal

We conduct Certificate renewals on a three-yearly basis, planned at the previous surveillance visit and agreed with you.

The Certificate renewal planning process contains three steps: Review, Preview, and Planning.

Review

This step includes the review of past performance such as:

- trend information on complaints and other performance indicators;
- system documentation improvements;
- lessons learned from audits;
- trends in our findings.

Based on this review of past performance, our assessor will identify any potential risks in the present management system regarding successful implementation of the strategies and objectives.

Preview

The aim of the preview is to align our assessment activities with your strategy and objectives. The assessor will use the conversation with senior (site) management to understand your longer term expectations, for example, strategy issues, food safety risks, changes to internal and external environment etc. Our assessor will establish, through the interview, whether these expectations, objectives, and strategies will impact your FSMS or the stakeholders of your organization.

We will use the preview stage to identify further themes that can be used in the coming Certificate renewal visit and for the next three-year cycle.

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Planning

The next step in the visit is planning the Certificate renewal. In this part of the visit, our assessor will:

- identify any aspects of the system that have not been appropriately addressed during the surveillance cycle, and plan how to review these;
- use the information gained during the review and preview stages to support the planning process
- if appropriate, consider how best to give attention to any themes identified;
- identify the areas, departments, processes and activities to be assessed;
- agree with you sensible durations for each of these, commensurate with risk;
- try to identify the best use of resources, and avoid duplication;
- add appropriate time for reporting, consolidating and presenting reports;
- consolidate the information into a sensible visit plan.

Our assessor will allow time for discussion with all relevant managers and for a review of records for all relevant departments.

The Objective of the Certificate renewal visit

This visit is used as the re-assessment of the implementation of the management system based on the results of the Certificate renewal planning visit. This is to re-confirm conformity with certification requirements such as the assessment criteria and certification scope, any applicable statutory, regulatory and contractual requirements and to ensure that the system is meeting its specified objectives. To address all issues outstanding from previous visits and any changes to your organization or system that impact on the approval.

Conducting Certificate renewal visits

We conduct the Certificate renewal visit similarly to a Stage 2 assessment. In addition, we include a review of your system documentation to ensure that it:

- continues to suit your company, and
- scope of certification, including continual improvement.

Unannounced audits

An unannounced audit shall be carried out during one of the two yearly surveillance audits in the 3-years certification cycle. LRQA will decide which of the scheduled surveillance audits shall be chosen for the unannounced audits. A company can voluntary choose to have both surveillance audits unannounced.

The unannounced audit is a fully unannounced audit and will cover all elements of the FSSC requirements. A company is not notified ahead of the date of the unannounced audit. The unannounced audit will take place during operational working hours including night shifts.

The auditor will audit the organization operating on a representative number of product lines covered by the scope of certification. The auditor shall spend at least 50% of the time in production areas.

The organization can communicate in writing days of extreme inconvenience during which the client would find it difficult to participate fully and/ or there is no production, so called black-out days.

The maximum number of black-out days is 15 days (divided in a maximum of 3 periods) + non-operational periods.

The validity of the non-operational periods will be checked during the audits.

The organization can communicate (in writing to the local LRQA office) these days any time up to 5 months after the latest on-site audit. If no information is received, no black-out days are valid. After communicating the black-out days, the organization has 72 hours to change the dates, otherwise these black-out days are fixed.

Head offices controlling certain functions pertinent to certification separate to the site(s) are not audited during the unannounced audit but are audited in an announced manner.

Secondary sites (off-site activities) and off-site storage, warehouses and distribution facilities are also audited during

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the unannounced audit.

Changes to your approval

For any increase or decrease in your certificate of approval, please submit a formal request for the change. LRQA will review the request to consider:

- additions or changes to competency requirements for the visit team(s);
- additions or reductions in visit duration requirements.

You will be notified of any changes by an amended contract. We will undertake a separate document review visit (Stage 1) if the change requested has meant a major change or addition to your documented system.

The change to approval visit will be performed in line with our process for Stage 2 assessment visits, although a formal visit plan is not normally produced. If no document review (Stage 1) has been undertaken, time will be allowed during the visit for the team leader to review relevant documentation and to agree a plan for any additional visit activities.

Such visits may be carried out as separate visits or may be combined with a scheduled (Surveillance or Certificate renewal) visit.

LRQA will issue an amended certificate(s), using the same expiry date as on the current certificate.

The objective of this visit is the assessment of the implementation of the management system for an additional site or activity, which expands the existing scope of approval. To address all issues outstanding from previous visits and any changes to your organization or system that impact on the potential approval.

Reporting

The assessor will ensure that the report is sufficiently detailed to clearly show the level of conformity of your Food Safety Management System with the standard.

We fill in visit reports to record assessment findings, progress against the visit plan, positive comments, and also points of clarification or interpretation. We record assessment findings in a Findings Log, and identify them as Critical Nonconformity, Major Nonconformity or Minor Nonconformity. We define these findings as follows:

Critical Nonconformity:

Circumstance in which direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/ or certification integrity are at stake.

A major non-conformity of an audit that has been not addressed within the appropriate time

Direct consequence: immediately suspension for a maximum period of six (6) months.

Our team leader will make arrangements with you for follow up.

Follow up of critical non-conformities

When a critical nonconformity is issued during an audit, the organization must provide LRQA with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP). This shall be provided to LRQA within 14 days after the audit.

An on-site follow-up audit shall be conducted by LRQA within the six (6) month timeframe to verify the closure of the critical nonconformity. The sooner the critical nonconformity can be closed, the sooner the suspension will be lifted.

The certificate shall be withdrawn when the critical nonconformity is not effectively solved within the six (6) month timeframe.

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In case of a certification audit, the full certification audit shall be repeated.

The objective of the onsite follow up visit is to review the effectiveness of the correction and corrective action taken after the raising of a Critical Nonconformity. This follow up includes the review of the documented root cause analysis by the company, actions taken and documented evaluation by the company for the effective close out of the non-conformity.

Major Nonconformity:

nonconformity that negatively affects the capability of the management system to achieve the intended results.

In other words: the absence of, or the failure to implement and maintain, one or more management system elements, or a situation which would, on the basis of the available objective evidence, raise significant doubt of the management to achieve:

- the policy, objectives or public commitments of the organisation;
- compliance with the applicable regulatory requirements;
- conformance to applicable customer requirements;
- conformance with the audit criteria deliverables.

Generally, a major nonconformity will be a system failure that:

- is already affecting system effectiveness or deliverables;
- puts at risk the capability of the management system;
- requires immediate containment;
- requires immediate root cause analysis and corrective action.

A major nonconformity is raised (on management responsibility and resource allocation) in the event of non-completion of the approved action plan of a minor nonconformity at the next scheduled on-site audit

Our team leader will make arrangements with you for follow up.

Follow up of major non-conformities

When a major nonconformity is issued during an audit, the organization must provide LRQA with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP). This shall be provided within 14 days after the audit. The corrective action shall be implemented by the organization within 14 days after the audit and evidence of this implementation shall be send to the auditor (team leader).

Our assessor will plan an follow-up audit within 28 days after the audit, to review the corrective action plan and related objective evidence of implementation, challenge it if necessary and determine its effectiveness and approve the CAP and corrective action (CA).

The objective of the follow up audit is to review the effectiveness of the correction and corrective action taken after the raising of a Major Nonconformity. This follow up includes the review of the documented root cause analysis by the company, actions taken and documented evaluation by the company for the effective close out of the non-conformity.

In cases where documentary evidence is sufficient to close out the major nonconformity, the auditor may decide to perform a desk review.

The completion of corrective actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causative factors. In such cases the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented.

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In such cases, the major nonconformity can be downgraded by the auditor to a minor nonconformity.

A follow-up audit shall be conducted to verify the permanent corrective action and to close the nonconformity.

Downgrading of a major nonconformity is not possible if the major is defined based on the event of non-completion of the approved action plan of a minor nonconformity

Recommendation for certification is not possible when major nonconformities are not closed or downgraded to minors.

Minor Nonconformity:

non conformity that does not affect the capability of the management system to achieve the intended results.

In other words: a finding indicative of a weakness in the implemented and maintained system, which has not significantly impacted on the capability of the management system or put at risk the system deliverables, but needs to be addressed to assure the future capability of the system.

Generally, a minor nonconformity will be a weakness in an internal facing process or procedure; or a finding where any further deterioration of control could reasonably be considered likely to result in the system becoming ineffective.

Follow up of minor non-conformities

If a minor non-conformity is reported at the initial assessment, certificate renewal audit or surveillance visit with a change in certificate, the company has drawn up a documented proposed corrective action plan.

This proposed corrective action plan shall consist of mentioning the immediately correction (if needed) to mitigate the risk, and information on when and how the root cause analysis will be carried out by the company and a direction of what corrective actions will be needed.

In order to meet the required timings for the proposed corrective action plans, please note that your LRQA assessor will request proposed corrective action plans while on-site. For each nonconformity, the LRQA assessor needs to approve the proposed corrective action plan before recommendation for certification can be done.

If it is not possible to create such a proposed corrective action plan at the end of the audit, the company must provide the corrective action plan to the LRQA office before 90 days of the completion of the visit or before the expiry of the certificate, whichever the sooner.

A repeat audit is necessary in case the company fails to send in the proposed corrective action plan in due time.

The corrective action plan will form part of the independent review by the auditor and technical reviewer, before your certificate is issued.

In all cases of minor nonconformities, including minor nonconformity raised during surveillance audits, the organization has to submit within 3 months after the audit the root cause analyses, corrections and corrective actions and the status of implementation to the LRQA office/ LRQA auditor. Based on this information a remote follow up is planned.

The corrective actions shall be implemented by the organization within 12 months after the audit. Implementation of the corrective action plans shall be reviewed, at the latest, at the next scheduled on-site audit. The LRQA auditor will review the corrective action plan and the evidence the company reviewed its effectiveness of implementation.

It is recommended to send in this corrective action plan with identification of the root cause analyses, actions to take and way of evaluation immediately after the audit. The company has at maximum 3 months to submit this

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corrective action plan after the receipt of the list with non-conformities. Its implementation will be verified during the next regular visit.

The objective of the onsite follow up is to review the documented root cause analysis by the company, actions taken and documented evaluation by the company for the effective close out of the non-conformity.

Please keep copies of all our visit reports for three years. In exceptional circumstances, we may ask you to provide copies of previous reports.

Special Surveillance visits

In the event of complaints against the FSMS of your company that is within the scope of this approval, or in the event that you notify LRQA of significant changes which are likely to affect the management system's compliance with the criteria referred to and the approvals issued under your approval, LRQA will carry out either an unannounced or short notice visit for the purposes of investigating the complaint or reviewing the changes made.

Sampling

It is important to remember that even though a problem may not have been identified in an area of activity, it does not necessarily mean that there are no problems. As assessment work is based on sampling techniques, statistically there is always a possibility that issues will not be identified during an assessment. You should always remember this when you audit your own management system.

Certification decision

Following an assessment visit where an assessor makes a recommendation in relation to your certification, accreditation rules require that this recommendation will be subject to an independent review or certification decision, only following this decision will certification be either granted, renewed, extended, reduced, suspended or withdrawn.

This certificate will show the FSSC22000 logo, the name and address of your organization, your activities/ processes, the initial certification date and the expiry date. The certificate has a validity of 3 years. After 3 years we will conduct a recertification audit. A positive result will result in an extension of the certificate for a further 3 years.

FSSC database

FSSC requires the receipt of a basic report and all issued certificates. It uses them to list information about certified organizations on their website.

Confidentiality

We will not pass on any of the information we gather about your organization (including the contents of reports) to any other person or organization without your permission (except as required by the accreditation body).

Further information

To find out more about how LRQA can help you to increase performance and reduce risk, please visit our website www.lrq.com. From here you can also visit one of our country specific websites to find out about LRQA in your country.

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END of Report