FSSC 22000 V4.1 – NEW ADDITIONAL REQUIREMENTS – JANUARY 2019

Introduction

The Food Safety System Certification 22000 is acknowledged by the Global Food Safety Initiative (**GFSI**). Due to the GFSI recognition of the Food Safety Management System a certified organization can demonstrate to their clients the organization complies with the requirements regarding their certified Food Safety Management System.

The GFSI developed Benchmarking Requirements, the so called GFSI Guidance Document/Benchmarking requirements, which are subject to continuous developments. As a result of the extensive benchmarking process, the Board of Stakeholders (BoS) for FSSC 22000 version 4.1, decided that additional interpretation shall be taken into account for thirteen requirements by all FSSC licensed Certification Bodies like DNV GL.

In addition to the requirements mentioned in the ISO 22000 (version 2005) standard, the additional interpretations apply as of **January 1st, 2019.**

As per **January 31st, 2019**, DNV GL shall assess this thirteen additional requirements during the audits.

The additional interpretations are outlined and explained in to more detail in the following pages. Please note that most additional interpretations only apply to a certain food chain (sub-) category.

The main difference will be the **closing of Minor Nonconformities**. If a Minor Nonconformity is issued during a new audit, **evidence of the correction** (*correction: action to eliminate a detected nonconformity*) shall be send by the organization to the Certification Body for verification and approval latest 3 months after the audit.

The current approach to accepting the **corrective action** plan (*corrective action: action to eliminate the cause of a nonconformity and to prevent recurrence*) for a minor Nonconformity remains unchanged. The new expectation is the requirement for **evidence of the correction** as part of the corrective action plan (CAP) within 3 months after the audit.

Beside above mentioned information, specific additional interpretations are applicable for particular requirements. These additional interpretations are mentioned in more detail in the annexes.
The FSSC 2000 scheme consists of three different components:

- ISO 22000
- Additional FSSC requirements
- Sector specific prerequisite pograms (PRP'S).

The ISO 22000 and Additional FSSC requirements are applicable for ALL FSSC certified organizations. In **annex 1** the additional interpretations are mentioned for ISO 22000 and Additional FSSC requirements.

Which sector specific prerequisite program is applicable for your organization, depends on the scope of your organization which including the applicable prerequisite programs (PRP's) and food categories. The PPR's and food categories are mentioned at the certificate and the audit reports.

The additional interpretations are applicable for the next Prerequisite programs:

- ISO/TS 22002-1:2009 Prerequisite programmes on food safety – Food Manufacturing – See **annex 2**
- ISO/TS 22002-4:2013 Prerequisite programmes on food safety – Food packaging – See **annex 3**.

Some additional interpretations may be limited depending on the scope and category of your organization. Please take note of information which is mentioned between the brackets at the additional interpretations which are mentioned at the **Annexes**.

At the closing meeting of the audit, the auditor will summarize the detected Nonconformities and indicate which actions are required by the organization.

ANNEX 1

ISO 22000:2005 FOOD SAFETY MANAGEMENT SYSTEMS – REQUIREMENTS FOR ANY ORGANIZATION IN THE FOOD CHAIN

5 Management responsibility **5.7 Emergency preparedness and response**	
Requirement	**Additional interpretation**
Top management shall establish, implement and maintain procedures to manage potential emergency situations and accidents that can impact food safety and which are relevant to the role of the organization in the food chain.	The Certification Body is required to assess if the organization has an incident management procedure in place that is regularly tested (only for food chain categories C, D, I, G and K).

7 Product realization ISO 22000:2005 **7.9 Traceability system**	
Requirement	**Additional interpretation**
The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records. The traceability system shall be able to identify incoming material from the immediate suppliers and the initial distribution route of the end product. Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements and customer requirements and may, for example, be based on the end product lot identification.	The Certification Body is required to assess if the organization has specified traceability requirements in place for unique identification of its final products (only for food chain categories C, I and K).

7 Product realization **7.10 Control of nonconformity** **7.10.3.2 Evaluation for release**	
Requirement	**Additional interpretation**
Each lot of product affected by the	The Certification Body is required to

nonconformity shall only be released as safe when any of the following conditions apply: a) evidence other than the monitoring system demonstrates that the control measures have been effective; b) evidence shows that the combined effect of the control measures for that particular product complies with the performance intended (i.e. identified acceptable levels as identified in accordance with 7.4.2); c) the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned.	assess if the organization has a product release procedure in place (only for food chain categories C, I, G and K).

ADDITIONAL FSSC REQUIREMENTS

2.1.4.1 Management of services	
Requirement	**Additional interpretation**
1) The organization in the food chain shall ensure that all services that may have an impact on food safety a) have specified requirements which are regularly reviewed. b) are described in documents to the extent needed to conduct hazard analysis. c) are managed in conformance with the requirements of technical specification for sector PRPs. d) are assessed and approved demonstrating compliance with specified requirements e) are monitored to assure continued service provider	The CB is required to assess if the organization, in case of an emergency, a non-approved supplier shall be assessed and the product shall meet the specification (only for food chain categories C, I, G and K).

approval status	

2.1.4.8.2 Formulation of products (for sub-category DII, pet food for dogs and cats only)	
Requirement	**Additional interpretation**
Formulation procedures shall be in place to manage the use of ingredients that contain nutrients that can have adverse animal health impact	The Certification Body is required to assess that the organization properly manages the use of ingredients that contain substances that can be deleterious to certain classes of animals (for food chain categories DI and DII only).

ANNEX 2

ISO/TS 22002-1:2009 PREREQUISITE PROGRAMMES ON FOOD SAFETY – FOOD MANUFACTURING

9 Management of purchased materials **9.2 Selection and management of suppliers**	
Requirement	**Additional interpretation**
There shall be a defined process for the selection, approval and monitoring of suppliers. The process used shall be justified by hazard assessment, including the potential risk to the final product, and shall include: a) assessment of the supplier's ability to meet quality and food safety expectations, requirements and specifications; b) description of how suppliers are assessed; NOTE Examples of a description of how suppliers are assessed include: 1) audit of the supplying site prior to accepting materials for production; 2) appropriate third party certification. c) monitoring the performance of the supplier to assure continued approval status. NOTE Monitoring includes conformity with material or product specifications, fulfilment of COA requirements, satisfactory audit outcomes.	The Certification Body is required to assess if the organization has a policy in place for the procurement of animals, fish and seafood which are subject to control of prohibited substances such as pharmaceuticals, veterinary medicines, heavy metals and pesticides (only for food chain category CI).

10 Measures for prevention of cross contamination **10.1 General requirements**	
Requirement	**Additional interpretation**
Programmes shall be in place to prevent, control and detect contamination. Measures to prevent physical, allergen and microbiological contamination shall be included.	The Certification Body is required to assess that the organization has specified requirements for an inspection process at lairage and/or at evisceration to ensure animals are fit for human consumption (only for food chain category CI).

16 Warehousing 16.2 Warehousing requirements	
Requirement	**Additional interpretation**
Effective control of warehousing temperature, humidity and other environmental conditions shall be provided where required by product or storage specifications. It is recommended that where products are stacked, consideration is given to measures necessary to protect the lower layers. Waste materials and chemicals (cleaning products, lubricants, and pesticides) shall be stored separately. A separate area or other means of segregating materials identified as non-conforming shall be provided. Specified stock rotation systems (FIFO/FEFO) shall be observed. Gasoline- or diesel-powered fork-lift trucks shall not be used in food ingredient or product storage areas.	The Certification Body is required to assess that the organization has specified requirements in place that define post-slaughter time and temperature in relation with chilling or freezing of the products (only for food chain category CI).

ANNEX 3

ISO/TS 22002-4:2013 PREREQUISITE PROGRAMMES ON FOOD SAFETY – FOOD PACKAGING MANUFACTURING

4.6 Management of purchased materials and services **4.6.3 Incoming raw materials**	
Requirement	**Additional interpretation**
Loads on delivery vehicles shall be checked prior to and during unloading to verify that food safety and safety of raw materials have been maintained during transit. Where tamper-evident seals are used, a verification process shall be in place to verify conformance to relevant customer or regulatory requirements. All incoming raw materials shall be inspected, tested or covered by COA/DOC to verify conformance to specified requirements prior to acceptance or use. The method of verification shall be documented. Sufficient data shall be available to enable hazard analysis for food contact. NOTE 1 For example where incoming raw materials are from a recycled source or are plant-based materials, it is intended that appropriate measures be in place to verify food safety and traceability requirements are met prior to acceptance. NOTE 2 The inspection frequency and scope can be based on the risk presented by the material and the risk assessment of the specific suppliers. Raw materials that do not conform to relevant specifications shall be handled under a documented procedure that prevents their	The Certification Body is required to assess that the organization has specified requirements in place when recycled material, plant based material or functional additives are used, there shall be sufficient data to ensure safe food contact and documentation of claims (only for food chain category I).

unintended use. Access points to bulk raw materials receiving lines shall be identified and, if appropriate, capped and secured. Discharge into such systems shall take place only after approval and verification of the raw materials received.	

4.7 Measures for prevention of contamination **4.7.1 General requirements**	
Requirement	**Additional interpretation**
A hazard analysis shall be carried out. If applicable, measures to prevent microbiological, physical and chemical contamination shall be implemented. Where external product testing is required, it shall be carried out by an accredited test facility or one that follows international test facility guidelines. Where in-house testing is carried out, calibration of equipment shall be carried out against national Standards or other accurate means. Mixing of raw or intermediate products shall be prevented where hazard analysis reveals a food safety hazard. Whenever a contamination incident occurs, the process of cleaning up or the maintenance shall be carried out under the control of a designated person. After cleaning up or maintenance a documented release procedure shall follow. Any contaminated product that cannot be effectively cleaned shall be discarded.	The Certification Body is required to assess that the organization has addressed the potential for contamination from other materials carried on the same vehicle (only for food chain category I).

4.10 Personnel hygiene and facilities **4.10.5 Illness and injuries**	
Requirement	**Additional interpretation**
Personnel shall follow the organization's documented guidelines for injuries and diseases. **CAUTION — Personnel infected with, or carrying, a disease or**	The Certification Body is required to assess that the organization has a medical screening procedure in place when permitted by law (only for food chain category I).

illness transmissible through food should be prevented from handling food packaging. A medical screening procedure may be inplace. All injuries, including minor cuts, shall be treated immediately and in an appropriate manner. Dressings shall be controlled and changed at appropriate intervals. Self-adhesive plasters shall not contaminate the product. They shall be differentiated from the product (e.g. by colour).	

4.14 Food packaging information and customer communication	
Requirement	**Additional interpretation**
The organization shall be able to demonstrate compliance with food safety requirements and agreed specifications. The organization shall obtain the information necessary to determine that the food packaging to be provided is suitable for the intended use and will meet the food safety requirements. In case of changes to the food packaging, the organization shall assess any implications for food safety and compliance. The organization shall provide and update food safety relevant information on product applicability and restrictions of use to its customers. NOTE Information can be provided by labelling or other means, such as company websites and advertisements and may include storage, instructions applicable to the product. Where as part of the process food safety, information is provided on the food packaging, this information shall	The Certification Body is required to assess that the organization has specified requirements in place in case packaging is used to impart or provide a functional effect on food, such as shelf life extension, shall, where known, be effective within its own specified criteria (only for food chain category I).

be complete, legible and controlled to prevent misprinting.	