



# Food Safety System Certification 22000 Version 4.0

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### Introduction

First published in 2010.

Need to revise the FSSC 22000 Scheme documents:

- Update of Scheme documents
- Expected publication of GFSI Benchmarking Requirements document Version 7
- Publication of FSMA in the USA

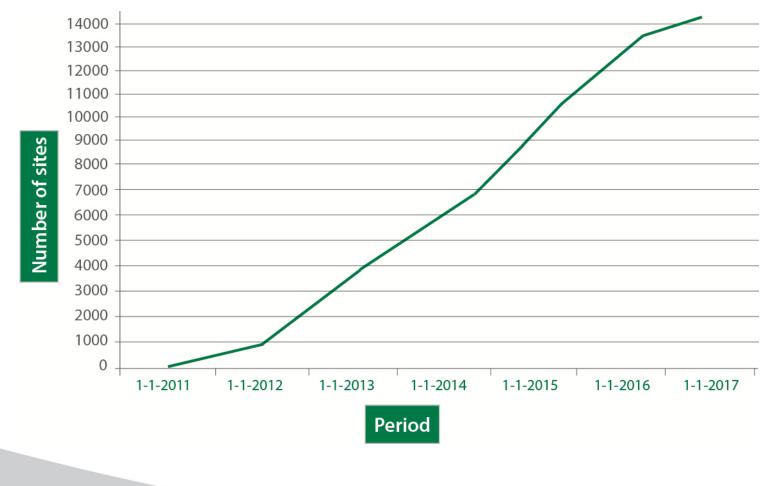


### **Mission FSSC 22000**

"To be the world's leading, independent, GFSI recognized, ISO based food safety and quality management system for the entire food supply chain."

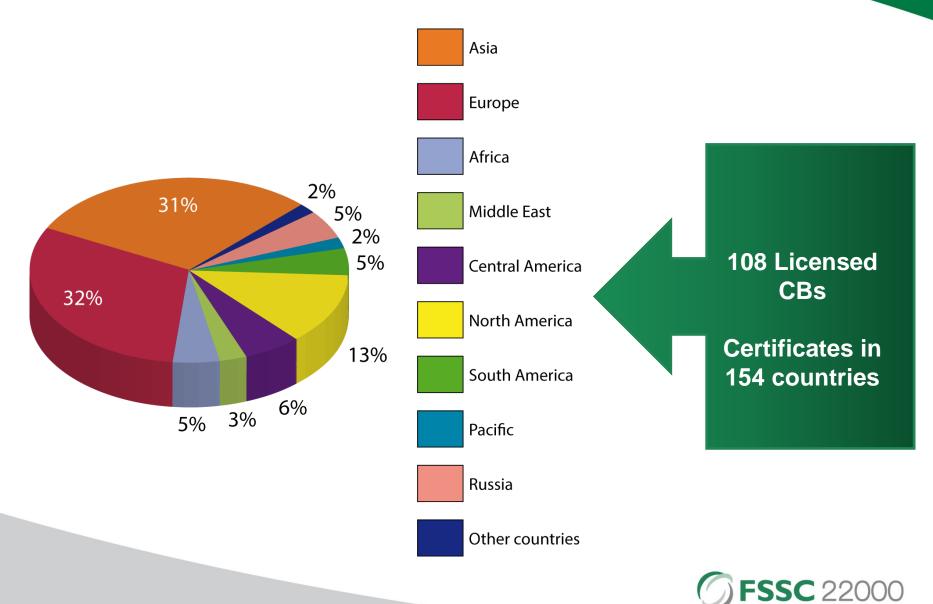


### 14,000+ FSSC 22000 certificates





# **Geographic distribution**



### **Global brands using FSSC 22000**





### New scheme document

- The new FSSC 22000 scheme documents can be found on the FSSC 22000 website
- <u>www.fssc22000.com</u>
- All documents can be downloaded from this website



### **New Scheme documents**

- Part 0; Definitions
- Part 1; Scheme overview
- Part 2; Requirements for certification
- Part 3; Requirements for certification process
- Part 4; Requirements for certification bodies
- Part 5; Requirements for accreditation bodies



### **New Scheme documents annexes**

- Annex 1 Part IV; Certificate scope statements
- Annex 2 Part IV; Audit time calculation
- Annex 3 Part IV; Nonconformity grading
- Annex 4 Part IV; Audit report template
- Annex 5 Part IV; Auditor competence
- Annex 6 Part IV; Certificate templates



### **New elements**

- 1. Unannounced audits
- 2. Food Fraud prevention and Food Defense
- 3. Auditor competence
- 4. Nonconformity grading
- 5. Audit report template
- 6. Audit and report time
- 7. Guidance documents included in Scheme documents
- 8. Scope extensions
- 9. Off-site activities
- 10. Multi-site



# 1. Unannounced audits

- Expectation by governments
- Wish from the industry after horsemeat scandal
- GFSI Benchmarking Requirements version 7
- Some schemes already practice it
- Pilots conducted



### **Unannounced audits**

- One of the surveillance audits unannounced
- Unannounced audit (UA) is full surveillance audit
- Audited site is not notified in advance
- UA takes place during operational working hours and can include night shifts
- A defined blackout period can be agreed
- If UA is refused, certificate shall be suspended



### Definition of 'black out days'

"Time periods shared by the applicant or certified organization with the CB that prevents the unannounced audit from occurring when the organization is not operating for legitimate business reasons"

Black out days are not further defined. CB and organisation have to mutually agree.



# 2. Food Fraud prevention & Food Defense

#### Food defense

The organization shall have a documented and annually reviewed food defense threat assessment procedure in place to identify potential threats and prioritize food defense mitigation measures.

#### Food Fraud prevention

The organization shall have a documented food fraud vulnerability assessment procedure in place to identify potential vulnerabilities and prioritize food fraud mitigation measures.



### Audit team

- The audit shall be carried out in a mutually agreed language
- Use of translators and technical experts is allowed



### **Auditor rotation**

- An audit team is not allowed to perform more than two 3 year certification cycles (six years) at the same certified site
- If an auditor starts auditing within the 3 year certification cycle he/she will be rotated out after 6 years



# 4. Requirements for follow-up on audits

- Three grading levels:
  - Critical nonconformity
  - Major nonconformity
  - Minor nonconformity
- FSSC does no longer allow the use of OFI



# Critical nonconformity (1)

- A critical nonconformity is issued where there is a critical failure to assure food safety, legality or certification integrity
- When a critical nonconformity is issued at a certified site, the certificate shall be immediately suspended for a maximum period of six (6) months



# **Critical nonconformity (2)**

- A follow-up audit shall be conducted by the CB within the 6 month time frame to verify the closure of the critical nonconformity
- The certificate shall be withdrawn when the critical nonconformity is not effectively solved within the six months time frame
- In case of a certification audit the full certification audit shall be repeated



# **5. Audit report template**

FSSC 22000 will require a mandatory audit report content:

- The client report can be in the native language
- The audit report that is uploaded in the FSSC 22000 is always in English



### 6. Additional on-site audit time

- 0.5 auditor day on-site when site has:
  - Less than 250 employees; and,
  - <u>Less</u> than 3 HACCP studies
- 1.0 auditor day on-site when site has:
  - 250 employees or more; or,
  - 3 HACCP studies or more



# 6. Additional preparation and reporting time

- At least 0.25 auditor day (2 working hours) shall be added to the FSSC 22000 on-site audit time for auditor audit preparation
- At least 0.5 auditor day (4 working hours) additional shall be added to the FSSC 22000 onsite audit time for audit reporting



### 7. "Old" guidance documents

- The FSSC 22000 version 3 guidance documents contained normative requirements
- These requirements are all included in the version 4 Scheme documents
- FSSC 22000 version 4 is more transparent and easy to understand



### 8. Scope extension

- Storage and transport (NEN-NTA 8059)
- Catering (ISO/TS 22002-2)
- Retail (BSI-PAS 221)



### 9. Off-site activities

The current FSSC 22000 split- process exemption is redrafted to include "off-site activities" in the FSSC 22000 certification Scheme

This is an exemption that requires permission of FSSC 22000.

"Split-process" is replaced by "off-site activities".

Off-site storage can be included in the FSSC 22000 scope of certification.



# **Requirements for off-site activities**

- 1. There is a primary manufacturing site and secondary sites for defined process steps
- 2. There is clearly one process involved, resulting in a finished product, which fits within the Scheme scope
- 3. The audit shall clearly include all relevant requirements at both the primary and secondary sites and allow audit and findings to be identified as site specific
- 4. The locations are under the same overall FSMS
- 5. The certificate shall show the product groups of all sites involved, but shall clearly identify which is the primary site
- 6. Full details of the off-site production locations shall be included in the audit report



# 10. Multi-site

- Certification of multi-site organizations and multi-site sampling (as described in ISO/TS 22003 and ISO/IEC 17021) is not applicable these food chain categories as listed in ISO 22003:2013
  - CI IV
  - DI and DII
  - I and K
- Multi-site shall be applicable for
  - Animal farming
  - Storage and transport
  - Catering
  - Retail



# **Transition period**

### FSSC 22000 Scheme version 4

• All certified sites, shall be audited against version 4 after January 1, 2018

### Additional audit time

- FSSC requires additional audit time for the upgrade to FSSC 22000 version 4
- Scheduled surveillance audit additional audit time
- Scheduled recertification audit no additional audit time



# **Transition period**

#### Accreditation

 The CB has to be accredited by the AB for FSSC 22000 version 4

### GFSI

 FSSC 22000 will be benchmarked against GFSI Benchmarking document Version 7



## **Transition period**

### Transition PAS 222 to ISO 22002-6

- As of January 1, 2018 it will also not be allowed anymore to issue PAS 222 certificates
- Certificates shall be transferred to ISO 22002-6
- ISO 22002-6 Available in database per July 2017



### **Priorities 2017**

- Roll-out FSSC 22000 version 4
- Benchmarking GFSI BR v7
- Integrity Program
- Technical support through webinars
- Regional approach
- Cooperation with governments





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