

DNV GL – Business Assurance and IFSQN

FSSC 22000 – AN UPDATED TOOL FOR TODAY'S REGULATORY ENVIRONMENT



with
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DNVGL – Business Assurance
and
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FSSC 22000

Who is DNVGL?

POSITION

Leading global
assurance provider

INDUSTRY FOCUS

- Food & Beverage
- Sustainability
- Other areas

LIFE SCIENCES

- Food & Beverage
- Healthcare
- Laboratories

ASSURANCE SERVICES

- Process
- Products
- Supply Chain

GEOGRAPHIES

- Leading Economies
- NA, EMEA, LATAM, APAC

CUSTOMERS

- Key/Global
- Enterprise
- Commercial

DIFFERENTIATORS

- Trust, independence, competence, global presence.
- A risk-based approach to sustainability.
- Significant difference: digitalization & big data.

Our role as an independent assurance provider

Assuring performance across industry sectors..

we operate throughout the value chain

.. helping our customers build stakeholder trust.



Supply Chain Management & Assurance

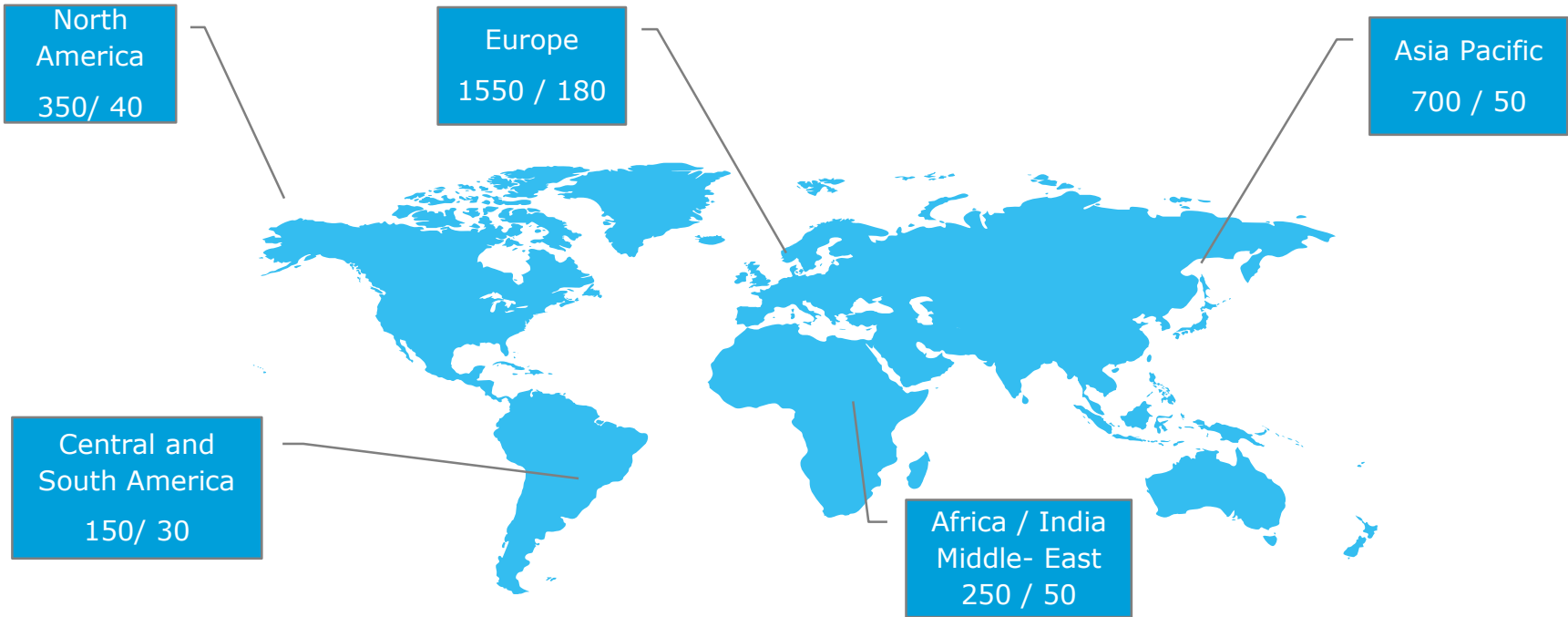
Our Services

- GFSI Certifications
 - BRC, IFS, SQF, **FSSC**, GlobalGAP
- Supply Chain Assessments
- Allergen Assessments
- Sustainable products
- Sustainable Sourcing
- Supply Chain Management
- Water & carbon foot printing
- Sustainability report assessment
- Sustainability strategy
- Training
- ...and more

Sourcing standards

- DNV GL's **Responsible Supply Chain Process Certification**
- **SMETA** (Sedex Members Ethical Trade Audit): Ethical auditing guidelines, a standard global auditing methodology.
- **BSCI** (Business Social Compliance Initiative): Improve working conditions in factories and farms.
- **ICS** (Initiative Clause Sociale) code of conduct: Ensure compliance with universal human rights principles and local labor regulations.
- **EICC** (Electronic Industry Citizenship Coalition) code of conduct: Ensure workplace safety, fairness and environmental responsibility.
- **SCC** (Safety Checklist for Contractors): Safety management by contractors engaged in hazardous work.
- **ETHIC Intelligence**: Anti-corruption policy
- **ISO 28000 & TAPA FSR**: Supply chain security management standards.

Global reach – Local competence



3000+

Auditors worldwide

350+

Food Safety Auditors globally

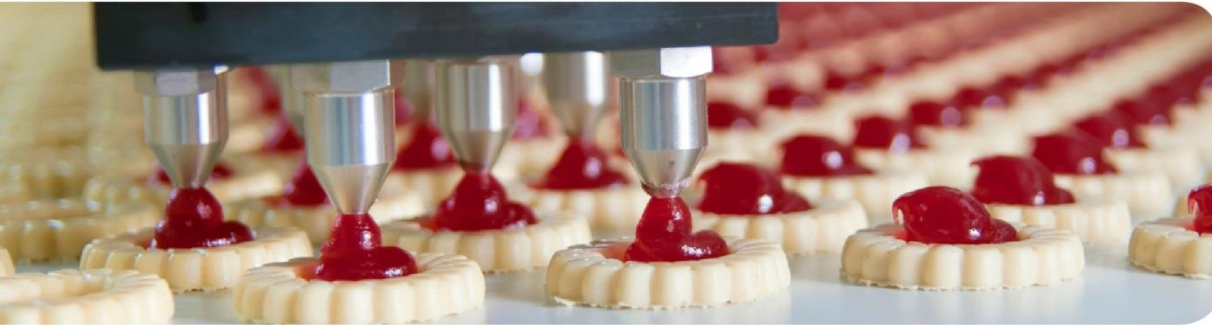
(see second numbers in the view here over)

60 % +

Auditors are our own employees

Global

We are present where you are, and/or where your suppliers are



FSSC 22000- An Updated Tool for Today's Regulatory Environment

Jacqueline Southee US Liaison, FSSC 22000
IFSQN – August 2017

Outline

- What is FSSC 22000
- Current status
- Why did it need to be updated
- New key elements
- How can it help with regulatory compliance

What is FSSC 22000?

Mission

“To be the world’s leading, independent, GFSI recognized, ISO based food safety and quality management certification scheme for the entire food supply chain.”



Why ISO?

- International Standards Organization (Est. 1946)
- Voluntary Standards developed by consensus
- Provide a common Global language
- Allows integration with other (ISO) management system standards such as:
 - ISO 22000, ISO 9001, ISO 14000, ISO 5000

FSSC 22000 comprised of 3 components

ISO 22000

- Food Safety Management System defines commitment, communication and engagement
- Applicable across the supply chain

PRP's

- Sector specific requirements for sanitation, hygiene , pest control, etc.
- Equivalent to GMP's (e.g. ISO/TS 22002-1)

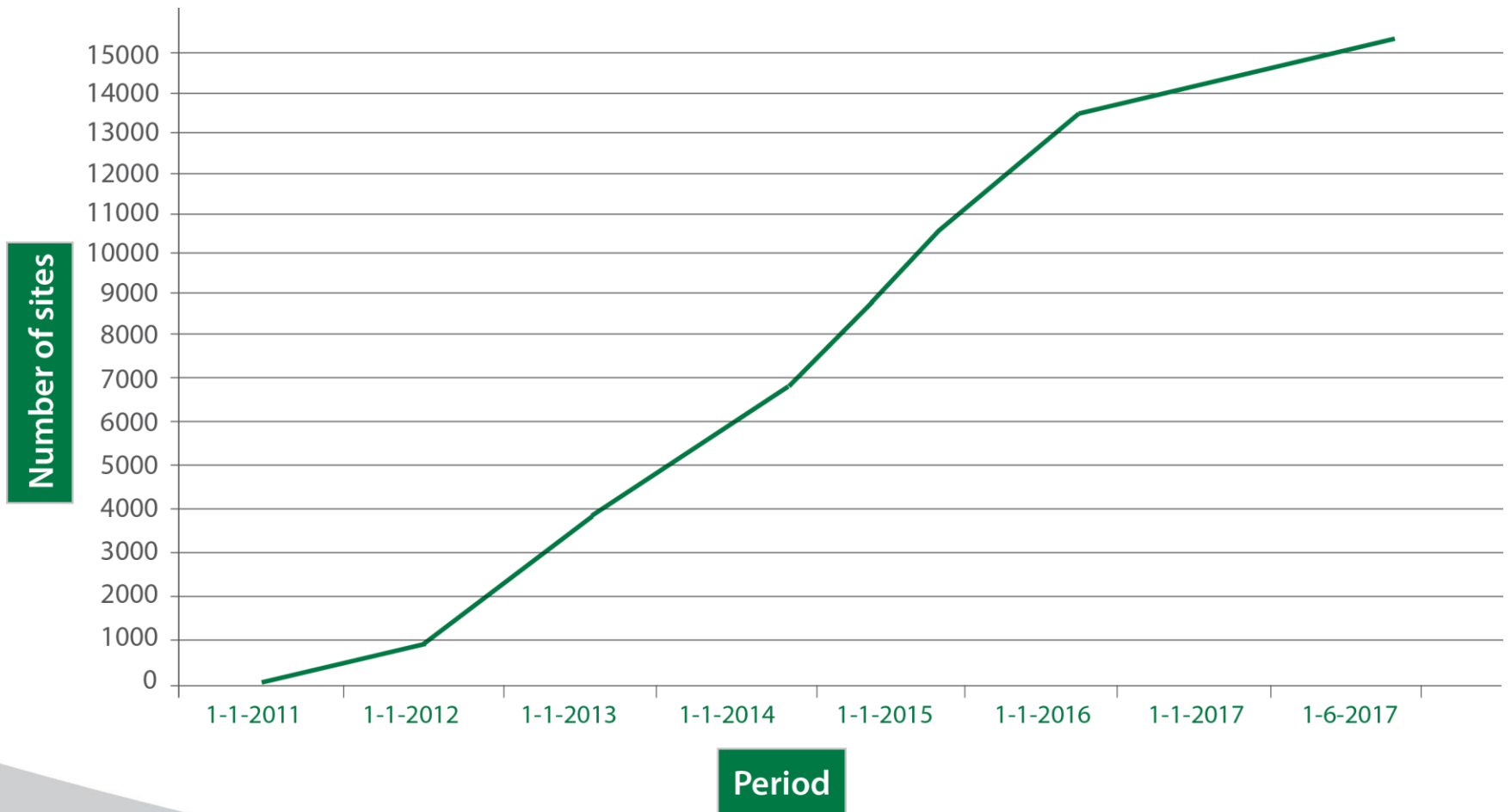
FSSC 22000 Additional Requirements

- Additional elements that are not covered by ISO 22000 or PRPs but required by major stakeholders

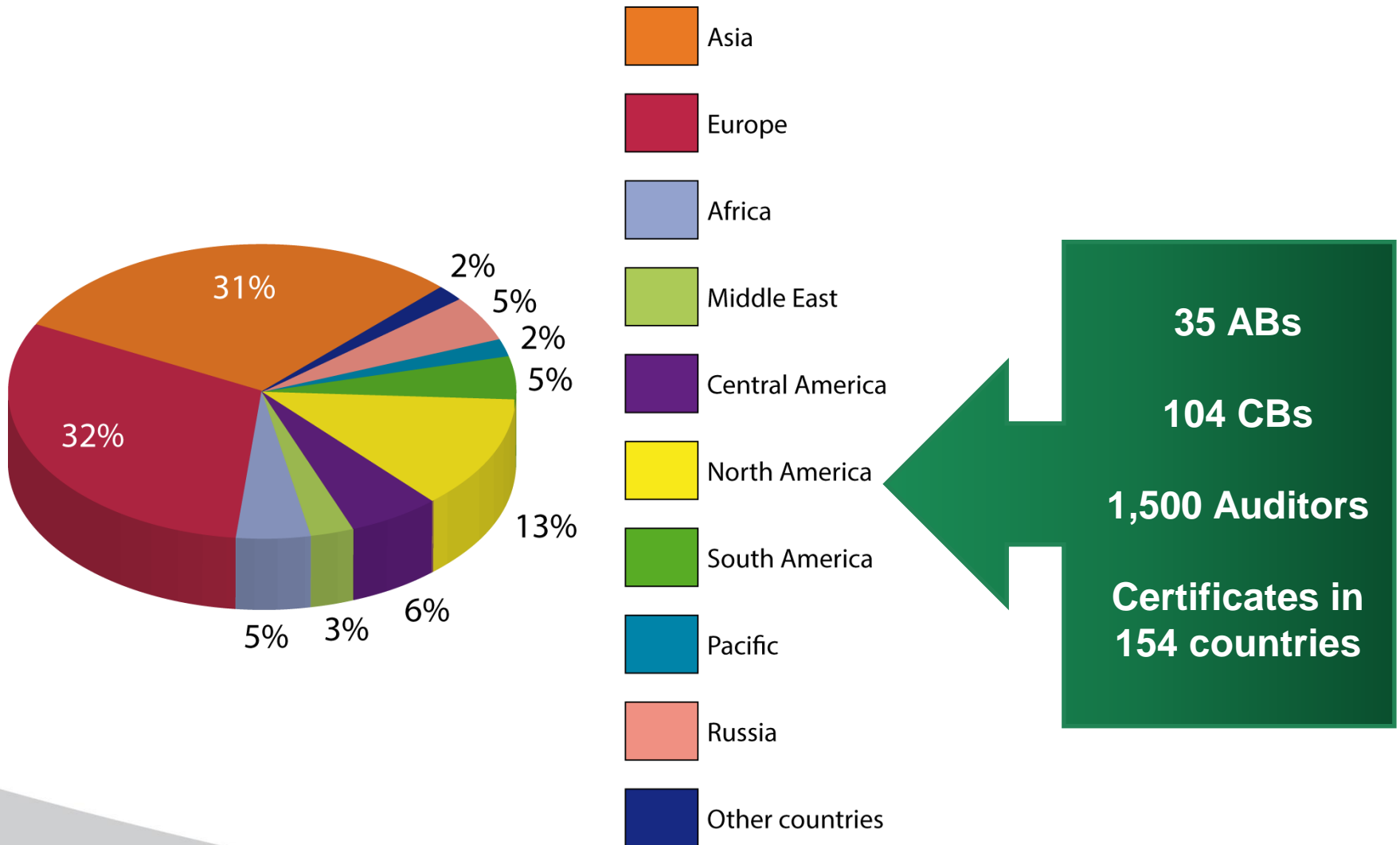
Current Status

- Revised to FSSC 22000 V 4.1
- Addition of Scopes
 - Retail, Catering and Storage & Transportation
- Inclusion of FSSC 22000-Quality
- Close to 17,000 certificates worldwide
 - Manufacturing = 14,500
 - Packaging = 2,500

Almost 17,000 FSSC 22000 certificates



Geographic distribution



Global brands using FSSC 22000



Scopes covered in the Scheme



Why Version 4.1

- Need to update; FSSC 22000 V1 published 2010
 - 2011 (V2) and 2013 (V3)
- Publication of GFSI GD v7.1
- EA Evaluation against EA1/22 requirements
- CB and AB Feedback
- New Requirements published July 2017

Reorganization of Scheme Requirements

Part 0 – Definitions

Part 1 – Scheme overview

Part 2 – Requirements for certification

Part 3 – Requirements for certification process

Part 4 – Requirements for CBs

Part 5 – Requirements for ABs



Revised Elements in FSSC 22000 V4

1. Unannounced audits
2. Food Fraud prevention and Food Defense
3. Auditor competence
4. Nonconformity grading
5. **Standardized Audit report template**
6. **Scope extensions**
7. Off-site activities
8. Multi-site
9. FSSC-Quality

Unannounced audits

- Expectation by governments
- Wish from the industry after horsemeat scandal
- GFSI Benchmarking Requirements version 7
- Pilots conducted
- Replace at least one surveillance audit

Food Defense

- Requirement for a documented threat assessment procedure to identify potential threats, develop control measures to reduce or eliminate identified threats.
- The defense plan will include procedures and records, will be supported by the organization's Food Safety Management System and comply with applicable legislation.

Food Fraud prevention

- Requirement for a documented food fraud vulnerability assessment procedure to identify potential vulnerabilities and prioritize food fraud mitigation measures.
- The plan will include control measures to control or eliminate vulnerabilities, will be supported by the organization's Food Safety Management System and comply with applicable legislation.

Allergen Management

- Requirement to consider potential allergen cross contamination and take measures to control or eliminate risk
- Controls measures will be subject to validation and verification
- Products intentionally or potentially containing allergenic materials labelled according to regulatory requirements.

Environmental Monitoring

- Requirement for an environmental monitoring program to verify the effectiveness of cleaning and sanitation programs which shall meet the verification requirements as described in ISO 22000
- Program will meet the verification requirements as described in ISO 22000.

Other revisions include...

- Addition of scopes
 - Storage & Transportation
 - Retail
 - Catering
- Requirement for a standard audit report format
- Refined requirements for auditor competence and accreditation

...and then there was FSMA

- Long awaited revision of the US Food regulation
- Update of GMPs and introduction of HARPC
 - Food safety plan with preventive controls
- US-Centric but with far reaching influences
 - Focus on supply chain, training and culture

**How can FSSC 22000 help with
FSMA compliance?**

GFSI certification vs FSMA compliance

- Gap analysis of FSSC 22000 vs FSMA



“FSSC 22000 required elements exceed the rule in several areas. Where it is not exceeding ...measure comparable to the Final Rule requirements”.

- *There are no elements of the FDA preventive control and cGMP requirements that are clearly just ‘missing’ in FSSC 22000 that we could determine...”*

“A GFSI certified facility will be in a good place to meet the requirements of FSMA..”

FSMA and FSSC 22000 – Similarities

- Preventive controls and flexible management system approach
- Both require flexibility with accountability
- HARPC compares with HACCP and oPRPs
- Food Safety Plan compares with FSMS
- Training and engagement is important
- Communication and Commitment



“Mind the Gap”

- Great alignment – but differences in the details
 - Specific nature of regulatory requirements
 - Increased documentation (Sub Part F)
 - Supply chain preventive control (Sub Part G)
- Where are the gaps?

FDA FOOD SAFETY
MODERNIZATION ACT

 **FSSC** 22000

Closing the Gap with V4.1

- Line by line Comparison
 - FSSC 22000 vs PCHF
- Supplement to be produced
- Focus on the demands of FSMA
 - Increased documentation
 - Verification of suppliers
 - Preventive controls for allergen management, sanitation and supply chain

FDA FOOD SAFETY
MODERNIZATION ACT

 **FSSC** 22000

FSSC 22000 as a tool to aid compliance

- Offers a common approach to food safety management and risk assessment
- Develop public – private partnerships
- Extend resources of FDA
- Transparency to help in supplier verification
- Continuous improvement by data sharing
- Contribute to global food safety

Let's connect!

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SAFER, SMARTER, GREENER

Q&A