



Food Safety Compliance training

With our Food Safety Compliance for QA managers training we go back to the basics, the foundation to properly fulfill the complex function of QA manager, now and in the future.

Part 1: Introduction

- Food Safety Compliance
- HACCP introduction
- Methodology
 - Prerequisite program
 - Control measures
- HACCP study: specific hazards
- HACCP study: decision tree, raw materials and processes
- Our company: HACCP
- Legislation
 - EU regulations & Information sheets & Recall
 - Food Safety Authority

Introduction

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In which field
do we operate?



Food Management:

- Dynamic playing field
 - 2000 quality requirements
 - 100 suppliers
 - 100 customers
 - 100 employees
 - 400 legislative changes



Legislation: HACCP

- Hazard analysis
- Overview of pathogens, chemical hazards
 - Pathogenic bacteria
 - Mycotoxins
 - Other biotoxins
 - Viruses, ricketts and prions
 - Parasites & Pests
 - Chemical & Physical
 - Zoonoses & Extensive Toxins
 - Spoilers

- Hazard analysis
 - Control of raw material hazards
 - Process hazard management
 - HACCP-team
 - Decision tree
 - Control measures



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HACCP



Analysis:

Physical hazards

- Physical hazards usually involve foreign substances such as metal particles, glass, bones, or stones that can cause cuts in the mouth, break teeth, cause choking, or perforate the gastrointestinal tract.
- This includes various materials such as those originating from land, animals, glass objects, metal objects etc. With respect to chemical and biological hazards, physical hazards are often visible and can be felt.



Analysis: Chemical hazards

- Chemical hazards include substances that adversely affect health, because they are acutely dangerous or because they cause damage in the long term. The following types of substances should be considered:
 - Substances of natural origin,
 - (Agricultural) chemicals,
 - Environmental pollution.



Analysis: Biological hazards

- When making an inventory of the biological hazards, it is important to identify those factors and microorganisms that play a role in the occurrence of food spoilage, food infection, and food poisoning. The presence and occurrence of microorganisms in food is determined by three factors, namely:
 - Factors determining the “introduction” (sources).
 - Factors influencing the growth of microorganisms (conditions).
 - Factors by which microorganisms are killed (processes).



Biological hazards:

Bacteria

- Examples of infectious pathogens:
Campylobacter jejuni, *Salmonella*,
Shigella, *Escherichia coli*, *Vibrio cholerae*, *Vibrio parahaemolyticus*,
Listeria, etc.
- Examples of toxigenic pathogens:
Bacillus cereus, *Clostridium botulinum*,
Clostridium perfringens, *Staphylococcus aureus*, fungi, etc.



Biological hazards:

Viruses

- Small round structured viruses (SRSV's) appear to be the main cause of food-related viral infections.
- The food-related infections are mainly caused by people contaminating ready-to-eat food.



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Methodology

- Firstly, the prerequisite program (PRP) must be completed.
- The entire food safety plan is based on a prerequisite program, followed by HACCP-based procedures.
- In the HACCP study, specific hazards are related to the raw materials and the processes.
- For the purpose of clarifying generic hazards that are reduced to an acceptable level by means of the PRP, an additional control measure table has been drawn up to also operationalize the PRP in procedures.
- This is not necessary according to the principles of HACCP.
- The hazard analysis is based on the Codex Alimentarius, scientific documents and legal texts.
- The hazard analysis has been drawn up per process step and per product (raw material, admixture, end products). This involved looking at microbiological, chemical, and physical hazards. All this according to the likelihood and consequence principle.

Prerequisite program

- Prerequisite program
- Reference: Codex Alimentarius, 'General Principles of Food Hygiene' CAC/RCP 1-1969, Rev. 3, 1997, Amended 1999.

Prerequisite program (1/6)

- 2. Establishment: design and facilities
 - 2.1.1 Establishment
 - 2.1.2 Equipment
- 2.2 Premises and rooms
 - 2.2.1 Design and layout
 - 2.2.2 Internal structures and fittings
 - 2.2.3 Temporary / mobile premises, vending machines
- 2.3 General
 - 2.3.1 Food control and monitoring equipment
 - 2.3.2 Containers for waste and inedible substances
- 2.4 Water supply
 - 2.4.1 Drainage and waste disposal
 - 2.4.2 Cleaning
 - 2.4.3 Personnel hygiene facilities and toilets
 - 2.4.4 Temperature control
 - 2.4.5 Air quality and ventilation
 - 2.4.6 Lighting
 - 2.4.7 Storage

Prerequisite program (2/6)

- 3.1 Control of food hazards
 - 3.2.1 Time and temperature control
 - 3.2.2 Specific process steps
 - 3.2.3 Microbiological and other specifications
 - 3.2.4 Microbiological cross contamination
 - 3.2.5 Physical and chemical contamination
- 3.3 Incoming materials requirements
 - 3.3.1 Specifications
 - 3.3.2 Control at reception
 - 3.3.3 Stock rotation
- 3.4 Packaging
 - 3.4.1 Design and materials
 - 3.4.2 'Food-grade' materials and gases
 - 3.4.3 Reusable packaging
- 3.5 Water
 - 3.5.1 Water in contact with food

Prerequisite program (3/6)

- 3.5.2 Reuse of re-circulated water
- 3.5.3 Reuse of re-circulated, non-treated water
- 3.5.4 As an ingredient
- 3.5.5 Ice and steam
- 3.6 Management and supervision
 - 3.6.1 Type of control and supervision
 - 3.6.2 Knowledge required
- 3.7 Documentation and records
 - 3.7.1 Retain records
 - 3.7.2 Effectiveness and credibility
- 3.8 Recall procedures
 - 3.8.1 Effective procedures
 - 3.8.2 Tracing & Tracking
 - 3.8.3 Destroy or reprocess

Prerequisite program (4/6)

- 4 Establishment: maintenance and sanitation
 - 4.1 Maintenance and cleaning
 - 4.1.1 General
 - 4.1.2 Cleaning procedures and methods
 - 4.2.1 Specifications
 - 4.2.2 Monitoring and verification
 - 4.3 Pest control
 - 4.3.1 General
 - 4.3.2 Preventing access
 - 4.3.3 Harborage and infestation
 - 4.3.4 Monitoring and detection
 - 4.3.5 Eradication
 - 4.4 Waste management
 - 4.4.1 Removal, storage
 - 4.4.2 Cleaning
 - 4.5 Sanitation systems
 - 4.5.1 Monitoring
 - 4.5.2 Verification
 - 4.5.3 Review

Prerequisite program (5/6)

- 5 Establishment: personal hygiene
 - 5.1 Health status
 - 5.1.1 Access prevention
 - 5.2 Illness and injuries
 - 5.2.1 Conditions to be reported
 - 5.3 Personal cleanliness
 - 5.3.1 Protective clothing
 - 5.3.2 Cuts and wounds
 - 5.3.3 Washing hands
 - 5.4 Personal behavior
 - 5.4.1 Smoking, eating, sneezing
 - 5.4.2 Jewelry
 - 5.5 Visitors
 - 5.5.1 Cleanliness and behavior

Prerequisite program (6/6)

- 6 Transport
 - 6.1 General
 - 6.2 Requirements
 - 6.3 Use and maintenance
- 7 Product information and consumer awareness
 - 7.1 Batch identification
 - 7.2 Product information
 - 7.3 Labelling
 - 7.4 Consumer education
- 8 Training
 - 8.1 Awareness and responsibilities
 - 8.2 Training programs
 - 8.3 Instruction and supervision
 - 8.4 Refresher training

Our company

Question 1: How does the Prerequisite program look like for our company?



Pure and honest

Methodology specific hazards

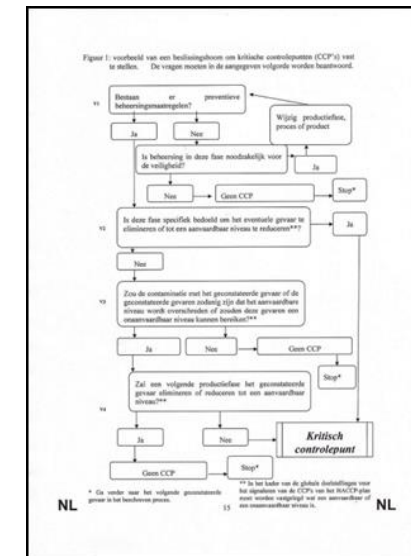
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HACCP study: specific hazards

- Hazard analysis
 - Overview of pathogens, chemical hazards
 - ✓ Pathogenic bacteria
 - ✓ Mycotoxins
 - ✓ Other biotoxins
 - ✓ Viruses, rickets and prions
 - ✓ Parasites & Pests
 - ✓ Chemical & Physical
 - ✓ Zoonoses & Extensive Toxins
 - ✓ Spoilers
 - Specific hazards: Codex approach
 - ✓ Raw materials and information sheets like 64/65/85 (Dutch Authority)
 - ✓ Processes
 - HACCP approach validated weekly in audits and part of the iMIS Food Updates.
- Hazard analysis
 - ✓ Control of raw material hazards
 - ✓ Process hazard management
 - ✓ HACCP-team
 - ✓ Decision tree
 - ✓ Control measures



HACCP study: specific hazards background information

iMIS Food Legislation

Legislation

- iMIS Food Legislation
 - Bad Bug Book FDA
 - Codex Alimentarius
 - EFSA Journals
 - ENG Consolidated Regulations
 - ENG IMIS Food categories
 - ENG IMIS Hazards
 - ENG IMIS Hazard tables
 - ENG IMIS Product Groups
 - ENG IMIS Status Food Safety
 - FAO Documents
 - Food Safety Authority of Ireland
 - Forms
 - FSA UK Documents
 - Consolidated Regulations
 - Old Consolidated Regulations
 - iMIS Food HACCP training material
 - traded Hazards
 - iMIS Hazard tables**
 - Chemical
 - Physical
 - Mycotoxins
 - pests
 - Other biotoxins
 - parasites
 - Pathogenic bacteria
 - Viruses, ricket and prions
 - Zoonoses (Not relevant for Food)

iMIS Food Legislation

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 - iMIS Food HACCP training material
 - traded Hazards
 - iMIS Hazard tables
 - iMIS Product groups
 - NVWA expertise statements
 - NVWA Food Additives Handbook
 - NVWA Food labeling manual
 - NVWA Novel Food Handbook
 - NVWA Nutrition and Health Claim
 - NVWA Food Safety Handbook
 - NVWA Information Sheets
 - NVWA Knowledge Sheets**
 - 3-Monochloropropandiol-1,2
 - 4-Hexylresorcinol (4-HR)
 - Acrylamide

NVWA Knowledge Sheets

Bron; VOICE

NVWA knowledge Sheets

- 3-Monochloropropandiol-1,2
- 4-Hexylresorcinol (4-HR)
- Acrylamide
- Abbreviations
- Aflatoxin
- General Allergens - Food Allergy and Food Intolerance
- General crop protection products
- General Marine Toxins
- General mycotoxins
- General vitamins
- Aluminium
- Arsenic
- Azaspic acid poisoning (AZP)
- Bacillus cereus
- Bacillus seleniformis
- Bacillus subtilis
- Bacterial poisonings and infections
- Barium
- benzene
- Bioterrorism, Biological Agents with Guidance
- Assurance of food safety in the food chain regarding the dangers associated with the purchase of ready-to-eat products
- Brucella melitensis
- Butyl Hydroxy Anisole (BHA)
- Cadmium
- Campylobacter spp.

Risk determination method

Systematics Statement

Risk analysis statement (based on: Probability x Severity = Risk)

Probability:

Probability level 0 = there is no danger or the danger is not (yet) known

probability level 1 = the reality that a hazard can occur

Severity:

Severity level 0 = no danger to public health

Severity level 1 = any known threat to public health

Risk:

By combining the probability with the severity, the degree of risk can be determined, see table below PROBABILITY x SERIOUS = RISK

Probability ▼

1	No risk	Risk
0	No risk	No risk
Severity ►	0	1

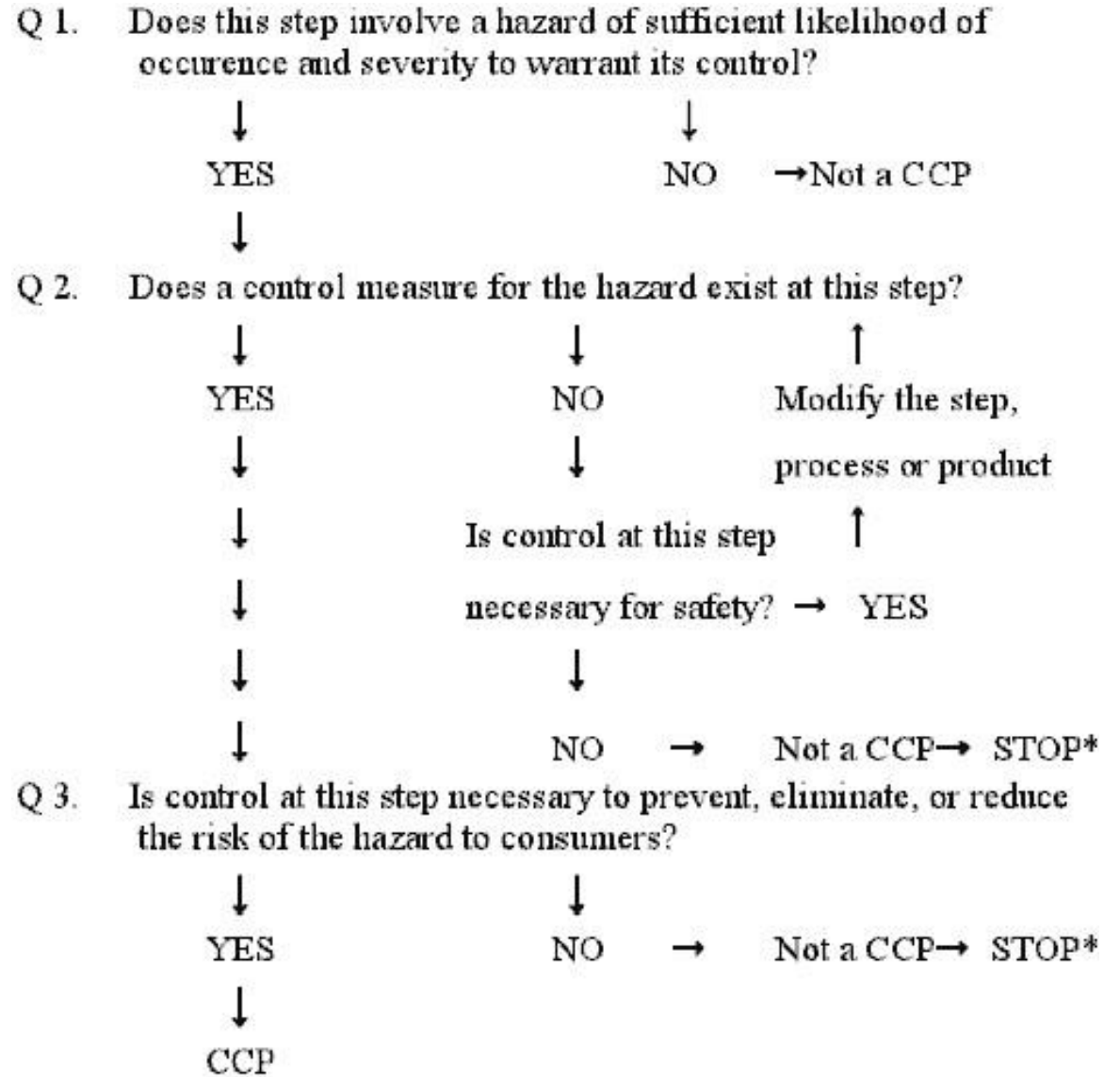
Red – CCP

Green – no risk

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Decision tree



HACCP study: raw materials and processes

Raw material	Hazard	Type of Hazard	Cause	Potential effect	Probability to occur	Risk = probability x potential effect	Control measure	Is control of this risk necessary?	Is this phase specifically intended to eliminate the potential hazard or	Would the contamination with the identified hazard be such that the	Will a subsequent production phase eliminate the identified	CCP: Critical control point	Nr.	Substantiation
All kinds of unprocessed poultry meat	Presence of pathogenic microorganisms such as Salmonella and parasites	Microbiological	Incorrect slaughtering process	1	1	1	None, but minimal purchasing on specification	Yes	No	Yes	Yes			The meat will be heated at a later stage in which the vegetative pathogenic microorganisms will be killed.
All kinds of unprocessed poultry meat	Residues of veterinary drugs	Chemical	Misuse of veterinary medicines	1	0	0	None, but minimal purchasing on specification	No						No risk due to National plan
All kinds of unprocessed game	Presence of pathogenic microorganisms such as Salmonella and parasites	Microbiological	Incorrect slaughtering process	1	1	1	None, but minimal purchasing on specification	Yes	No	Yes	Yes			The meat will be heated at a later stage in which the vegetative pathogenic microorganisms will be killed.

HACCP study: raw materials and processes

Raw material	Hazard	Type of Hazard	Cause	Potential effect	Probability to occur	Risk = probability x potential effect	Control measure	Is control of this risk necessary?	Is this phase specifically intended to eliminate the potential hazard or	Would the contamination with the identified hazard be such that the	Will a subsequent production phase eliminate the identified	CCP: Critical control point	Nr.	Substantiation
General														
Receives perishable raw materials	Outgrowth of pathogenic microorganisms	Microbiological	Incorrect transport of raw materials	1	1	1	Measure the temperature	Yes	Yes			CCP	1	The meat will be heated at a later stage in which the vegetative pathogenic microorganisms will be killed.
Receipt of frozen products	Outgrowth of pathogenic microorganisms	Microbiological	Transport temperature too high	1	0	0	None	No				Legal condition (LCP)		Only when frozen products are delivered above 7 ° C can there be dangers for public health. There is, however, a legal requirement of -15 ° C.
Receipt of other raw materials	No specific danger													
Storage of frozen products	Outgrowth of pathogenic microorganisms	Microbiological	Transport temperature too high	1	0	0	Frozen temperature measurement	No				Legal condition (LCP)		Only when frozen products are delivered above 7 ° C can there be dangers for public health. There is, however, a

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Our company

- Question 2: How does the HACCP study look like for our company?
- Question 3: How does the CCP and OPRP monitoring table look like?

Cornelis Bartlema
FOOD GROUP

Pure and honest

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Legislation: EU regulations

- 1990-496 Nutritional information
- 2002-178 General Food Law
- 2005-2073 Microbiological criteria
- 2005-396 Pesticide residues
- 2006-1881 Contamination of food
- 2006-1924 Nutrition and health claims
- 2008-1333 Additives
- 2008-1334 Aromas
- 2011-1169 Food information

Legislation: Info Sheets & Knowledge Sheets

Info Sheets: how to deal with sampling

- Info sheet 64
- Info sheet 65
- Info sheet 85

Knowledge Sheets

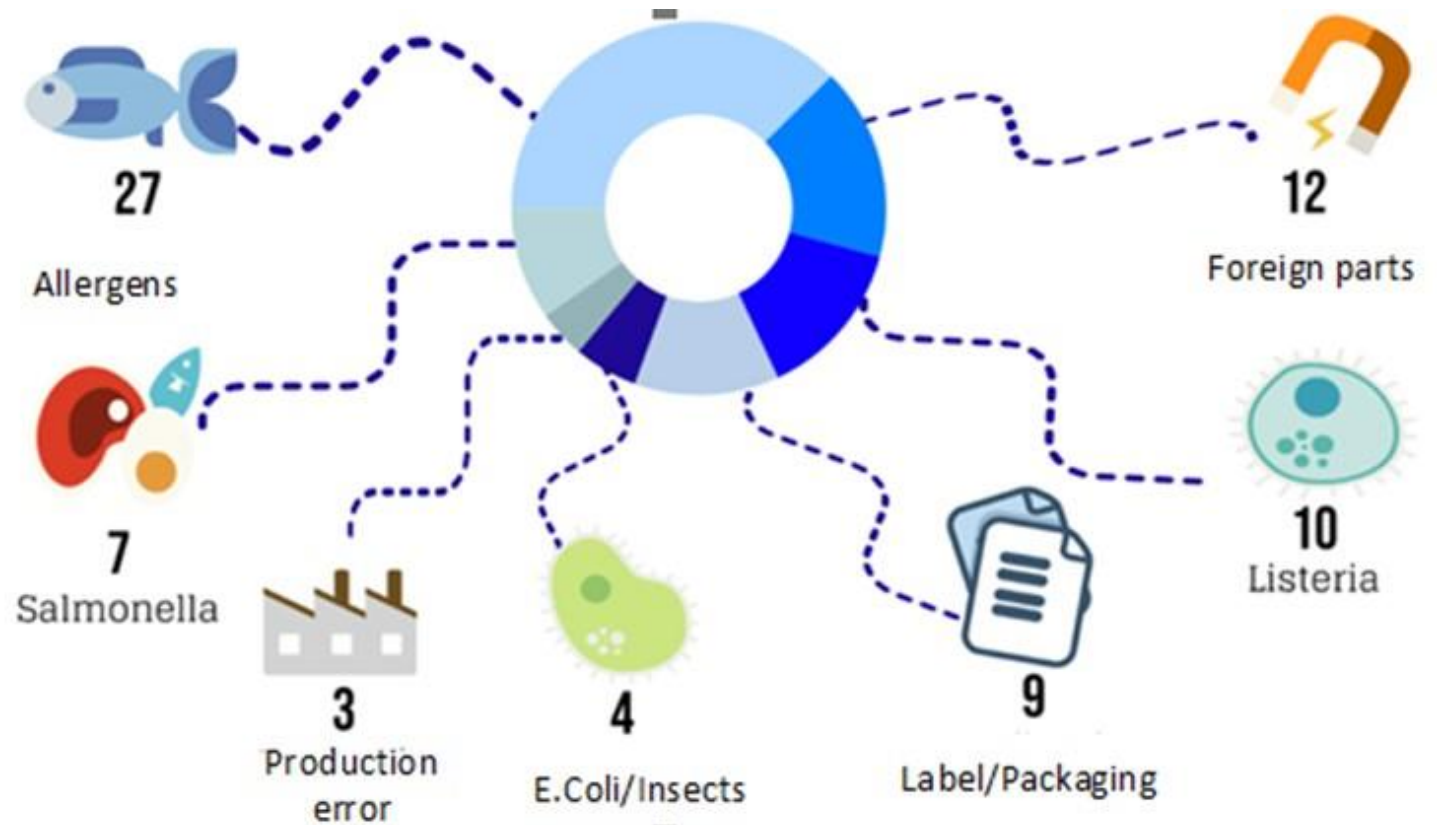
- Food allergy and food intolerance
- Bioterrorism, biological agents with guideline
- Contaminants from PVC packaging
- Contaminants from packaging by irradiation
- Paralytic shellfish poisoning (PSP)
- Toxoplasma gondii
- Zoonoses

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Legislation: Recall

- 2002-178 General Food Law
 - Article 19: By order of competent authority
 - Office for risk assessment
 - Reporting guide
 - Issue management
-
- RASFF - Food and Feed Safety Alerts

Legislation: Dutch recalls 2019





Our company

- Question 4: What does our Recall procedure look like?
 - Does this refer to the reporting guide?
 - Does it state when the certifier must be contacted?

Cornelis Bartlema
FOOD GROUP

Pure and honest

Food Safety Authority

- 1. Tracing
 - Properly recording the current method of tracing all normal products as well as any biological flow.
 - Describe any missing trace actions in more detail and record them in additional records.
 - Method of tracing closed weekly: demonstrably correct.
- 2. Additives
 - Raw materials, Recipes, End products up to date
 - 2 E-number analysis on this product portfolio
 - Keep E-number analysis up to date

Food Safety Authority

- 3. Microbiology
 - Check microbiological plan for legislation.
 - Check microbiological plan last year for compliance.
 - Carefully implement current year microbiological plan.
- 4. Listeria
 - Demonstrable compliance with Listeria legislation.
 - Analysis of current product portfolio in which FSSP (listeria modeling software) must be substantiated with, among others, why Challenge tests have or have not been carried out.
 - Describe the Listeria approach that demonstrably meets the legal requirements.

Food Safety Authority

- 5. STEC
 - 5A Using the product portfolio, analyze which raw products to be consumed can have STEC as a problem.
 - 5B Conform STEC to EU policy and guarantee these products regarding STEC
 - 5C Info sheet 64 of Dutch Authority (NVWA) considered for STEC
- 6. Electronical Data Processing (EDP) audit
 - 6A Administrations may be taken without any reason / suspicion

NVWA fines the company half a million euros for not cooperating with a recall of potentially contaminated pork.

NVWA fined a meat processing company of more than EUR 500,000. In 2018, despite the NVWA's urging, the company did not take sufficient measures to remove pork that may have been contaminated with *Salmonella* from the market. In addition, the meat processor has asked its customers to ignore instructions from the NVWA to withdraw products from the market.



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Part 2: Contents

- Food Safety Compliance
- FSSC22000
- What should you pay attention to?
- FSSC22000, version 5 HLS
- QESH standards
- HACCP team: tasks
- HACCP team: annual reports

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QUALITY HOLISTICS



			Specifications	Quality Activity Monitoring	Traceability	Assessment
QUALITY STANDARDS			CERTIFICATION MANAGEMENT			
EFQM INK ISO9001:2000 ISO17025	SQF Eurepgap GMP Animal Feed AIB	HACCP BRC IFS EFSIS	real time standard requirements	Operational Framework	Test	Risk Quality Standard evidence based practice
ACCREDITATIONAL BODIES		CERTIFICATIONAL BODIES				
CUSTOMERS		CONSUMERS		DEMAND RELATIONSHIP MANAGEMENT (SRM)		
Retail Organisations Food Service Wholesalers and Trade Food Manufacturers Out of Home Outlets Hospitals	Habits, Attitudes Preferences Allergens Quality Needs Information Needs	product, process requirements	Information Centre Demand Quality Information Centre (DQIC)	Products Specifications	Customer Satisfaction Consumer Needs	
FOOD AND DRINK FACTORY			BUSINESS PERFORMANCE MANAGEMENT (BPM)			
FOOD & DRINK MANAGEMENT			process, product and people requirements	Training, Support, Procedures, Quality Documents, Quality Database	Ingredients, Semi-products	Business System
LABORATORIES	PRODUCT SUPPLIERS	SERVICE SUPPLIERS	SUPPLY RELATIONSHIP MANAGEMENT (SRM)			
Microbiological Analytical	Raw materials Equipment Packaging Machines	Cleaning and Hygiene Pest Control Measurements Cooling Systems	process, product and people requirements	Supply Quality Information Centre (SQIC)	Raw materials Specifications	Suppliers
GOVERNMENT CONTROL BODIES			LEGISLATION MANAGEMENT			
Global International National Where appropriate	General Food Law Codex Alimentarius		legal requirements	legal requirements: - people - products - process - building	Informed	Risks Legal evidence based practice
LEGISLATIONS						



PLAN

Risk Assessment
Legal Compliance
Blue Print
Operational Framework
Yearly Plan

DO

Document Generator
Audit-system
SpecCheck
Training
Supportive Material
Track and Trace

CHECK AND ACT

Quality Data Warehouse
Quality Cockpit
Standard Reports

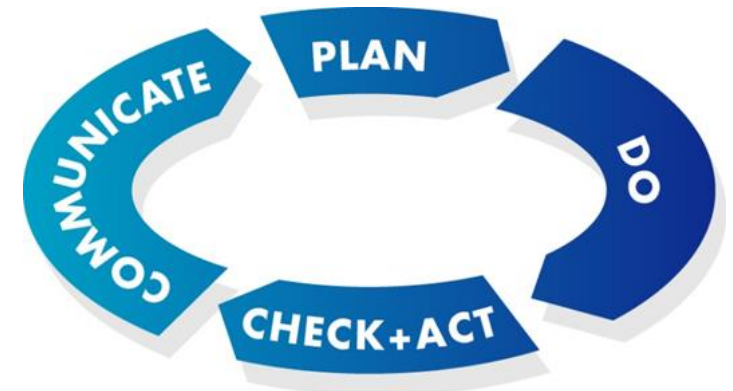
COMMUNICATE

Newsletter
www.iMISQA.com
SpecReport
Quality Information Centre
Supplier Portal



iMIS Food content & software

- iMIS: integral Management & Information System
- Food: for real-time management of food safety
- Content
 - Operational framework for food safety
 - Food Safety standards: HACCP, FSSC22000, BRC, IFS
 - Extra for QESH: ISO9001, 14001, 26000
- Software
 - User-friendly



Food Management:

- Dynamic playing field
 - 2000 quality requirements
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Standards

- Quality:
 - BRC
 - IFS
 - FSSC22000
 - SQF
 - Dutch HACCP
 - Quality marks such as HALAL, SKAL, UTZ
- Environment: ISO14001
- Occupational health and safety: ISO45001
- Corporate Social Responsibility:
 - CSR Performance Ladder (ISO26000)



Standards

- Food Production parameters
 - Product
 - Process
 - Person
 - Production area

- Food Defense
- Food Fraud
- Not just for production: traders too
 - HACCP of the entire chain

- Retail customer? 2 Certifying Institutes and 2 Certificates!
- Freelance auditors...
- Organic certification <-> Food Safety Authority <-> EDP audit



Standards in practice

- Most food companies are BRC, IFS, or FSSC22000 certified
- What are the differences and similarities between these standards?
- How do you set up your quality system, documentation, and compliance?
- How do you deal with difficult audit situations?
- As a company, can you cancel the audit yourself if you want to?
- Based on more than 500 audits, knowledge is transferred about how you can best demonstrably meet the quality standards
- How are the certification bodies organized?
- Expand the food safety system to ISO9001, ISO14001 and the CSR performance ladder

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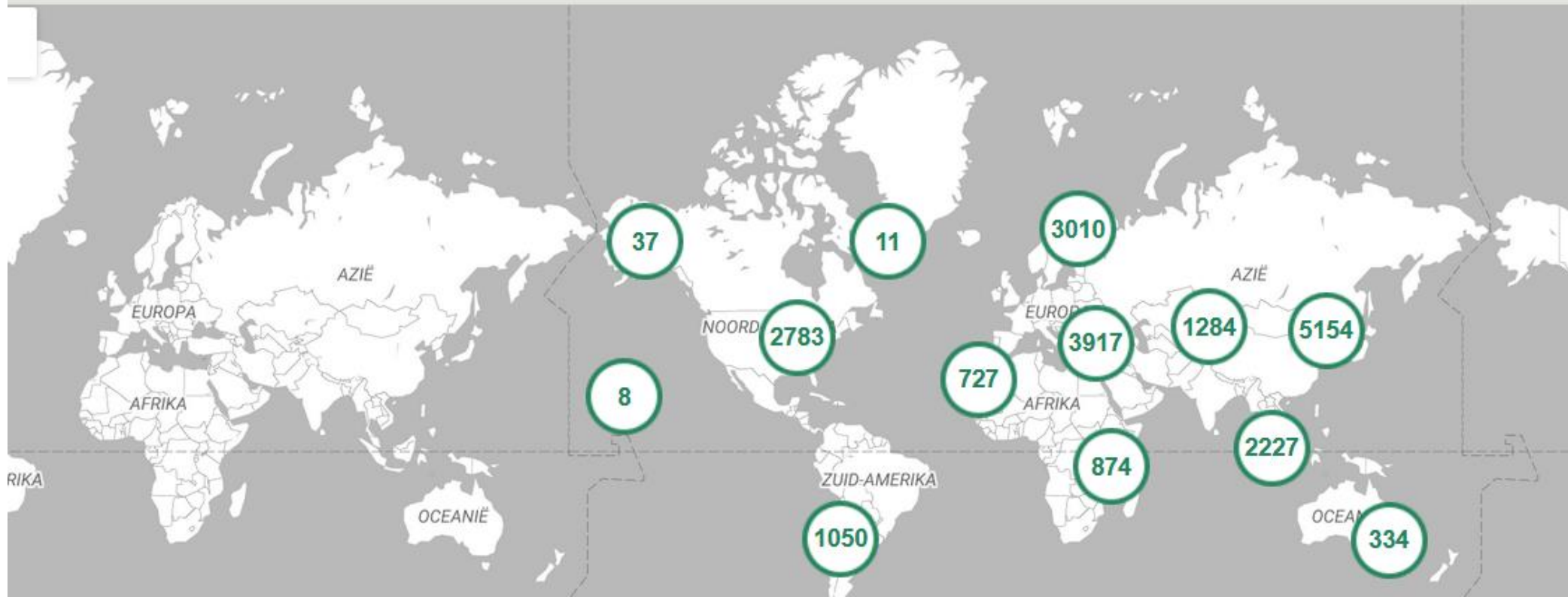
FSSC22000

- FSSC 22000 stands for Food Safety System Certification 22000 and is an internationally recognized form of demonstrable food safety.
- The FSSC 22000 has its origins in the Codex Alimentarius and is a standard developed by the Foundation for Food Safety Certification
- The FSSC 22000 standard is becoming increasingly popular within the food industry, because it has been approved by the GFSI (Global Food Safety Initiative).



FSSC

Found **23768** Certified Organizations



What is FSSC 22000 based on?

- ISO 22000:2018
- Sector specific Pre-Requisite Program (PRP) ISO/TS 22002
- Specific FSSC 22000 requirements
- The FSSC 22000 standard is a food safety management system that focuses on the PDCA approach
- Both at the organizational level and at the operational level
- Focus on risk-based thinking and in the field of HACCP

ISO22000: standard requirements

- 4 Context of the organization
- 5 Leadership
- 6 Planning
- 7 Support
- 8 Operation
- 9 Performance evaluation
- 10 Improvement

ISO/TS 22002 15 standard requirements

- 4 Construction and layout of buildings
- 5 Layout of premises and workspace
- 6 Utilities – air, water, energy
- 7 Waste disposal
- 8 Equipment suitability, cleaning and maintenance
- 9 Management of purchased materials
- 10 Measures for prevention of cross contamination

ISO/TS 22002 15 standard requirements

- 11 Cleaning and sanitizing
- 12 Pest control
- 13 Personnel hygiene and employee facilities
- 14 Rework
- 15 Product recall procedures
- 16 Warehousing
- 17 Product information/consumer awareness
- 18 Food defense, biovigilance and bioterrorism

•FSSC 22000 does not work with scores on the certificate. There is, however, a three-year cycle in which one unannounced audit is compulsory in those three years.

FSSC22000 audits

- Do not forget the appendix: extra standard requirements (nice surprise during an audit if these are not explained in the cross table)
- FSSC 22000 does not work with scores on the certificate. There is, however, a three-year cycle in which one unannounced audit is compulsory in those three years.
- Use PAS 96 for Food Defense

Other standards relative to FSSC 22000

- The big difference between FSSC 22000 and, for example, the BRC and IFS, is that there is no checklist stating exactly what is and what is not accepted (as is the case with BRC/IFS)
- The FSSC 22000 standards leaves more room for interpretation and personal insight. This is both an advantage and disadvantage.
- Certain risks can be excluded by means of well-founded arguments in the HACCP-analysis. In this way, a practical and workable system can be created for every company.

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What should you pay attention to?

- Do not forget Appendix FSSC, including services
- Knock Outs at IFS
- Fundamentals at BRC
- Management board expectation:
 - 80% of audit results dependent on the auditor
 - Focus with QA on a working system AND do not use the standard as an improvement tool.
 - BRC and IFS are often a settlement instrument, make sure that everything is correct on the days of the audit and that open action points that are standard related are also resolved.
 - Enough QA managers and advisors can wrongly do something else after an undesired score.

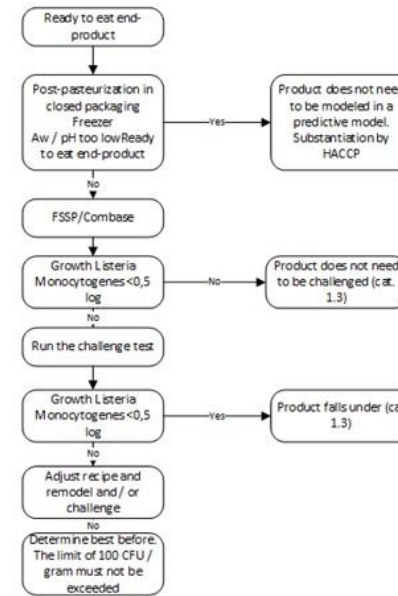
What should you at least arrange properly?

- Food Production parameters
 - Product: product assurance & development
 - Process : Cleaning and disinfection
 - Person: screening for diseases and hygienic working
 - Production area
- Food Defense
- Food Fraud
- Evidence Based practice:
Evidence: everything done for food safety
- Make sure all data is stored in the company! Code microbiology so that you don't fall victim to external errors.
- Plant Based chilled // ready to heat



What should you at least arrange properly?

- Make sure everyone knows the location of:
 - HACCP study
 - Management reports
 - Listeria and additives overview
- Train relevant colleagues in
 - The management system
 - HACCP
 - Internal auditing
 - Location information sources
 - Traceability
 - ERP system and Backups
- Use a separate system for consumer & chain information



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FSSC22000 version 5:
general

The FSSC 22000 Scheme has 3 required components

ISO 22000

- ISO 22000 a provides common framework across the entire supply chain to manage requirements, communication internally & externally, and continually improve the system

PRPs

- Sector specific Pre-Requisite Programs (ISO/TS standards/BSI PAS)

FSSC 22000 requirements

- FSSC 22000 adds specific requirements to ensure consistency, integrity, and to provide governance and management of the Scheme

FSSC22000 version 5: general

ISO 22000:2018 The difference between OPRPs and CCPs

<p>8.5.4.2. Critical limits and action criteria Action criteria for OPRPs are measurable or observable. Compliance with action criteria helps to ensure that the acceptable level is not exceeded.</p>	<p>8.5.4.2. Critical limits and action criteria. Critical limit values for CCPs are measurable. Compliance with critical limit values ensures that the acceptable level is not exceeded.</p>
<p>8.5.4.3. Monitoring system for OPRPs: method and frequency must be appropriate to the probability of failure and the severity of the consequences.</p>	<p>8.5.4.3. Monitoring systems at CCPs: method and frequency are able to detect any failure in time, so that the product can be blocked.</p>
<p>8.9.2.3. Action criteria not met: a) identify the consequences of the deviation; b) determine the causes of the deviation; c) Identify products to be treated according to 8.9.4.</p>	<p>8.9.2.2 Critical limits not met: identify affected products as potentially unsafe and handle them according to 8.9.4.</p>

FSSC22000 version 5: general

- iMIS Food: procedures for Food Defense and Food Fraud
- TACCP and VACCP reports based on FSSC guidelines



10 clause structure - Main clauses of High Level Structure (HLS)

- FSSC22000 version 5: ISO22000 changes

01 Scope

02 Normative references

03 Terms and definitions

04 Context of the
organization

05 Leadership

06 Planning

07 Support

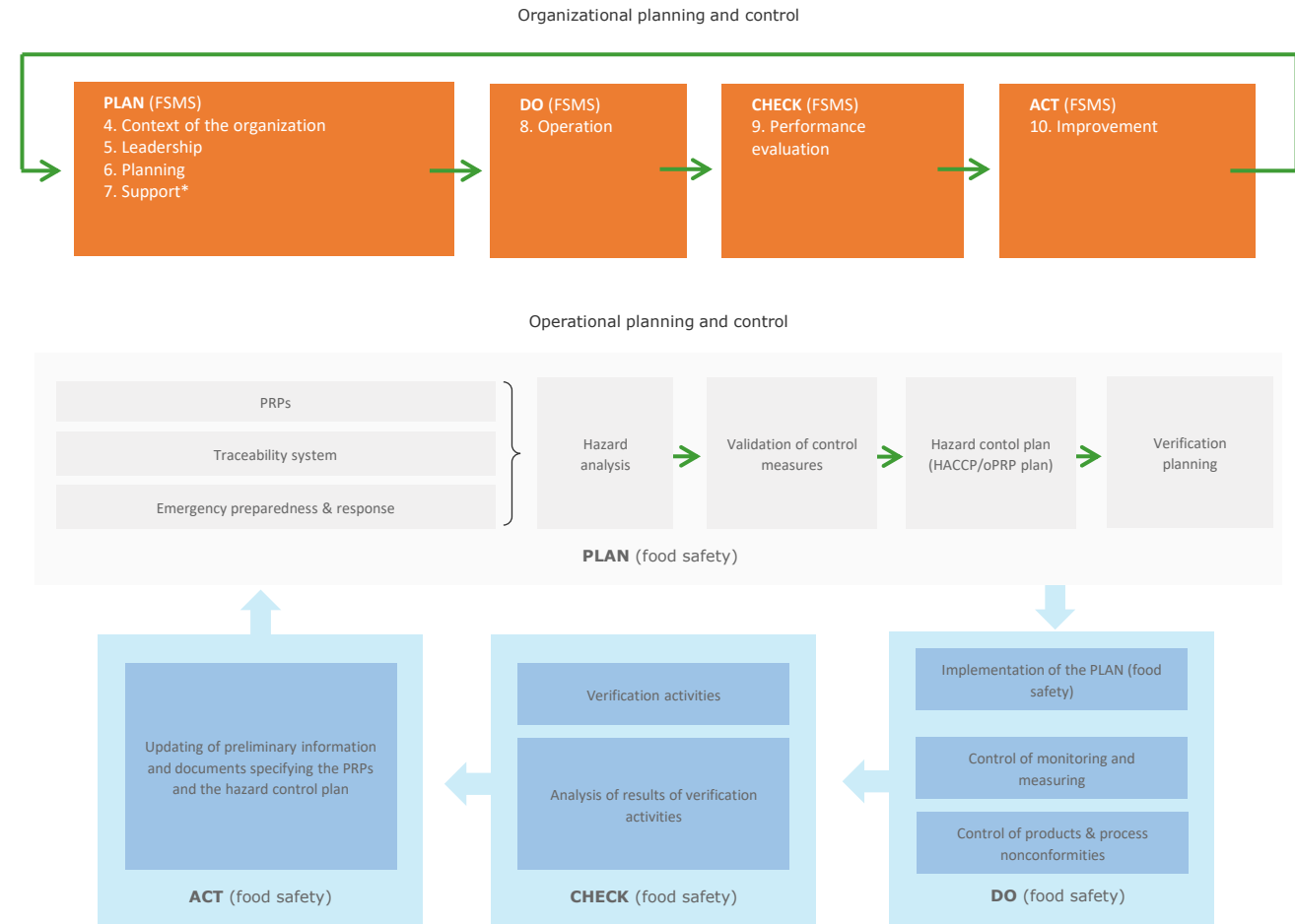
08 Operation

09 Performance evaluation

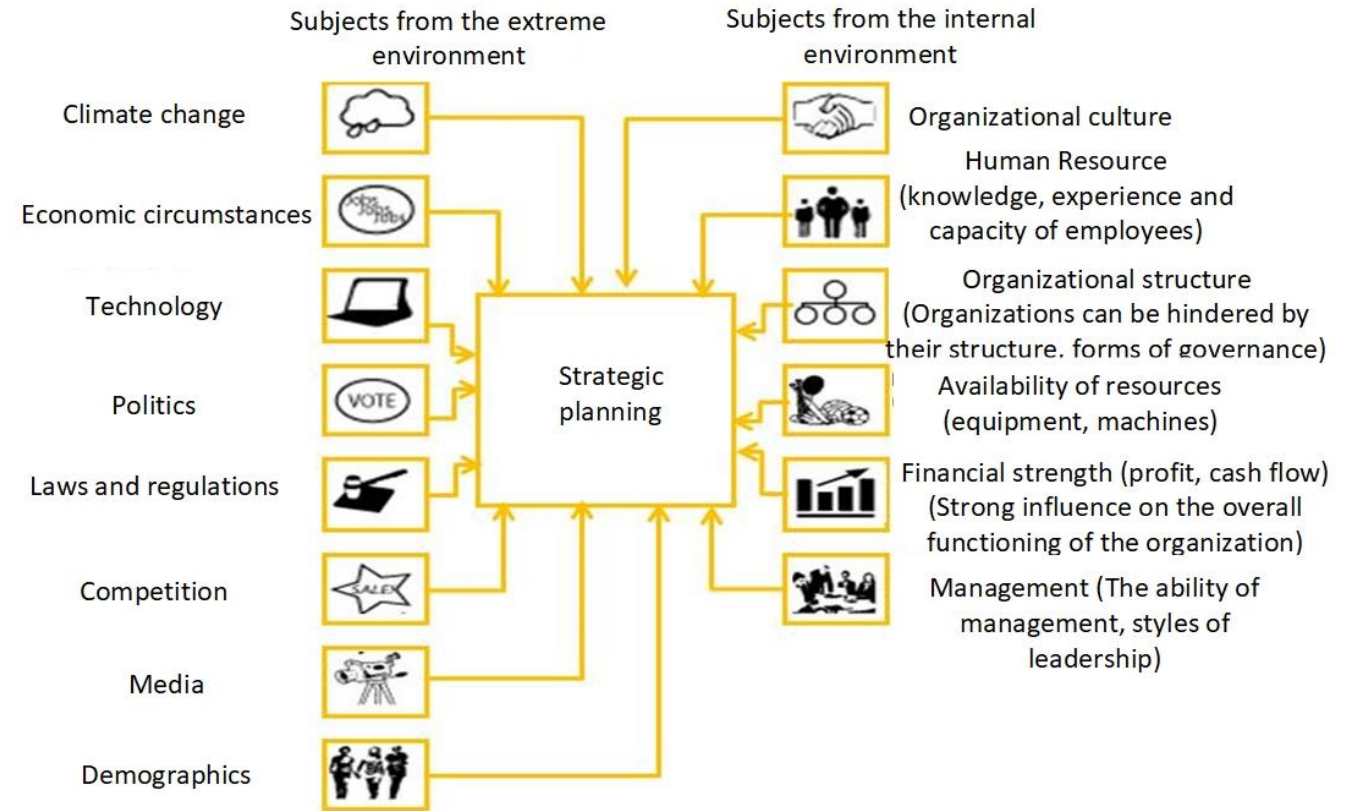
10 Improvement

FSSC22000 version 5: ISO22000 changes

- Risk on 2 levels
- Strategic
- Company risks
- Management is leading
- Operational
- HACCP
- QA is leading



FSSC22000 version 5: Context analysis and SWOT



FSSC22000 version 5: Context analysis and SWOT

	A	B	C	D	E
1	Stakeholder analysis				
2	version 1.0				
3	date:				
4	carried out by:				
5	Stakeholder / layout	Degree of influence	Degree of importance	Score	
6	Customers	Very high	Very high	24	
7	Consumers	Very high	Very high	24	
8	Providers of services; employment agency, pest control, transport, company clothing, maintenance. cleaning company	Very high	High	18	
9	Suppliers of goods; raw materials, materials, resources, equipment, building and facilities	Very high	High	18	
10	Cooperation partners	High	High	12	
11	Legislators and Competent Authority; NVWA, Environment Agency, Inspectorate SZW, Dutch Data Protection Authority	Very high	Very high	24	
12	Certifying body	High	High	12	
13	Gatekeeper / waste disposal flows	Moderate	Moderate	4	
14	Competition	High	High	12	
15	Trade associations	Moderate	Moderate	4	

FSSC22000 version 5: Context analysis and SWOT

- Step 1 Determining stakeholder: all stakeholders with a score of 8 or higher are considered relevant
- **Step 2 Determining expectation from a stakeholder's point of view**

Relevant stakeholders	Specific expectations	Associated Risks	Required action general (current control measures)
Customers	Project Quality and food safety, availability, price / margin, support / service, delivery reliability, certification, product development, brand support, image	Increasing power and requirements, price pressure, no / less purchase, non-compliance with payment obligations or agreements.	Customer satisfaction survey, annual interviews, customer visits (retail, catering wholesaler and retailers, food service). Market research, complaint analysis
Consumers	Ease of use, product quality, taste, price, no negative impact on health, shelf life, food safe.	Complaints, product does not meet expectations or there is no need for this product (demand too low)	Market research, complaint analysis, social media / internet discussions
Providers of services; employment agency, pest control, transport, company clothing, maintenance, cleaning company	Compliance with agreements / agreements made, timely payment, continuity	Company does not meet the requirements, does not comply with agreements, does not comply with legislation / permits. Errors can lead to unsafe situations. Food defense. not deliver or insufficient.	Verification
Suppliers of goods; raw materials, materials, resources, equipment, building and facilities	Fulfillment of agreements / contracts, payment, continuity	Delivery not according to conditions and specifications, insufficient availability, not good price / quality. Fraud, food defense, recalls, image, failure to comply with delivery agreements (delivery reliability), price fluctuations, increasing power due to growth.	Verification
Cooperation partners	Meeting contracts, financial obligations, continuity, mutual benefits	Failure to adhere to agreements or delivery obligations. Product or service does not meet specification. Recalls, image damage. Fraud, food defense. Lost certification.	Verification

FSSC22000 version 5: Context analysis and SWOT

- Step 1 Determining stakeholder: all stakeholders with a score of 8 or higher are considered relevant
- Step 2 Determining expectation from a stakeholder's point of view
- **Step 3 Risk analysis: internal and external issues**

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	External Issues														
2	C ultural, social, political, legal, financial, technological, economic and natural surroundings including the environment in which the organization operates														
3	Who the competitors are and any contractors, subcontractors, suppliers, partners and providers														
4	National and international law														
5	Industry drivers and trends which have influence on the organization														
6	The organization products and services and their influence on food safety														
7	Availability and variety of external providers of services/ products														
8	Changes in consumption patterns														
9	Capacity of changes regarding premises (landlord)														
10															
11															
12	Internal Issues														
13	Governance, organizational structure, roles and accountabilities														
14	Policies, objectives and the strategies in place to achieve them														
15	Competence of personnel														
16	Food Safety culture within the organization and the relationship with workers														
17	Process for the introduction of new products, materials, services, tools, software, premises and equipment														
18	Working conditions														
19	Resources (under-utilisation of resources)														
20	Retention of skilled employees														
21	Number and variety of clients/ customers														
22	Linkage to a certain activity, location and/or period														
23															
24															
25	SWOT														
26	PESTE														
27															

FSSC22000 version 5: Context analysis and SWOT

Strengths:

Knowledge of the market, experience
Brand awareness products
Relationships in food service, catering entrepreneurs
Loyal and (in-house) trained staff
Part of group (sharing knowledge, economies of scale, sharing functions)
Assortment meets the needs of different moments and consumers

Weaknesses:

Scale in relation to customers (catering wholesalers, retail)
Products can be copied at a lower price
Brand awareness among consumers
Brand awareness among young people
Not constant quality of raw materials for etc etc.
Product quality not constant, baking problem, etc.

Opportunities:

More spending space for consumers, good financial conditions in the Benelux (economic growth)
The culture of drinks or food etc / going out has grown in NL
A healthier image of meat in the (sports) canteen compared to snacks and fries
Export markets
Seen in demand for healthy products or products with a healthy image.
Responding to the needs of consumers of immigrant origin (halal ..)
Products suitable for airfryer or oven

SWOT analysis
Customer name trial

Threats:

Cheaper alternatives, me-too products, also under PL
A lot of competition, also indirectly from other products that meet the same need (moment of use, drinks, snacking)
Strong negotiating position from customers and suppliers.



Our company

- How is our context analysis, stakeholder analysis and SWOT?
 - Same for the TACCP and VACCP study
 - How is our procedure for Food Defense and Food Fraud?

















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ISO9001

-  ISO09001_Management review.docx
-  ISO09001_Procedure Intern auditen.docx
-  ISO09001_Procedure Management review.docx
-  ISO09001_SWOT analyse.docx
-  ISO9001_Auditrapport.doc
-  ISO9001_Beleidsverklaring.doc
-  ISO9001_Jaarplanning.xls
-  ISO9001_Klachten, verbeternotitie.doc
-  ISO9001_Leveranciersbeoordeling.xls
-  ISO9001_opleidings en competentieoverzicht.xls
-  ISO9001_Procedure contextanalyse.docx
-  ISO9001_Procedure klachten en verbeteren.docx
-  ISO9001_Procedure Selectie en beheer leveranciers.docx
-  ISO9001_Risico's en kansanalyse.xls
-  ISO9001_Stakeholderanalyse.xls
-  ISO9001_stakholders&risico analyse gecombineerd (ook MVO).xls

ISO14001

-  ISO014001_Procedure Intern auditen.docx
-  ISO014001_Procedure Management review.docx
-  ISO014001_SWOT analyse.docx
-  ISO14001_Auditrapport.doc
-  ISO14001_Beleidsverklaring.doc
-  ISO14001_Jaarplanning.xls
-  ISO14001_Klachten- verbeternotitie.doc
-  ISO14001_Leveranciersbeoordeling.xls
-  ISO14001_Management review.docx
-  ISO14001_milieuaspecten inventarisatie met risico's en kansen.xls
-  ISO14001_opleidings en competentieoverzicht.xls.xlsx
-  ISO14001_Procedure contextanalyse.docx
-  ISO14001_Procedure klachten en verbeteren.docx
-  ISO14001_Procedure milieuaspecten inventarisatie en evaluatie.docx
-  ISO14001_Procedure Selectie en beheer leveranciers.docx
-  ISO14001_Stakeholderanalyse.xls
-  ISO14001_Wettelijk toetsingstabel.xls

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HACCP team: tasks (1/2)

- The HACCP team has the following responsibilities:
 - Conduct a hazard analysis to determine which hazards need to be controlled, which degree of control is required to achieve food safety and what combination of control measures is required.
 - Plan and implement processes necessary for the validation of control measures and/or combinations of control measures, and to improve the food safety management system verification and improvement.
 - Assess changes in the production process that have a negative effect on the food safety.
 - Verification of the food safety system.
 - Indicate per process step, including all products, all processes and all elements of the PRP on which these have been assessed and justify whether it is a Critical Control Point (CCP or OPRP).
 - Check whether the food safety system falls within the scope and whether the scope covers the entire food safety system.
 - Make adjustments to keep the food safety system up to date and correct either by verification or validation.

HACCP team: tasks (2/2)

- Management of training courses for staff to ensure that everyone has sufficient knowledge related to the necessary food safety.
- Determining and verifying the scope.
- In case of changes in raw materials, packaging materials, processing methods, infrastructure and/or equipment, the HACCP plan is revised to ensure that the product safety requirements are met.
- In the hazard analysis, attention is also paid to the position in the chain and will be taken into account with our suppliers and customers.
- It is essential that the HACCP team has sufficient expertise. The expertise and composition of the HACCP team is recorded in the HACCP team responsibility overview. Due to the current composition of the HACCP team, all necessary knowledge and expertise is available for the daily course of events. For additional specific information, QAssurance B.V. is used.
- The HACCP team has the approval of the management and is supported where possible with
- the necessary resources, facilities and time.

HACCP meetings

- An HACCP team consultation takes place according to a fixed frequency in which it is at least assessed whether:
 - The food safety system is up-to-date and effective.
 - The measures taken have been adequately implemented/taken.
 - New processes and/or products must be or have been assessed.
 - Developments with regard to legislation, technology, knowledge, etc. that have an impact on us.
 - Incidents or new information regarding food fraud or food defense that affect us.
 - Furthermore, any calamities and standard violations are reviewed and possible improvements identified. The realization of formulated objectives are assessed and the identified cause is investigated in the event of non-achievement of targets. Then the measures are defined.
 - The meetings are reported.

HACCP team: input (including from directive)

- New products;
- New raw materials;
- New excipients;
- Recipe adjustments;
- New or changed processes, investments;
- New location of equipment or environment;
- New suppliers of product or service, new services;
- New customer requirements that need to be translated to the shop floor;
- Changes in cleaning and disinfection (method, means, frequency, etc.);
- Possible legal changes or changes in standards;
- Changes in packaging and/or packaging material;
- Changes in storage or transport;
- Changes in the organisation, competences, responsibilities and authorities;
- Complaints and alerts;
- State of the art, new knowledge, research results;
- New knowledge about food safety hazards and control measures;
- Quality Level changes
- Objectives.

Our company

- Who is in the HACCP team why; and who is the HACCP team leader?
- What are the latest HACCP procedures?
- What were the latest changes in the company that have an impact on the study?
- When was the last time validated?
- What about the central action list and what is the next annual plan?

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Food Safety Compliance training

With our Food Safety Compliance for QA managers training we go back to the basics, the foundation to properly fulfill the complex function of QA manager, now and in the future.